

Effect of Anshen Dingzhi Wan Combined with Transcranial Magnetic Stimulation on Mental Retardation of Heart-Gallbladder Qi-Deficiency Type

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Abstract: The objective of this paper is to observe the curative effect of Anshen Dingzhi Wan combined with repeated transcranial magnetic stimulation on mental retardation of heart-gallbladder Qi-deficiency type. The methods of this paper is sixty enrolled children were randomly divided into treatment group and control group with 30 cases each. The treatment group was given Anshen Dingzhi Wan repeated transcranial magnetic stimulation therapy and rehabilitation training, while the control group was given rehabilitation training only. The Chinese revised Wechsler Intelligence Scale for infants and Children was used for blind assessment of the intelligence level of the children in the two groups, and then the efficacy was compared, and the increase rate of IQ score was calculated according to the Nimodipine method. The results of this paper is Anshen Dingzhi Wan was effective in the treatment of mental retardation of heart-gallbladder Qi-deficiency type. The clinical efficacy of the treatment group was far better than that of the control group, and the difference between the treatment group and the control group was statistically significant ($P < 0.05$). The conclusion of this paper is Anshen Dingzhi Wan combined with repeated transcranial magnetic stimulation has significant effect on mental retardation of heart and gallbladder Qi deficiency type and low side effects.

Intellectual development disorder, also known as intellectual deficiency (ID/IDD), refers to the developmental disorders of children whose intelligence is obviously lower than the normal level during the development period, and who suffer from cognitive dysfunction and social adaptability defects. The patients mainly suffer from language dysfunction, so the Traditional Chinese Medicine regards children's intellectual development disorder as the category of language delay. Through the investigation, we found that the incidence of mental retardation in Chinese children is about 1.2%, and the incidence is increasing year by year[1]. Its etiology mainly includes genetic and non-genetic causes, including congenital metabolic disorders, chromosome abnormalities, single gene diseases, premature delivery, trauma, poisoning and lack of education, etc. [2]. With the development of

Chinese society, children's intellectual development disorder is more worthy of attention, it not only affects the children's development and social adaptability, but also causes great trouble to the patient's family. If children are not treated in time, they will even have a variety of negative effects on society when they grow up. In terms of treatment, Western medicine currently treats mental retardation mainly for the treatment of etiology, that is, according to the existing data of the causes of disease, such as long-term malnutrition, improper diet, hearing and vision level decline, a variety of chronic diseases, poisoning and so on, adopt different treatment means to remove the etiology, so as to improve or recover their intelligence. Moreover, for IDD caused by social, psychological and cultural reasons, we should change the environment, strengthen education, create a good social psychological and cultural atmosphere and harmonious family environment, so as to improve intelligence level.

Clinically, we found that Western medicine has a single treatment for IDD, and the efficacy is not ideal. The innovation and development of traditional Chinese medicine provides a new idea for the treatment of mental retardation. Chinese medicine treatment is rich, can take different treatment methods combined treatment. In clinical practice, we have found that synergies between therapies are far more effective than monotherapies. Therefore, different treatment methods can be used in combination. Under the guidance of TCM theory, TCM characteristic therapy combined with Western medicine etiology treatment and rehabilitation treatment, with full coverage of early treatment and late prognosis, can improve the cognitive function and social adaptability of children, improve their intelligence level and quality of life, achieve the effect of treating both symptoms and root causes. In the past two years, Anshen Dingzhi wan combined with repeated transcranial magnetic stimulation and rehabilitation training have been used in our hospital to treat children with mental retardation of heart-gallbladder Qi-deficiency type with outstanding efficacy, and the following reports are reported.

1. Clinical Data

1.1. General Information

Sixty-four children with mental retardation of heart-gallbladder Qi-deficiency were selected from Xi'an Brain Disease Hospital of Traditional Chinese Medicine from July 2021 to October 2022. They were randomly divided into the treatment group and the control group according to the time of visit. In the treatment group, there were 32 cases, including 18 males and 14 females, 24 mild cases, 5 moderate cases, 2 severe cases and 1 extremely severe case. There were 32 cases in the control group, including 17 males and 15 females, 23 mild cases, 5 moderate cases, 2 severe cases and 2 extremely severe cases. There was no significant difference in the general information between the two groups ($P > 0.05$).

1.2. Diagnostic Criteria

1.2.1. Diagnostic Criteria of Western Medicine [3]

① Intelligence level is significantly lower than the average level, that is, IQ is 2 standard deviations lower than the average of the normal population. The average IQ is below 70. Clinically, mental retardation is divided into four levels [4] based on IQ: mild: IQ between 51-70, moderate: IQ between 36-50, severe: IQ between 20-35, and extremely severe: IQ<20. ② There are cognitive dysfunction and social adjustment deficits. ③ It appears in the early developmental stage.

