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The Impact of Xinkeshu on Cognitive Function in First-Diagnosed Hypertensive Patients

Jiechun Li[1], Dongxia Jin[2]*

[1]Department of Traditional Chinese Medicine, Tianjin University Hospital, Tianjin 300072, China
[2]Department of Cardiology, Tianjin Chest Hospital, Tianjin 300222, China

***Corresponding author**: Jin Dongxia, jdxkl@126.com

Abstract: Hypertension is the most prevalent cardiovascular disease, leading to pathophysiological changes in the brain and deterioration of cognitive function by affecting cerebral blood supply and oxygenation. Xinkeshu, a new-generation specific drug for treating coronary heart disease, hypertension, and psycho-cardiological diseases in modern medical research, exhibits antioxidant, myocardial protective, and left ventricular hypertrophy-improving effects in hypertensive patients. However, its impact on cognitive function in hypertensive patients remains unclear. This study included 100 patients first diagnosed with hypertension and initiating antihypertensive treatment at the hypertension outpatient clinic of Tianjin Chest Hospital. Patients were randomly divided into a monotherapy antihypertensive group and a combined Xinkeshu and antihypertensive treatment group (Xinkeshu 4 tablets tid combined with antihypertensive treatment), with 50 patients in each group, and followed up for 3 months. Cognitive function was assessed using the Montreal Cognitive Assessment (MoCA) scale, Logical Memory Test (LMT), and Auditory Verbal Learning Test (AVLT) on the day of enrollment and after 3 months of treatment. *Results:* After 3 months of antihypertensive treatment, all patients showed significant improvement in immediate recall and recognition tests. The combined treatment group demonstrated more significant improvements in MoCA scores, LMT-immediate recall, AVLT-immediate recall, and AVLT-short delay recall scores after 3 months of treatment, while improvements in LMT-delayed recall and AVLT-long delay recall were not significant. This suggests that antihypertensive treatment and combined treatment for 3 months can improve cognitive function by enhancing immediate recall in hypertensive patients. *Discussion:* Xinkeshu may improve cerebral blood supply and oxygenation through the combined effects of its five individual herbs and their separate pharmacological components, thereby improving cognitive function in hypertensive patients.

Keywords: Xinkeshu; Hypertension; Cognition; Memory

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1. Introduction

Hypertension, currently the most common cardiovascular disease, induces certain cerebral pathophysiological changes, such as vascular remodeling, impaired cerebral autoregulation, small lacunar infarcts, white

matter lesions, microbleeds, and amyloid angiopathy, leading to various central nervous system-related complications, such as stroke and vascular dementia, and deterioration of cognitive function. Xinkeshu is a cardiovascular disease treatment drug developed in modern pharmacy, a pure natural traditional Chinese medicine compound preparation mainly composed of *Salvia miltiorrhiza*, *Panax notoginseng*, *Pueraria lobata*, *Aucklandia lappa*, and *Crataegus pinnatifida*. It is clinically used for the intervention of coronary heart disease, hypertension, and psychocardiological diseases. This drug significantly reduces gastrointestinal adverse reactions while retaining efficacy, has clear antioxidant activity, and protects the myocardium and improves left ventricular hypertrophy in hypertensive patients [1,2]. However, its impact on cognitive function in hypertensive patients remains unclear. Therefore, this study included first-diagnosed hypertensive patients, divided them into a conventional antihypertensive treatment group and a conventional antihypertensive combined with Xinkeshu group, and followed them up for 3 months to evaluate the impact of Xinkeshu on cognitive function in hypertensive patients.

2. Subjects and methods

2.1. Subjects

A total of 100 patients first diagnosed with hypertension and initiating antihypertensive treatment at the hypertension outpatient clinic of Tianjin Chest Hospital from August 2023 to December 2023 were selected. They were randomly divided into a combined treatment group (Xinkeshu 4 tablets tid combined with antihypertensive treatment) and a monotherapy antihypertensive group in a 1:1 ratio using a random number table, with 50 patients in each group. The study was approved by the Ethics Committee of Tianjin Chest Hospital (approval number 2025YS-049-01). This study was sponsored by Tianjin Health Project " Multimodal Early Warning and Clinical Prediction Research of Coronary Heart Disease Based on Pericoronary Adipose Tissue (Grant No.TJWJ2025MS035)".

