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# Clinical Observation on the Efficacy of Modified Guipi Decoction in Treating Cognitive Dysfunction in Senile Dementia

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**Abstract:** ***Objective:*** ***To observe the therapeutic effect of the modified Chinese herbal compound Guipi Decoction on cognitive dysfunction in elderly patients with Alzheimer's disease.*** ***Methods:*** ***Eligible patients with Alzheimer's disease and cognitive dysfunction were randomly divided into a treatment group and a control group. The control group received conventional Western medicine, while the treatment group received both conventional Western medicine and modified Guipi Decoction for 12 weeks. Cognitive function (MMSE, MoCA scores) and daily living ability (ADL score) were compared before and after treatment.*** ***Results:*** ***After treatment, the MMSE and MoCA scores in the treatment group were significantly higher than those in the control group, while the ADL score was significantly lower (P < 0.05).*** ***Conclusion:*** ***The combination of modified Guipi Decoction and conventional Western medicine effectively improved cognitive function and daily living ability in elderly patients with Alzheimer's disease, demonstrating superior efficacy compared to Western medicine alone.***

**Keywords:** Modified Guipi Decoction, Alzheimer's disease, Cognitive dysfunction.

## 1. Introduction

Alzheimer's disease (AD), also known as senile dementia, is a common neurodegenerative disorder characterized by progressive cognitive dysfunction and behavioral impairment. With the acceleration of global population aging, the incidence of AD has been increasing annually, imposing a heavy burden on families and society. Current clinical treatments for AD primarily rely on Western medications, including cholinesterase inhibitors (e.g., donepezil) and N-methyl-D-aspartate (NMDA) receptor antagonists (e.g., memantine). However, these drugs have limitations and are associated with frequent adverse effects with long-term use. Traditional Chinese Medicine (TCM) offers unique advantages in treating AD, as herbal compounds can act through multiple targets and pathways to improve cognitive function and quality of life. This study aims to evaluate the therapeutic efficacy of the modified Chinese herbal formula Guipi Decoction in treating cognitive dysfunction in AD patients, providing evidence for clinical practice.

## 2. Materials and Methods

### 2.1 General Information

A total of 120 AD patients with cognitive dysfunction treated in the Department of Neurology of our hospital from September 2022 to September 2024 were enrolled. Inclusion criteria: (1) meeting the diagnostic criteria for AD outlined in the Chinese Expert Consensus on the Prevention and Treatment of Cognitive Dysfunction; (2) Mini-Mental State Examination (MMSE) score <24; (3) Montreal Cognitive Assessment (MoCA) score <26; (4) age 60–80 years; (5) signed informed consent from patients and their families. Exclusion criteria: (1) severe dysfunction of the heart, liver, or kidneys; (2) cognitive impairment caused by other neurological diseases; (3) psychiatric disorders; (4) allergy to the study drugs. Patients were randomly divided into a treatment group and a control group, with 60 cases each. The treatment group included 32 males and 28 females, aged 60–78 years (mean 68.5±5.2 years), with disease duration of 1–5 years (mean 2.8±1.2 years). The control group included 30 males and 30 females, aged 61–80 years (mean 69.2±5.5 years), with disease duration of 1–6 years (mean 3.0±1.3years). No statistically significant differences were observed in baseline characteristics between the two groups (P > 0.05), ensuring comparability.

### 2.2 Treatment Methods

The control group received conventional Western medicine: Donepezil Hydrochloride Tablets (Chongqing Zhisi Pharmaceutical Co., Ltd., National Medicine Approval No. H200101723) at an initial dose of 5 mg/day, taken orally before bedtime. After 4 weeks, the dose was increased to 10 mg/day if well tolerated. The treatment group received both conventional Western medicine and the modified Guipi Decoction, which contained the following herbs: Astragalus membranaceus (Huangqi, 30g), Panax ginseng (Renshen, 10g), Angelica sinensis (Danggui, 15g), Ligusticum chuanxiong (Chuanxiong, 10g), Acorus tatarinowii (Shichangpu, 10g), Polygala tenuifolia (Yuanzhi, 10g), Poria cocos (Fuling, 15g), Atractylodes macrocephala (Baizhu, 10g), Ziziphus jujuba var. spinosa (Suanzaoren, 15g), and Glycyrrhiza uralensis (Gancao, 6g). One dose per day was decocted in water to yield 400 ml of liquid, divided into three warm doses taken in the morning, noon, and evening. Both groups were treated continuously for 12 weeks.

