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Clinical Study

Clinical study of acupuncture combined with medication for the elderly with Alzheimer disease

针药并用治疗老年阿尔茨海默病患者的临床研究

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Abstract
Objective: To observe the impact of mind-regulating acupuncture plus donepezil on the cognitive ability, mean cerebral blood flow velocity, event-related potential P300, and activities of daily living (ADL) in the aged patients with Alzheimer disease (AD).
Methods: Sixty senile AD patients were divided into a treatment group and a control group following the envelope method for random allocation, with 30 cases in each group. Based on the conventional treatment of the internal medicine, the control group received oral donepezil, and the treatment group received oral donepezil plus mind-regulating acupuncture. After 4-week treatment, the two groups were evaluated by the mini-mental state examination (MMSE), Alzheimer disease assessment scale-cognitive part (ADAS-Cog), and ADL; changes in P300 and the mean cerebral blood flow velocity were also observed.
Results: Before treatment, there were no significant differences in the scores of MMSE, ADAS-Cog, or ADL between the two groups (P>0.05). The MMSE score increased after treatment in both groups and was notably higher in the treatment group than in the control group, showing intra-group and inter-group statistical significance (P<0.05). After treatment, the ADAS-Cog and ADL scores dropped in both groups and were markedly lower in the treatment group than in the control group, also showing intra-group and inter-group statistical significance (P<0.05). Compared with the same group before treatment, the latency of P300 was shortened and the amplitude was extended in both groups, all with statistical significance (P<0.05); the latency was shorter and the amplitude was larger in the treatment group than in the control group after treatment, presenting significant between-group differences (P<0.05). The mean blood flow velocity accelerated after the intervention in both groups, and the differences were statistically significant (P<0.05); the improvement in the treatment group was more notable than that in the control group (P<0.05).
Conclusion: Mind-regulating acupuncture plus donepezil can regulate the latency and amplitude of P300, increase cerebral blood flow, and improve the learning and memory abilities of AD patients.
Keywords: Acupuncture Therapy; Acupuncture Medication Combined; Donepezil; Alzheimer Disease; Activities of Daily Living; Event-related Potentials, P300

【摘要】目的: 观察调神针法配合多奈哌齐对老年性阿尔茨海默病(AD)患者认知能力、平均脑血流速度、事件相关电位P300以及日常生活能力(ADL)的影响。**方法:** 按照随机分配信封法将60例老年性AD患者分为治疗组和对照组，每组30例。在常规内科治疗的基础上，对照组口服多奈哌齐治疗；治疗组在对照组的基础上加用调神针刺法。两组均治疗4周后评价简易智力状态评价量表(MMSE)、阿尔茨海默病评估量表认知部分(ADAS-Cog)及ADL评分，观察P300和平均脑血流速度的变化。**结果:** 治疗前两组患者MMSE、ADAS-Cog及ADL评分比较，差异无统计学意义(P>0.05)。治疗后两组患者MMSE评分均高于治疗前，且治疗组MMSE评分显著高于对照组，组内及组间差异有统计学意义(P<0.05)。治疗后两组患者ADAS-Cog及ADL评分均降低，且治疗组评分明显低于对照组，组内及组间差异有统计学意义(P<0.05)。与同组治疗前比较，两组患者治疗后P300潜伏期均缩短，波幅均延长，差异有统计学意义(P<0.05)；治疗组患者治疗后潜伏期小于对照组，波幅高于对照组，组间差异有统计学意义(P<0.05)。治疗后两组血管平均血流速度均较治疗前升高，差异有统计学意义(P<0.05)，且治疗组改善情况优于对照组(P<0.05)。**结论:** 调神针法联合多奈哌齐可以调节P300的潜伏期及波幅，提高患者的脑血流量，同时改善老年性AD患者的学习记忆能力。