2.2. Diagnostic criteria

(1) Blood pressure measurement

Strictly follow the standardized measurement specifications issued by the World Health Organization in 1999. Subjects discontinued medications that might interfere with blood pressure before the test and rested quietly in a sitting position for 30 minutes. A mercury sphygmomanometer was used to measure the blood pressure of the right brachial artery, and the mean of three measurements on different days was used as the final blood pressure data.

(2) Hypertension

Hypertension diagnosis refers to the 2013 ESH/ESC hypertension guidelines and the 2024 revised edition of the "Chinese Guidelines for the Prevention and Treatment of Hypertension", with systolic blood pressure ≥ 140 mmHg and/or diastolic blood pressure ≥ 90 mmHg as the diagnostic threshold; for those already receiving antihypertensive treatment, a comprehensive diagnosis is made based on past medical history and ambulatory blood pressure monitoring results.

2.3. Inclusion and exclusion criteria

(1) Inclusion criteria

Patients meeting the diagnostic criteria for hypertension and first diagnosed with hypertension, aged

20–65 years, male and female; native Chinese speakers with basic understanding, reading, writing, and communication abilities, and right-handed.

(2) Exclusion criteria

Non-hypertensive patients (SBP < 140 mmHg and DBP < 90 mmHg), aged < 20 years and > 65 years, patients with known psychological and behavioral disorders or any other central nervous system disorders that might interfere with memory and psychomotor function, patients taking other medications known to affect memory and psychomotor function (sedatives, antipsychotics, antidepressants, antihistamines), and those unable to cooperate with testing and medication administration.

2.4. Drug intervention and grouping

All enrolled patients were prescribed conventional antihypertensive drugs by clinicians according to their condition. Patients in the monotherapy antihypertensive group received conventional antihypertensive drugs; the combined treatment group received oral Xinkeshu tablets (Wohua Pharmaceutical) 4 tablets/time, 3 times/day, in addition to conventional antihypertensive treatment, for 3 months. Conventional antihypertensive drugs mainly include ACEIs, ARBs, β-blockers, CCBs, and diuretics. All patients underwent two cognitive function tests and blood pressure measurements on the day of enrollment and after 3 months of antihypertensive treatment, with the mean taken as the final value. To ensure medication adherence and follow-up success rate, all hypertensive patients underwent outpatient follow-up every two weeks.

2.5. Cognitive function assessment

Cognitive function was assessed in all enrolled patients on the day of enrollment and after 3 months of treatment using the Montreal Cognitive Assessment (MoCA) scale, Logical Memory Test (LMT), and Auditory Verbal Learning Test (AVLT).

The Montreal Cognitive Assessment (MoCA) scale is used to comprehensively assess an individual's overall cognitive function, including 8 cognitive domains: visuospatial and executive function (5 points), naming (3 points), attention (3 points), calculation (3 points), language function (3 points), abstraction (2 points), memory (5 points), and orientation (6 points), with a total score of 30 points. A lower score indicates more significant cognitive impairment, and a score < 26 points can be determined as cognitive dysfunction. To reduce assessment bias due to education level, 1 point is added to the raw score for those with ≤ 12 years of education for correction.

The Logical Memory Test (LMT) is a classic neuropsychological test for assessing verbal logical memory, consisting of two assessment stages: immediate recall and delayed recall. The assessment process involves the examiner reading standardized story paradigm materials, and the subject completing immediate free recall; delayed free recall is conducted after a 30-minute interval. The test sets 20 target memory keywords, and correct recall item scoring is used, with 1 point awarded for each correctly recalled item. A lower total score indicates more severe logical memory impairment.