### 2.3 Outcome Measures

2.3.1 Cognitive Function

Cognitive function was assessed using the Mini-Mental State

Examination (MMSE) and Montreal Cognitive Assessment (MoCA) before and after treatment. The MMSE evaluates multiple domains: orientation (time and place), memory (immediate and delayed recall), attention and calculation (simple arithmetic tasks), language (expression, repetition, naming), and recall ability. The total score is 30, with lower scores indicating more severe cognitive impairment. The MoCA assesses key domains: attention (digit span, task-switching), executive function (trail-making test), memory (visual and verbal), language (expression, comprehension, fluency), visuospatial skills (figure copying), abstract thinking (similarity judgment), calculation (arithmetic tasks), and orientation (time and place). The total score is 30, with lower scores reflecting worse cognitive dysfunction. Assessments were conducted by trained neurologists following standardized protocols to ensure reliability.

2.3.2 Daily Living Ability

The Activities of Daily Living (ADL) scale was used to evaluate daily living ability. The ADL includes two components: basic self-care (e.g., eating, dressing, grooming, toileting, bathing) and instrumental activities (e.g., using a telephone, shopping, cooking, medication management, financial handling). The total score is 64, with higher scores indicating greater dependency and poorer daily living ability. Assessments were performed by rehabilitation therapists through interviews and observation of patient behavior.

2.3.3 Statistical Analysis

Data were analyzed using SPSS 22.0. Continuous variables are expressed as mean± standard deviation (x±s). Independent samples t-test was used for between-group comparisons, and paired samples t-test for within-group comparisons before and after treatment. Categorical variables are presented as percentages (%), with $\chi^2$ test for group comparisons. AP-value < 0.05 was considered statistically significant.

## 3. Results

### 3.1 Comparison of MMSE Scores Between Groups

Before treatment, there was no significant difference in MMSE scores between the control and treatment groups (P > 0.05). After 12 weeks of treatment, the control group's MMSE score increased from 18.52 ± 3.21 to 21.05 ± 3.56 (P < 0.05), while the treatment group's score increased from 18.38 ± 3.15 to 24.58 ± 3.82 (P < 0.05). Post-treatment between-group comparison revealed that the treatment group had significantly higher MMSE scores than the control group (P < 0.05).

**Table 1:** Comparison of MMSE Scores Between Two Groups Before and After Treatment (x±s,)

| Group | n | Before Treatment | After Treatment |
|---|---|---|---|
| Control | 60 | 18.52±3.21 | 21.05±3.56 |
| Treatment | 60 | 18.38±3.15 | 24.58±3.82 |

Notes: *P < 0.05 vs. before treatment; P < 0.05 vs. control group.

### 3.2 Comparison of MoCA Scores Between Groups

Before treatment, MoCA scores of the control and treatment groups were compared using an independent samples t-test. The resulting P-value was >0.05, indicating no statistically significant difference in baseline MoCA scores between the two groups, confirming comparable multidimensional cognitive function at baseline. After 12 weeks of treatment: Control group: MoCA scores increased from 16.25 ± 3.08 (pre-treatment) to 18.56±3.32 (post-treatment), with a paired samples t-test showing significant improvement (P < 0.05). Treatment group: MoCA scores increased from 16.19 ± 3.02 (pre-treatment) to 21.85 ± 3.58 (post-treatment), also demonstrating significant improvement (P < 0.05, paired samples t-test). An independent samples t-test comparing post-treatment MoCA scores between groups revealed that the treatment group achieved significantly higher scores than the control group (P < 0.05). Detailed data are presented in Table 2.

**Table 2:** Comparison of MoCA Scores Between Two Groups Before and After Treatment (x±s,)

| Group | n | Before Treatment | After Treatment |
|---|---|---|---|
| Control | 60 | 16.25±3.08 | 18.56±3.32 |
| Treatment | 60 | 16.19±3.02 | 21.85±3.58 |

Notes: *P < 0.05 vs. before treatment 2; P < 0.05 vs. control group.

### 3.3 Comparison of ADL Scores Between Groups

Before treatment, an independent samples t-test revealed no significant difference in baseline ADL scores between the control and treatment groups (P > 0.05), indicating comparable baseline daily living abilities. After 12 weeks of treatment: Control group: ADL scores decreased from 45.28±5.63 (pre-treatment) to 40.56±5.12 (post-treatment), with a paired samples t-test confirming significant improvement (P < 0.05). Treatment group: ADL scores decreased from 45.35 ± 5.58 (pre-treatment) to 35.82±4.85 (post-treatment), also showing significant improvement (P < 0.05, paired samples t-test). An independent samples t-test comparing post-treatment ADL scores between groups demonstrated that the treatment group achieved significantly lower scores (greater functional improvement) than the control group (P < 0.05). Detailed data are presented in Table 3.

**Table 3:** Comparison of ADL Scores Between Two Groups Before and After Treatment (x±s,)

| Group | n | Before Treatment | After Treatment |
|---|---|---|---|
| Control | 60 | 45.28±5.63 | 40.56±5.12 |
| Treatment | 60 | 45.35±5.58 | 35.82±4.85 |

Notes: *P < 0.05 vs. before treatment; P < 0.05 vs. control group.