【关键词】针刺疗法；针药并用；多奈哌齐；阿尔茨海默病；日常生活活动；事件相关电位, P300
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Alzheimer disease (AD), a sneaky neurodegenerative disorder significantly affecting the quality of life of the aged population, has become a real challenge to geriatrics[1]. AD's typical clinical manifestation is cognitive impairment. In the long term, AD may also bring negative emotions, including depression, anxiety, agitation, etc., which will, in turn, aggravate AD's clinical symptoms[2]. According to the ancient physicians' elaboration of the Governor Vessel-brain-mind theory, when people are old and fragile, the marrow sea will become deficient, and the mind will lack nourishment, subsequently leading to AD. The Governor Vessel charges Yang Qi of the whole body, connects the brain, kidney, and marrow, and is an essential meridian for treating brain disorders[3]. Traditional Chinese medicine (TCM) holds that the priority should fixate on treating the mind in acupuncture treatment. Consequently, some doctors propose treating the mind first to treat brain diseases. Based on these theories, this trial adopted mind-regulating acupuncture by selecting points from the Governor Vessel plus donepezil to treat AD.

1 Clinical Materials

1.1 Diagnostic criteria

We referred to the diagnostic criteria for AD jointly stipulated by the National Institute of Neurological and Communicative Disorders and Stroke and the Alzheimer's Disease and Related Disorders Association (NINCDS-ADRDA)[4].

1.2 Inclusion criteria

Met the diagnostic criteria for AD; age ≥60 and ≤80 years old, males or females; scored 10-25 points by the mini-mental state examination (MMSE); approved by the ethics committee and the written informed consent obtained; not taking any medications to treat AD within the previous 2 weeks.

1.3 Exclusion criteria

Showed poor compliance and failed to stick with the treatment protocol; serious hearing or visual impairment; severe organic or mental disorders; allergic to donepezil or with a history of fainting during acupuncture.

1.4 Statistical methods

The SPSS version 23.0 software was used for data analysis. The normally distributed measurement data were described as mean ± standard deviation ($\bar{x} \pm s$), checked by the paired samples *t*-test in intra-group comparisons or group *t*-test in between-group comparisons. If not meeting normal distribution, the measurement data would be expressed as median (interquartile range) [M (IQR)], checked by the paired samples rank-sum test in intra-group comparisons or the two independent samples rank-sum test in between-group comparisons. The enumeration data were expressed as rates and analyzed using the Chi-square test. $P<0.05$ indicated statistical significance.

1.5 General data

Sixty AD patients visiting the Second Affiliated Hospital of Heilongjiang University of Chinese Medicine between January 2019 and February 2021 were recruited. The Ethics Committee of the Second Affiliated Hospital of Heilongjiang University of Chinese Medicine approved the trial protocol (Approval No. 2019-27). We adopted the envelope method using a computer to randomly assign the patients to a treatment group or a control group at a ratio of 1:1, with 30 cases in each group. The general data were statistically equal between the two groups ($P>0.05$), suggesting comparability. The details are shown in Table 1.

Table 1 Comparison of the general data

Group	*n*	Gender/case		Mean age/year ($\bar{x} \pm s$)	Mean disease duration/year ($\bar{x} \pm s$)	Education level/case		
		Male	Female			Illiterate	Primary school	Junior middle or higher
Treatment	30	12	18	68.9±8.3	2.7±0.6	2	5	23
Control	30	16	14	69.7±8.1	3.1±0.4	3	7	20

2 Treatment Methods

The patients received interventions for primary diseases, including reducing blood pressure, blood glucose, and lipids. They also received health education on diet and living habits.

2.1 Treatment group

Patients in the treatment group were intervened by mind-regulating acupuncture plus donepezil.

Points: Fengfu (GV16), Baihui (GV20), and Shenting (GV24).