The Auditory Verbal Learning Test (AVLT) is a standardized neuropsychological assessment tool for assessing auditory verbal memory, mainly consisting of three core modules: immediate recall, delayed recall, and recognition. During the assessment, the subject completes 3 rounds of learning-immediate recall cycles for 12 target words, with 1 point awarded for each correctly recalled word and 0 points for incorrect or unrecalled words, with a total immediate recall score of 36 points. After immediate recall, short-delay

and long-delay free recall are conducted after delays of 5 minutes and 20 minutes, respectively, with a total score of 12 points for each stage. Immediately after long-delay recall, a discrimination recognition test is conducted, presenting 12 target words mixed with 12 distractor words. Correct identification of a target word awards 1 point, while misjudging a distractor word as a target word deducts 1 point, with a total recognition score of 12 points. Scores in each dimension are positively correlated with auditory memory function, and a lower score indicates more obvious memory impairment.

2.6. Statistical analysis

Experimental data were statistically analyzed using SPSS 25.0 software. For measurement data, normally distributed data are expressed as mean ± standard deviation ($\overline{x} \pm s$), and skewed distributed data are described by the median (M). Independent sample *t*-tests are used for intergroup comparisons of normally distributed data; the Mann-Whitney U test is used for intergroup comparisons of non-normally distributed data. Count data are expressed as the number of cases and percentage [n (%)], and intergroup comparisons are conducted using the χ^2 test. A p-value < 0.05 is considered statistically significant.

3. Results

3.1. Comparison of baseline data between the two groups

The antihypertensive-only group consisted of 25 males and 25 females, with an average age of (59.34 ± 12.72) years; the combination therapy group consisted of 27 males and 23 females, with an average age of (59.72 ± 12.65) years, showing no statistically significant difference. Additionally, there were no statistically significant differences between the two groups in terms of education level, smoking history, alcohol consumption history, baseline SBP, baseline DBP, baseline HR, MoCA, LMT-immediate recall, LMT-delayed recall, AVLT-immediate recall, AVLT-short-delay recall, AVLT-recognition scores, etc. ($p > 0.05$). There was no statistically significant difference in the prescription rates of β-blockers, ACEI/ARB, and CCB between the antihypertensive-only group and the combination antihypertensive therapy group ($p > 0.05$). The data between the two groups were comparable (see **Table 1**).

Table 1. Comparison of baseline data between the two groups

Indicator	Simple antihypertensive group (n = 50)	Combined treatment group (n = 50)	t/χ^2 value	p value
Male (n, %)	25 (50.00)	27 (54.00)	0.160	0.689
Age (years)	59.34 ± 12.72	59.72 ± 12.65	0.012	0.913
Education level (years)			3.486	0.323
≤ 6 years (n, %)	2 (4.00)	1 (2.00)		
> 6 and ≤ 9 years (n, %)	9 (18.00)	17 (34.00)		
> 9 and ≤ 12 years (n, %)	23 (46.00)	19 (38.00)		
> 12 years (n, %)	16 (32.00)	13 (26.00)		
Smoking history (n, %)	8 (16.00)	6 (12.00)	0.332	0.564
Alcohol consumption history (n, %)	12 (24.00)	17 (34.00)	0.000	1.000
SBP (mmHg)	162.06 ± 2.958	157.76 ± 2.932	2.523	0.115
DBP (mmHg)	89.90 ± 11.20	92.54 ± 10.44	0.286	0.594
HR (bpm)	78.64 ± 16.470	77.10 ± 14.401	0.002	0.966

MoCA (score)	25.68 ± 2.584	25.88 ± 2.097	3.256	0.074
LMT - Immediate recall (score)	11.57 ± 1.352	11.69 ± 1.657	1.271	0.262
LMT - Delayed recall (score)	10.04 ± 1.768	10.26 ± 1.335	0.702	0.484
AVLT - Immediate recall (score)	26.12 ± 2.84	25.24 ± 3.341	1.625	0.205
AVLT - Short-delay recall (score)	7.44 ± 1.768	7.07 ± 1.279	0.775	0.440
AVLT - Long-delay recall (score)	5.94 ± 0.89	5.58 ± 0.38	0.702	0.484
AVLT - Recognition (score)	6.54 ± 0.37	6.28 ± 0.40	0.691	0.562
Prescribed antihypertensive medications				
β-blocker (n, %)	38 (76.00)	30 (60.00)	2.941	0.086
ACEI/ARB (n, %)	23 (46.00)	27 (54.00)	0.640	0.424
CCB (n, %)	15 (30.00)	10 (20.00)	0.832	0.362

Note: A *p*-value less than 0.05 indicates a statistically significant difference.