1.2.2. Diagnostic Criteria of TCM syndrome Types [5]

Conform to the five retardations - Language Delay (low intelligence) TCM clinical diagnosis and treatment expert consensus. The clinical manifestations of children are as follows: ①children with slow response to external things; ②children are easy to be frightened; ③Children with restlessness, white face, fatigue, short sleep time, more dreams and poor appetite; ④children with pale tongue with whitish fur, deep and thin pulse.

1.3. Inclusion criteria

①It conforms to the diagnostic standards of Western medicine and the diagnostic criteria of TCM syndrome Types. ②Children should be less than 8 years old, able to adhere to systematic treatment (3 months as a therapeutic observation cycle) and have the consent of their parents or guardians.

1.4. Exclusion Criteria

①It does not conform to the diagnostic standards of Western medicine and the diagnostic criteria of TCM syndrome Types. ②Children's liver, kidney and hematopoietic function of were impaired. ③Other diseases accompanied by mental retardation, cannot accurately evaluate the therapeutic effect, such as cerebral palsy, etc. ④Children over the age of 8 years old, unable to adhere to systematic treatment, or participate in other treatments.

1.5. Exclusion and shedding criteria

①Children who were enrolled and not treated as required. ②Children who were enrolled and could not provide verification data. ③Children who were enrolled and dropped out before the end of the prescribed observation period.

2. Treatment Methods

2.1. Control group

The patients were given general acupuncture treatment and routine rehabilitation training. Rehabilitation training includes language training, cognitive training, sensory integration training and so on. Choose the corresponding rehabilitation training according to the different conditions of children. Children with rehabilitation training once a day, each time for 40 minutes of rehabilitation training.

2.2. Treatment group

1) Give the patient take Anshen Dingzhi Wan. Formula composition: Ginseng 15g, Poria cocos 10g, Tuckahoe with pine 10g, polygonia tenuifolia Willd 10g, Acorus tatarinowii 12g, Dens Draconis 12g. Decocted in water, one pair a day, morning and evening. 4 weeks is a course of treatment, three sessions in a row. 2) Combined with repeated transcranial magnetic stimulation: Our hospital adopts the neuromagnetic stimulator, model MagstimRapid2, manufactured by British Magsidd Co. , LTD. The basic prescription for mental retardation is as follows: Location: dorsolateral prefrontal area (alternating left and right); Exercise threshold: measured according to

the specific situation of different children; intensity: threshold value $\times 80\%$; Frequency: 5Hz; Stimulation time: 3s; Waiting time: 12s; Sequence number :80 groups; Total time: 20 minutes; 1200 pulses in total. According to the different symptoms of children, such as insomnia, tourette syndrome, hyperactivity, etc., the prescription can be adjusted accordingly. Five times a week, four weeks for a course, three courses. Contraindications:① Patients equipped with metal objects such as cardiac pacemakers and cochlear devices;② infants under two years old;③ patients with epilepsy; ④ patients with uncontrollable migraine;⑤ people with serious heart disease. 3) The patients were given general acupuncture treatment and routine rehabilitation training.

3. Observation and evaluation

3.1. Observation Indicators

Observation indicators are the basic elements of intelligence, such as comprehension, attention, observation, memory, expression and imagination.

3.2. Evaluation criteria for efficacy

The Chinese revised Wechsler Intelligence Scale for Infants and Children (C-WISC) was used in our hospital to score the children before and after treatment. We used the Nimodipine method to calculate the increase rate of IQ scores [6].

Clinical efficacy criteria refer to the therapeutic effect evaluation of National clinical key specialty five retardations (mental retardation) TCM diagnosis and treatment program in 2012. Obvious effect: increase rate of IQ score $\geq 30\%$; Effective: increase rate of IQ score $\geq 10\%$; Ineffective: increase in IQ score $< 10\%$.

4. Statistical Analysis

In this clinical observation, SPSS26.0 statistical software was used to analyze relevant data in our hospital and χ^2 was used as the statistical test. When the result was $P < 0.05$, it was statistically significant. The statistical analysis results are shown in Table 1.

5. Results

Table 1: Comparison of clinical effect between the two groups after treatment (*n*)

group	n	Apparent effect	effective	void	Total effective rate (%)
treatment group	32	18	11	3	90.60%
control group	32	11	11	10	68.80%

Note: After χ^2 test, $\chi^2=4.730$ $p=0.03$, there was a significant difference between the two groups ($0.01 < P < 0.05$).