Operation: The patient took a sitting position. The physician used disposable acupuncture needles of Hwato brand (Suzhou Medical Appliance Factory, Co., Ltd., China) for acupuncture. Fengfu (GV16) should be punctured with the needle tip toward the lower jaw, and the needle should go slowly 15-20 mm in depth. Baihui (GV20) and Shenting (GV24) were punctured using the subcutaneous needling method, with needles insertion for 20-30 mm under the epicranial aponeurosis. Then, the physician performed small-amplitude high-frequency (200 r/min or higher) twirling needling manipulations while puncturing the needle, 15 min later, and before removing the needle, 2 min

each time. The stimulating intensity should be within the patient's tolerance, and the needles should be remained for 30 min. The treatment was offered by the same senior physician once daily, 7 times as a course of treatment for 4 courses.

Medication: Donepezil tablets [State Food and Drug Administration Approval No. H2007081, Eisai China Inc., China] were taken orally, 5 mg each time, once daily, for 4 weeks.

2.2 Control group

Patients in the control group only took donepezil for treatment with the same dosage and duration.

3 Efficacy Observation

3.1 Observation items

3.1.1 MMSE score[5]

MMSE is known for its reliability and validity; a lower score indicates a worse cognitive ability.

3.1.2 Alzheimer disease assessment scale-cognitive part (ADAS-Cog)[6]

ADAS-Cog can assess the level of cognitive impairment. The higher the score, the more serious the cognitive impairment.

3.1.3 Activities of daily living (ADL)[7]

The ADL evaluates activities such as toilet use, feeding, and mobility. The lower the score, the worse the self-care ability.

3.1.4 Detection of event-related potential (ERP) P300

The ERP P300 was detected one day before treatment and the next day of the final session using the KEYPOINT electromyograph and evoked potential equipment (Medtronic Inc., USA). P300 is an endogenous core member of ERPs. A shorter latency and larger amplitude of P300 suggest better cognitive function.

3.1.5 Transcranial Doppler (TCD)

The CV550 Philips color Doppler ultrasonography (frequency 2 MHz) was used to measure the mean blood flow velocity of bilateral middle cerebral arteries (MCA), anterior cerebral arteries (ACA), bilateral posterior cerebral arteries (PCA), bilateral vertebral arteries (VA), and the basilar artery (BA) before and after treatment.

3.1.6 Adverse reactions

The adverse reactions of acupuncture treatment included fainting, ecchymosis, sustained needling sensations after needle removal, etc. The adverse reactions of the pharmaceutical treatment included dizziness, nausea, vomiting, diarrhea, etc. These reactions were kept a record by the physician who conducted acupuncture treatments.

3.2 Results

3.2.1 Comparison of the scores of MMSE, ADAS-Cog, and ADL

There were no significant differences in the MMSE, ADAS-Cog, or ADL scores between the two groups before treatment (P>0.05), indicating the comparability. After treatment, the MMSE and ADL scores increased in both groups (P<0.05) and were markedly higher in the treatment group than in the control group (P<0.05). The ADAS-Cog score dropped after treatment in both groups (P<0.05) and was significantly lower in the treatment group than in the control group (P<0.05). Please find the details in Table 2.

3.2.2 Comparison of the latency and amplitude of P300

The latency and amplitude of P300 were statistically equal between the two groups before treatment (P>0.05), suggesting comparability. After treatment, the latency of P300 was shortened, and the amplitude was extended in both groups, all showing statistical significance (P<0.05); the latency of P300 was shorter, and the amplitude was larger in the treatment group than in the control group, presenting significant between-group differences (P<0.05). The data are detailed in Table 3.

3.2.3 Comparison of the mean cerebral blood flow velocity

There were no significant differences in the mean cerebral blood flow velocities between the two groups before treatment (P>0.05), suggesting comparability. After treatment, the mean cerebral blood flow velocities increased after treatment in both groups, showing notable intra-group differences (P<0.05); the improvements were more significant in the treatment group than in the control group (P<0.05). The details are shown in Table 4 and Table 5.