3.2. Comparison of blood pressure reduction effects between the two groups after 3 months of treatment

After 3 months of treatment, the systolic blood pressure (SBP), diastolic blood pressure (DBP), and heart rate (HR) of patients in the antihypertensive-only group were significantly lower than those at enrollment ($p < 0.001$). However, there was no statistically significant difference in the magnitude of blood pressure reduction between the two groups ($p > 0.05$). (See **Table 2**)

Table 2. Comparison of blood pressure between the two groups after 3 months of treatment

Indicator	Antihypertensive alone group (n = 50)	Combination therapy group (n = 50)	t/χ^2 value	*p* value
SBP (mmHg)	127.06 ± 2.958*	122.76 ± 3.021*	2.523	0.115
DBP (mmHg)	77.46 ± 3.131*	72.34 ± 4.796*	3.699	0.067
HR (bpm)	64.92 ± 8.964*	66.86 ± 9.819*	0.494	0.484

Note: *$p < 0.001$ compared with baseline; a statistically significant difference is considered when $p < 0.05$.

3.3. Changes in cognitive abilities after three months of treatment in both groups

After three months of treatment, both groups of patients showed significant improvements in MoCA scores, LMT-immediate recall, AVLT-immediate recall, and AVLT-short-delay recall scores ($p < 0.001$). Compared with the antihypertensive-only group, the combined treatment group exhibited even more significant improvements in MoCA scores, LMT-immediate recall, AVLT-immediate recall, and AVLT-short-delay recall scores after three months of treatment ($p < 0.0001$). However, improvements in LMT-delayed recall and AVLT-long-delay recall scores were not significant in both groups after treatment. This suggests that antihypertensive treatment and combined treatment for three months can improve cognitive function by enhancing immediate recall in hypertensive patients, with the combined treatment of Xinkeshu showing a more pronounced effect on improving immediate recall compared to antihypertensive-only treatment. (**Table 3**)

Table 3. Comparison of cognitive function scores after three months of treatment between the two groups

Indicator	Antihypertensive alone group (n = 50)	Combination therapy group (n = 50)	t/χ^2 value	*p* value
MoCA (score)	27.55 ± 2.811*	29.08 ± 1.643*	1.278	0.042
LMT-immediate recall (score)	12.58 ± 2.02*	14.80 ± 1.35*	3.353	0.001

Indicator	Antihypertensive alone group (n = 50)	Combination therapy group (n = 50)	t/χ^2 value	p value
LMT-delayed recall (score)	10.59 ± 0.914	11.13 ± 0.653	3.471	0.001
AVLT-immediate recall (score)	26.68 ± 1.729*	27.64 ± 1.378*	3.656	0.000
AVLT-short delayed recall (score)	8.67 ± 1.143*	9.94 ± 1.550**	3.389	0.001
AVLT-long delayed recall (score)	7.93 ± 2.241	8.21 ± 3.692	0.702	0.381
AVLT-recognition (score)	7.630 ± 2.241	7.89 ± 1.557	0.681	0.423

Note: $p < 0.001$ compared with baseline, *$p < 0.001$ compared with baseline. A p-value < 0.05 indicates a statistically significant difference.

4. Discussion

In this study, the cognitive function of patients with first-diagnosed hypertension improved after antihypertensive treatment compared to baseline cognitive function, thanks to improvements in immediate recall function. This suggests that hypertension can lead to a decline in cognitive function, and antihypertensive treatment does not worsen cognitive function while lowering blood pressure; instead, it improves cognitive function in hypertensive patients. Moreover, the combined treatment with Xinkeshu demonstrated a more significant improvement in cognitive function in hypertensive patients.

Previous studies have shown that elevated blood pressure is associated with pathophysiological changes in brain tissue and may affect brain structure and function by influencing intracranial blood flow. Lipsitz et al. demonstrated that intracranial blood flow improved after six months of antihypertensive drug therapy [3]. Short-term antihypertensive treatments, such as beta-blockers and ACE inhibitors, have also been associated with improved intracranial blood flow in hypertensive patients. The improvement in cognitive and memory abilities observed in patients after antihypertensive treatment in this study may also be attributed to improved intracranial blood flow.