6. Discussion

Mental retardation are a series of clinical syndromes caused by poor mental system development in children, which have a great impact on children's development and social adaptability. In ancient Traditional Chinese Medicine books there is no "intellectual development disorder" this disease name. According to the clinical manifestations and characteristics of mental retardation, TCM classifies it into the category of "language retardation" in "Five retardations". "Language retardation" was first seen in "Theories on the origin of various diseases". It said: "The five viscera

have five voices, the voice of the heart is speech. Children four or five years old cannot speak, because in the fetus, the mother suddenly frightened, internal movement in the womb and heart Qi discord, resulting in children four or five years old cannot speak. It can be seen that congenital factors are very important factors of morbidity. Heart-gallbladder Qi-deficiency is one of the main syndrome types of Five retardations in traditional Chinese medicine. "Plain question" said: "The heart is the official of the monarch, hidden in the mind", "gallbladder is the official of the right, with the ability to decide things". Both heart and gallbladder play important roles in the mind and they are closely related. The decision function of gallbladder helps the heart to lead the mind, while the decision function of gallbladder needs the heart to lead. The two complement each other and jointly support part of the mental activities of the body. Both are based on the support of human gasification physiologically, and the disorder of Qi is also the main pathology. Children congenital Heart Qi disharmony will affect the physiological function of bile Qi, resulting in the common performance of Qi deficiency, Heart Qi deficiency cause child uneasy, sitting restlessness. Bile Qi deficiency cannot rise, determination function is impaired, resulting in phlegm in the body, disturb thinking, so this disease shows the symptoms of being easily frightened, timid and cowardly. Children's growth and development, rely on the human body's vitality to promote and warm. The heart is the ruler of the viscera and main thinking, Qi deficiency cannot nourish the human body, affect the children's judgment of their own and the surrounding environment, so often see slow reaction, look dull, as well as inferiority, isolation and other psychological. Pale tongue and thin white coat on the tongue, depth pulse are signs of heart-gallbladder Qi-deficiency. Our hospital adopts the method of Tong Qiao, Replenishing Qi, remove phlegm, calming thinking and intelligence. Anshen Dingzhi Wan decoction is used to treatment type is heart-gallbladder Qi-deficiency. Anshen Dingzhi Wan comes from Cheng Zhongling's Medical insight in the Qing Dynasty [7]. Modern studies have shown that Anshen Dingzhi Wan can regulate mood, anti-convulsion, and have outstanding efficacy in treating delirious disorders with few adverse reactions [8]. Formula composition: Ginseng, Poria cocos, Tuckahoe with pine, Polygonia tenuifolia, Acorus tatarinowii, Dens Draconis. The Sheng Nong's herbal classic says that Ginseng can "calm the mind. Modern pharmaceutical studies have found that ginseng extract contains banaculun, which can stimulate the heart, promote circulation and increase blood pressure, and contains glycogen, which can increase raw materials for blood production, replenish Qi and promote blood production [9]. With the light taste of Poria cocos to dehumidification, get rid of the phlegm left because of Qi deficiency, and can make thinking calm. The warm human environment creates conditions for the generation of Qi, Acorus tatarinowii have pungent taste, can TongQiao and expectoration, so it can help ginseng to replenish Qi, to achieve fill the five viscera effect. Modern pharmacological studies have found [10] that alpha-asarether in Acorus tatarinowii have anticonvulsant and sedative effects. Polygonia tenuifolia is used to enhance the Yang Qi of the heart and remove phlegm; The use of Dens Draconis can make the human body Yang latent, into the liver to calm the mind; Tuckahoe with pine is used to replenish the heart and calm the mind. All kinds of medicines are used together to Tong Qiao, Replenishing Qi, remove phlegm, calming thinking and intelligence.

Repetitive transcranial magnetic stimulation, as a non-invasive brain stimulation technique, has been widely used in clinic in recent years. Some studies have attempted to apply repetitive transcranial magnetic stimulation in the treatment of children with mental retardation and found that the clinical effect is good. Transcranial magnetism is generated based on the Faraday electromagnetic induction principle [11]. According to the positioning of the cerebral cortex on the body surface, the instrument is placed at the surgical site. The magnetic field generated will stimulate the cerebral cortex through the cranial cortex and skull, thus affecting the electrical activities, metabolic activities and excitatory activities of the neural tissue of the brain. Studies have

shown that [12] repetitive transcranial magnetic stimulation can improve brain function after sequelae of stroke, and has an alleviating effect on symptoms of epilepsy, PD and other diseases. Repetitive transcranial magnetic stimulation can be divided into low frequency and high frequency. Low frequency repetitive transcranial magnetic stimulation can inhibit brain tissue excitation, while high frequency repetitive transcranial magnetic stimulation can enhance brain tissue excitation.

The clinical application of transcranial magnetic field has high safety, few side effects and convenient operation. According to the specific symptoms of the children in our hospital, high-frequency stimulation was used as the main method, and the basic formula of repetitive transcranial magnetic stimulation for mental retarded patients was adopted, and the prescription of repetitive transcranial magnetic stimulation was adjusted dialectical, and the effect was significant.

Through the curative effect observation, the curative effect of Anshen Dingzhi Wan combined with repeated transcranial magnetic stimulation in the treatment group is much higher than that in the control group, and the side effect is low. The results showed that Anshen Dingzhi Wan combined with transcranial magnetic stimulation had a good clinical effect in the treatment of mental retardation of heart-gallbladder Qi-deficiency type. Therefore, the combined use of traditional Chinese medicine and modern scientific and technological equipment has curative effect in the treatment of developmental retardation in children, with obvious advantages.

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