Table 2 Comparison of the MMSE, ADAS-Cog, and ADL scores before and after treatment ($\bar{x}\pm s$) Unit: point

Group	n	MMSE score		ADAS-Cog score		ADL score	
		Pre-treatment	Post-treatment	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
Treatment	30	16.48±1.23	29.16±2.11[1)2)]	38.15±4.95	28.45±3.75[1)2)]	33.59±1.87	65.56±1.63[1)2)]
Control	30	16.42±1.34	23.27±2.13[1)]	38.35±4.23	33.46±4.01[1)]	34.32±1.81	45.87±1.59[1)]

Note: MMSE=Mini-mental state examination; ADAS-Cog=Alzheimer disease assessment scale-cognitive part; ADL=Activities of daily living; compared with the same group before treatment, 1) P<0.05; compared with the control group after treatment, 2) P<0.05.

Table 3 Comparison of the latency and amplitude of P300 before and after treatment ($\bar{x}$ ±*s*)

Group	*n*	Time	Latency/ms	Amplitude/μV
Treatment	30	Pre-treatment	369.78±18.54	4.85±0.56
		Post-treatment	336.54±14.10[1)2)]	7.98±0.59[1)2)]
Control	30	Pre-treatment	368.94±17.65	4.91±0.52
		Post-treatment	352.18±15.28[1)]	5.85±0.65[1)]

Note: Compared with the same group before treatment, 1) $P<0.05$; compared with the control group after treatment, 2) $P<0.05$.

Table 4 Comparison of the mean blood flow velocities of the anterior circulation ($\bar{x}$ ±*s*) **Unit: cm/s**

Group	*n*	Time	Anterior cerebral artery	Middle cerebral artery
Treatment	30	Pre-treatment	36.85±3.68	40.25±3.21
		Post-treatment	46.25±3.14[1)2)]	50.27±2.97[1)2)]
Control	30	Pre-treatment	36.57±3.51	41.07±3.15
		Post-treatment	42.35±3.24[1)]	45.37±2.68[1)]

Note: Compared with the same group before treatment, 1) $P<0.05$; compared with the control group after treatment, 2) $P<0.05$.

Table 5 Comparison of the mean blood flow velocities of the posterior circulation ($\bar{x}$ ±*s*) **Unit: cm/s**

Group	*n*	Time	Vertebral artery	Basilar artery	Posterior cerebral artery
Treatment	30	Pre-treatment	16.52±2.57	18.36±2.87	19.24±2.61
		Post-treatment	26.12±2.74[1)2)]	28.57±2.67[1)2)]	28.97±2.54[1)2)]
Control	30	Pre-treatment	17.21±2.69	18.25±2.94	19.19±2.74
		Post-treatment	20.38±2.78[1)]	23.27±2.47[1)]	24.19±2.58[1)]

Note: Compared with the same group before treatment, 1) $P<0.05$; compared with the control group after treatment, 2) $P<0.05$.

3.2.4 Adverse reactions

During the study, the treatment group had 1 case of needle fainting and 1 case of ecchymosis, which made the adverse reaction rate 6.67% in this group. One case of nausea happened in the control group during the treatment, and the adverse reaction rate was 3.33%. The symptoms were relieved after management, not affecting the following treatment. There was no significant difference in the adverse reaction rate between the two groups ($P>0.05$).

4 Discussion

AD is a neurodegenerative disease, clinically manifesting as declined learning ability and memory and progressive cognitive impairment, often accompanied by mental symptoms[8-9]. Each year, more and more people are diagnosed with AD in the rapidly aging society[10]. As the condition aggravates, AD dramatically affects the quality of daily life amongst older patients. Regarding the treatment of AD, pharmaceutical treatment alone acts slowly but costs high, let alone various adverse reactions. Therefore, finding a safe and effective treatment for AD becomes urgent. Donepezil, the medication selected in this study, is one of the principal drugs used to treat AD. Donepezil is a cholinesterase inhibitor that improves the patient's cognitive function by boosting the level of acetylcholine[11].