Xinkeshu tablets are formulated based on the principles of promoting blood circulation to remove blood stasis and regulating Qi to alleviate pain, with a rigorous combination of principal, assistant, adjuvant, and messenger herbs. Danshen (*Salvia miltiorrhiza*) and Sanqi (*Panax notoginseng*) are used in tandem to exert core pharmacological effects such as antiplatelet aggregation, improving microcirculation, and relieving vascular spasms. Muzhang (*Aucklandia lappa*), Shanzha (*Crataegus pinnatifida*), and Gegen (*Pueraria lobata*) assist the principal and assistant herbs, collectively regulating qi circulation, improving blood rheology, regulating blood lipids, protecting vascular endothelium, and promoting tissue blood supply.

The compatibility of herb pairs is a key entry point for elucidating the compatibility rules and pharmacological material basis of compound formulas. The combined effects and molecular mechanisms of core herb pairs in Xinkeshu tablets are as follows:

(1) Danshen-Sanqi herb pair

This compatibility embodies the classic formula concept of “mutual enhancement”. Pharmacological studies have confirmed that co-decoction of these two herbs significantly increases the dissolution rate of tanshinone and salvianolic acid components and enhances the chemical stability of active ingredients. Modern mechanistic studies indicate that this combination has a significant protective effect on vascular endothelial cell injury induced by hypoxia-reoxygenation, with mechanisms closely related to improving cellular energy metabolism, inhibiting lipid peroxidation reactions, and stabilizing cell membrane structure [4].

(2) Sanqi-Gegen herb pair

Experimental studies by Jin Wen et al. have revealed that a 6:4 ratio of Pueraria lobata flavonoids to *Panax notoginseng* saponins exhibits significant synergistic effects. This combination significantly improves the hypoxia tolerance of cerebral ischemia model animals, with mechanisms involving protecting mitochondrial membrane structure integrity, inhibiting excessive production of oxygen free radicals, thereby delaying the decline in superoxide dismutase (SOD) activity, and exerting a protective effect on damaged brain tissue [5].

(3) Danshen-Gegen herb pair

The combination of these two herbs demonstrates good clinical translational value in the treatment of cerebrovascular diseases. Pharmacological and clinical studies have shown that the combined use of puerarin and Danshen extract can effectively improve vertebrobasilar artery insufficiency and significantly reduce neurological deficit scores in patients with acute cerebral infarction [6,7]. In-depth mechanistic studies indicate that this compatibility can bidirectionally regulate vascular tone, upregulate plasma tissue-type plasminogen activator and nitric oxide levels while inhibiting the release of tissue-type plasminogen inhibitor and endothelin, thereby comprehensively improving vascular endothelial barrier function [8].

(4) Shanzha-Danshen herb pair

In hyperlipidemia pathological models, this herb pair exhibits excellent synergistic effects in regulating blood lipids and antioxidation. Experiments have shown that the combined use of these two herbs significantly reduces plasma total cholesterol, triglyceride, and low-density lipoprotein cholesterol levels, increases high-density lipoprotein cholesterol, and effectively counteracts the decline in SOD activity, suggesting significant pharmacological implications for improving blood rheology, anti-atherosclerosis, and reducing oxidative stress injury [9].

Regarding monomer components:

(1) Sanqi

The core active ingredient of Sanqi is *Panax notoginseng* saponins (PNS), which play prominent roles in cardiovascular and cerebrovascular regulation and brain nerve protection. In preventing and treating cardiovascular and cerebrovascular diseases, PNS can promote blood circulation to remove blood stasis and unblock meridians, reduce blood viscosity, inhibit platelet aggregation, dilate blood vessels, regulate blood lipids, protect vascular endothelium, and improve microcirculation disorders in the body. In brain nerve protection, PNS can promote protein synthesis in the brain, inhibit secondary brain injury, upregulate the expression of neurotrophic factors, exert anti-inflammatory effects, improve cerebral microcirculation, alleviate ischemia and hypoxia, block neuronal apoptosis, and improve memory [10].