## 4. Discussion

### 4.1 Complexity of Pathogenesis

Alzheimer's disease (AD), characterized by cognitive dysfunction in the elderly, involves highly complex mechanisms that remain incompletely understood despite extensive research. Key pathological hallmarks include: Aβ Deposition: Aβ peptides, derived from amyloid precursor protein (APP) via β- and γ-secretase cleavage, accumulate due to imbalance between production and clearance. These aggregates form senile plaques, disrupting synaptic signaling and inducing neuronal apoptosis. Tau Hyperphosphorylation: Normally stabilizing microtubules, tau proteins detach upon hyperphosphorylation in AD, leading to microtubule

disassembly and neuronal dysfunction. Multifactorial Interactions: Neurotransmitter imbalances (e.g., acetylcholine, dopamine), oxidative stress (free radical-mediated cellular damage), and neuroinflammation synergistically exacerbate neuronal degeneration and disease progression.

### 4.2 Traditional Chinese Medicine (TCM) Understanding of Dementia

In TCM, dementia is referred to as Dai Zheng or Dai Bing, categorized under Shenzhi Bing, mental disorders. It is clinically characterized by intellectual decline, memory impairment, and delayed responsiveness.

Huangdi Neijing: Early descriptions of dementia-like symptoms appear in the Lingshu·Tiannian chapter: "At sixty years… speech becomes prone to errors."

Tang Dynasty: Sun Simiao first formally named the condition Chi Dai in Hua Tuo Shen Yi Mi Chuan (Hua Tuo's Secret Medical Records). Zhang Jingyue in Jingyue Quanshu·Zabing Mo dedicated a chapter to psychosis and dementia, attributing its etiology to: Liver qi stagnation, Emotional disturbances, Overthinking, Prolonged fear or shock. He proposed the pathogenesis involved adverse qi stagnation in the Heart or Liver-Gallbladder meridians, disrupting mental clarity. Chen Shiduo in Bian Zheng Lu (Records of Syndrome Differentiation) detailed Dai Bing symptoms and emphasized its pathogenesis: Liver depression overwhelming the Spleen, Phlegm accumulation in the chest and heart orifice, Leading to clouded consciousness. Treatment: Focus on resolving stagnation, expelling phlegm, strengthening the Stomach, and regulating qi. Wang Qingren in Yi Lin Gai Cuo·Brain Marrow Theory linked dementia to age-related decline of Liver-Kidney essence and depletion of brain marrow, stating: "Children lack memory due to underdeveloped brain marrow; the elderly lose memory as brain marrow empties." According to classical TCM theories, dementia arises from: Deficiency Patterns Kidney Deficiency: Kidney essence governs brain marrow; insufficiency leads to cognitive decline. Qi-Blood Deficiency: Impaired nourishment of the Heart and Mind. Excess Patterns Liver Stagnation: Emotional stress disrupts qi flow. Phlegm Turbidity: Damp-phlegm obstructs the mind's orifices. Blood Stasis: Stagnant blood blocks brain collaterals. Heart-Liver Fire: Neuropsychiatric symptoms (e.g., agitation, anxiety) stem from fire disturbing the Shen (spirit). Core Pathogenesis: A combination of deficiency, phlegm, stasis, and fire.

### 4.3 Mechanisms of the Herbal Formula

The modified Guipi Tang formula demonstrates multifaceted therapeutic effects: Core Herbs: Huangqi (Astragalus) and Renshen (Panax ginseng) enhance cerebral blood flow, reduce oxidative stress, and inhibit neuronal apoptosis via ginsenosides and astragalosides. Danggui (Angelica sinensis) and Chuanxiong (Ligusticum chuanxiong) improve microcirculation and reduce blood viscosity, facilitating neural repair. Adjunctive Herbs: Shichangpu (Acorus tatarinowii) and Yuanzhi (Polygala tenuifolia) modulate neurotransmitter release (e.g., acetylcholine) and promote synaptic plasticity. Fuling (Poria cocos) and Baizhu (Atractylodes macrocephala) regulate metabolic homeostasis, mitigating neurotoxic edema. Suanzaoren (Ziziphus spinosa) improves sleep quality, critical for neural repair.

## 5. Conclusion

The treatment group exhibited superior outcomes: Cognitive Improvement: Higher MMSE and MoCA scores reflect enhanced orientation, memory, attention, language, and executive function. Functional Recovery: Lower ADL scores indicate improved independence in basic (eating, dressing) and instrumental (shopping, cooking) daily activities. The integrated therapy combining Guipi Tang with conventional treatment significantly improves both cognitive and functional outcomes in AD patients, likely through synergistic modulation of Aβ/tau pathology, neuroprotection, and metabolic regulation.

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