In TCM, AD belongs to the scope of "dementia". It is located in the brain and associated with weakness and aging, deficiency in the brain and marrow, and insufficient nutritional supply to the mind. According to TCM, the kidney's failure to produce sufficient essence and the malnourished brain are to blame for the development of dementia. The Governor Vessel runs through the brain, which is recognized as the sea of marrow; the kidney governs bones and is in charge of producing marrow. The Governor Vessel is the sea of Yang meridians and the commander of Yang Qi of the whole body and connects with the kidney. Hence, it is suggested that the Governor Vessel is closely linked with the brain, kidney, and spinal cord[12]. The mind is the foundation for regulating body activities[13]. Also, physicians from various generations hold that the Governor Vessel should be considered first for treating brain-related disorders. Therefore, we selected Fengfu (GV16), Baihui (GV20), and Shenting (GV24) in this study to treat AD by supplementing essence and marrow and unblocking and regulating the Governor Vessel to nourish the brain and mind and harmonize the mind and spirit. Data mining analysis reveals that Governor Vessel points are commonly selected in the treatment of cognitive impairment[14-15]. Acupuncture at

Governor Vessel points helps blood flow in the cerebral cortex and regulates cell metabolism to repair damaged cranial nerves[16]. In this study, we adopted the mind-regulating acupuncture method to regain the balance between Yin and Yang by modulating the patient's mind. This is an acupuncture method that can modulate the mind, Zang-Fu organs, Qi, blood, and body fluids[17]. Ancient TCM classics all emphasize the mind's role in the treatment process. In modern times, academician SHI Xuemin also points out that, "the mind is involved in the begging of various diseases[18]; the priority of acupuncture should lay on awakening the mind so that the flow of Qi becomes smooth and diseases can be eradicated". Therefore, to treat AD, we should treat the mind first. In this study, the acupuncturist always communicated with the patient before treatment to ensure the patient was in a good state, physically and emotionally, not anxious or stressed but entirely focused. Small-amplitude and high-frequency twirling acupuncture manipulations were offered 3 times during a treatment session to increase the stimulation. At the same time, the physician also observed the patient's responses and asked the patient to feel the needling sensation, which was supposed to reach the corresponding brain functional area through the epicranial aponeurosis to benefit the brain and intelligence and calm the mind[19-20]. After the acupuncture treatment, health education was offered to soothe the patient's heart and mind and help them develop a healthy lifestyle to achieve a better treatment result finally[21].

The MMSE and ADAS-Cog, two classic scales for evaluating the cognitive function, were used in this study. They have a high sensitivity and can evaluate the patient's cognitive function from multiple perspectives such as memory, language, and execution. The results here showed that both groups gained increases in the MMSE score after treatment, and the score was higher in the treatment group than in the control group; the ADAS-Cog score dropped after treatment in both groups and was lower in the treatment group than in the control group. Furthermore, ADL has been commonly used to evaluate AD patients' basic daily activities such as toilet use, dressing, bathing, etc. The study results showed that the ADL score increased after treatment in both groups and was notably higher in the treatment group.

Rheoencephalogram examines blood supply, elasticity, tone, and other brain blood vessel features. Research demonstrates that cerebral circulation improves, brain cell function recovers, cerebral metabolism strengthens, and brain neurons get repaired[22]. We observed enhanced cerebral blood flow in the current study after the intervention in both groups and more significant improvements in each mean cerebral blood flow velocity in the treatment group. P300 can reflect the brain's cognitive function[23]. In this study, the latency of P300 was shortened, and its amplitude became larger in both groups after treatment, and the latency was obviously shorter, and the amplitude was larger in the treatment group than in the control group.

To conclude, this trial tells that mind-regulating acupuncture plus donepezil can accelerate cerebral blood flow and modulate P300's latency and amplitude in AD patients to improve learning and memory abilities. However, due to the limited sample size, we did not stage long-term follow-ups in this study. Next, we will conduct multicenter studies to verify further the mechanism of mind-regulating acupuncture in treating AD.

Conflict of Interest

The authors declare that there is no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from all individual participants or their guardians.

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