(2) Danshen

The main monomer components are tanshinone IIA and salvianolic acid B, which cover multiple targets in the core pathological links of cerebral ischemia. Tanshinone IIA is the core lipid-soluble component of Danshen, covering multiple targets in the core pathological links of cerebral ischemia. It reduces the production of mitochondrial lipid peroxides by regulating the expression of Bcl-2 family apoptosis proteins, blocks abnormal apoptosis of brain cells induced by ischemia and hypoxia; inhibits the activity of sympathetic ganglion cells, reduces catecholamine release, dilates blood vessels, relieves spasms, and improves cerebral microcirculation; enhances SOD activity, scavenges oxygen free radicals, reduces ischemic brain injury; inhibits blood coagulation function and platelet aggregation, blocks calcium overload in brain

tissue cells, reduces cerebral edema, and prevents ischemia-reperfusion injury [11]. Salvianolic acid B is the most abundant water-soluble active ingredient in Danshen, focusing on exerting brain-protective effects by regulating endothelial function and improving energy metabolism. Salvianolic acid B can balance the levels of NO and ET in the body, correct vascular tone disorders, upregulate the expression of VEGF and its receptors, repair damaged microvessels, and optimize cerebral perfusion; simultaneously, it can enhance Na^+-K^+-ATPase activity, maintain ion balance in brain cells, correct energy metabolism disorders, and alleviate ischemic and reperfusion edema injury [12].

(3) Gegen

The effective monomer substance of Gegen is puerarin, which covers multiple molecular pathways and targets neuroprotection. It can upregulate the expression of vascular endothelial growth factor (VEGF) to improve microcirculation in ischemic areas, inhibit intracellular Ca^{2+} overload and optimize cerebral blood supply, balance the expression of the Bcl-2 apoptosis protein family to block neuronal apoptosis, and simultaneously counteract the toxicity of excitatory amino acids, upregulate the expression of NR2a and NR2b subunits in the hippocampal CA1 region, and improve memory ability in neonatal rats with hypoxia-ischemia [13].

(4) Shanzha

Quercetin and hyperoside in Shanzha are the main active ingredients for brain protection, which reduce secondary neural injury after cerebral ischemia through synergistic antioxidant and anti-inflammatory effects. Hyperoside can inhibit the abnormal release of nitric oxide (NO), enhance SOD activity, reduce oxygen free radical production, activate microglia, alleviate local inflammatory reactions, and brain tissue edema [14]. Quercetin can enhance the activity of endogenous antioxidant enzymes, scavenge oxygen free radicals, participate in oxidative stress reactions, and reduce the infarct area of cerebral ischemia [15].

(5) Muzhang

The brain-protective effects of Muzhang mainly originate from costunolide and volatile oils, which can dilate cerebral blood vessels and regulate cerebral blood flow. Pharmacological experiments have shown that Muzhang decostunolide volatile oil can increase cerebral blood flow by 14%, and total costunolide components can increase it by 35%. Both types of components exert indirect neuroprotective effects by improving cerebral perfusion and alleviating ischemia and hypoxia [16].

5. Conclusion

In summary, Xinkeshu tablets are reasonably formulated, addressing both symptoms and root causes, with pharmacological characteristics of multiple targets and pathways. Danshen, Sanqi, and Gegen in the formula are used to regulate blood rheology, representing an exquisite compatibility for improving microcirculation blood flow status and optimizing cerebral microcirculation perfusion. The entire formula uses herbs scientifically and rationally, improving lipid metabolism in the body, reducing blood lipids, significantly enhancing the activity of antioxidant enzymes and immune function; increasing cerebral oxygen content, improving cerebral blood circulation, protecting brain cells, and effectively improving intellectual decline and cognitive dysfunction in patients. Therefore, for patients with first-diagnosed hypertension, the combined treatment with Xinkeshu and antihypertensive drugs may improve cognitive function by improving intracranial blood flow and increasing cerebral oxygen content. However, due to the small sample size in this study, further observation with an expanded sample size is needed.

Disclosure statement

The authors declare no conflict of interest.

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