Clinical Research

Clinical observation on effect of cranial suture acupuncture combined with donepezil hydrochloride tablets for Alzheimer's disease

颅针结合盐酸多奈哌齐片治疗阿尔茨海默病的临床观察

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ABSTRACT

Objective To investigate the clinical efficacy of acupuncture combined with medicine for Alzheimer's disease. **Methods** Fifty-five patients of Alzheimer's disease were randomly divided into two groups in accordance with random number table: the drug group (n=28) was treated with oral donepezil hydrochloride tablets, once a day for 5–10 mg with 10 days as a course of treatment; the combined acupuncture and drug group (n=27) was treated with cranial suture acupuncture combined with donepezil hydrochloride tablets in the above-mentioned way. The cranial suture acupuncture was given once a day for 30 min with 10 days as a course of treatment. Both groups were given treatment for two courses. Mini-mental state examination (MMSE), Alzheimer's disease assessment scale (ADAS-Cog), activities of daily living scale (Barthel) and electroencephalogram (EEG) were checked before and after treatment, to evaluate the efficacy of each group via integral changes of Barthel. **Results** MMSE score increased, Barthel index score increased, and ADAS-Cog score decreased in the two groups after treatment (P<0.05, P<0.01), and the efficacy of the combined acupuncture and drug group was more significant (P<0.01). The α wave frequency and amplitude and θ wave frequency of EEG increased after treatment in both groups (P<0.05), θ wave amplitude decreased (P<0.01), and the efficacy of the combined acupuncture and drug group was superior to that of the drug group in terms of EEG improvement (P<0.05). The total effective rate of the combined acupuncture and drug group (88.9%, 24/27) was superior to that of drug group (67.9%, 18/28, P<0.05). **Conclusion** The effect of cranial suture acupuncture combined with donepezil hydrochloride tablets for Alzheimer's disease is more significant than only medicine therapy.

KEY WORDS: Alzheimer's disease; cranial suture acupuncture; acupuncture therapy

Alzheimer's disease (AD), known as senile dementia, is one of the most common diseases among elderly patients with steady decline in memory and cognitive function as main symptoms and is caused by degenerative changes in the central nervous system. Over the years, most researchers agree that its main pathological mechanism is the inflammatory reaction triggered by β-amyloid deposition activating microglia.

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Scholars have been trying multiple medications and therapies to improve the symptoms of AD patients. The author treated Alzheimer's disease with cranial suture acupuncture combined with donepezil hydrochloride tablets. Here's the report.

CLINICAL DATA

General data

Fifty AD patients were collected from inpatient and outpatient of Neurology Dept. and Dept. of Rehabilitation Medicine of Zhengzhou People's Hospital from December 2009 to May 2011. They were divided into the drug group (28 cases) and the combined acupuncture and drug group (27 cases) in accordance with random number table. In the drug group, there were 13 males and 15 females; aged 62–81 with an average of (70.7±9.1); course of the disease for 4 to 9 months with an average of (5.8±0.6) months. In the combined acupuncture and drug group, there were 14 males and 13 females; aged 61-78 with an average of (70.3±8.0) years old; course of the disease for 3 to 8 months with an average of (5.0±1.1) months. The differences of the indicators above in the two groups was not statistically significant (all $P>0.05$) and were comparable.

Diagnostic criteria

Conform to diagnostic criteria listed in the 4th edition of *The Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV)[2] prepared by American Psychiatric Association.

Alzheimer's disease: A. Various cognitive deficits occur, manifested by the two symptoms as follows: ① memory impairment (impairment of learning ability or failure to recall); ② at least one of the following cognitive impairments: (a) aphasia (language disorders); (b) apraxia (with motor function yet without the ability to perform an action); (c) agnosia (with sensory function yet without the ability to recognize or identify objects); (d) disorder of management functions (i.e. planning, organizing, sequencing and abstraction) . B. Defects in social or occupational functions caused by cognitive deficits in line with A1 and A2, and the functions significantly decline. C. The disease is characterized by gradual onset and continual decline. D. Cognitive deficits in line with A1 and A2 but not caused by the factors as follows: ① other disorders of central nervous system that may lead to progressive defects of memory and cognitive functions (e.g., cardiovascular disease, Parkinson's disease, Huntington's disease, subdural hematoma, normal pressure hydrocephalus and brain tumor); ② systemic disorders known to cause dementia (e.g., hypothyroidism, vitamin B12 or folate deficiency, niacin deficiency, hypocalcemia, neurosyphilis, HIV infection); ③ substance-induced disorders. E. The defects don't result from delirium. F. The defects don't arise from other disorders (such as major depression and schizophrenia).

Hachinski ischemic index scale is designed for identifying vascular dementia and Alzheimer's disease via 13 items with 1 to 2 points for each. The score ⩾7 points is diagnosed as vascular dementia, the score ⩽4 points as Alzheimer's disease and 5–6 points as mixed dementia.

Clinical dementia rating scale is designed for doctors to evaluate the degree of patients' cognitive impairment and rate the severity of the disease instantly by analyzing the information obtained by talking with patients and their families. The items assessed include memory, orientation, ability of judgment and problem solving, ability of work and communication, family life and hobbies and independent living skills. Each of the above six items is rated as five levels from non-impairment to severe impairment, and the score for each item is not repeatedly added. Instead, a score of the six items is totaled according to the total scoring standards, and the results are represented by 0, 0.5, 1, 2, 3, rated as normal, suspected, mild, moderate and severe respectively.

Inclusive criteria

Meet diagnostic criteria of DSM-Ⅳ, Hachiski ischemic scale score ⩽4 points, diagnosed as mild or moderate Alzheimer's disease according to the clinical dementia rating scale score. Patients signed an Informed Consent Form, and the study program were approved by the medical Ethics Committee of the hospital.

Exclusive criteria

Patients who could not cooperate in receiving psychological tests due to eye or ear disorders or mental diseases; patients with serious organic diseases such as heart, liver and kidney dysfunctions; patients who took drugs that might affect efficacy assessment in the past month.

METHODS

The drug group

5–10 mg of donepezil hydrochloride tablets (SFDA Approval No. H20020978) were taken once a day with 10 days as a course of treatment. Such