Evaluation of Rehabilitation and MRI Results of the Combined Therapy of *Bushenzhichan* Formula and Needle Embedding for Parkinson's Disease

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The present study was aimed to evaluate the rehabilitation conditions of Parkinson's disease patients using combined therapy of *Bushenzhichan* formula and needle embedding and analyze the Magnetic resonance imaging test results. In this investigation, 180 Parkinson's disease patients treated at the Beijing Rehabilitation Hospital were enrolled as study subjects. They were randomly divided into the control group and the research group, each containing 90 patients. The research group was treated with Madopar as well as combined therapy of *Bushenzhichan* formula and needle embedding, while the control group was given only Madopar. The rehabilitation conditions of the 2 groups were compared. The total therapeutic efficacy of the research group was higher than that of the control group (p<0.05). By comparing the unified parkinson's disease rating scale II and unified parkinson's disease rating scale III scores after treatment, the research group showed significant improvement over the control group (p<0.05). Moreover, Magnetic resonance imaging results showed low signal intensity in the red nucleus and substantia nigra. There was no significant difference in the volume of red nucleus and substantia nigra between the two groups. The combined therapy of *Bushenzhichan* formula and needle embedding could significantly improve the therapeutic efficacy and promote recovery in Parkinson disease patients

Key words: Bushenzhichan formula, needle embedding, Parkinson's disease, rehabilitation, MRI results

Parkinson's disease (PD) is a common disease among the middle-aged and elderly population, which is mainly characterized by motor symptoms such as tremor, muscle rigidity, bradykinesia and posture instability as well as non-motor symptoms such as hyposmia, constipation and depression^[1,2]. With the aggravation of the aging society, the number of people suffering from Parkinson disease is increasing, which has attracted much concerns in clinical medicine. It has been reported that approximately 90 % of PD cases are primary PD, while others are secondary PD syndromes, genetic degeneration Parkinson's syndrome and Parkinson's superposition syndrome^[3-5]. Numerous factors contribute to PD, which are closely related to genetic and environmental toxic factors and immunoinflammatory mechanisms. Currently, there is still a lack of effective treatment for PD. Thus, it is of great importance to explore more effective treatments and drugs. In this study, the rehabilitation conditions of PD patients treated with combined therapy of Bushenzhichan formula and needle embedding were evaluated and their MRI test results were analyzed.

About 180 PD patients who had been treated at the Beijing Rehabilitation Hospital from June 2015 to June 2018 were enrolled as research subjects. The patients' MRI images are shown in fig. 1. All cases met the diagnostic criteria of the Motor Disorder and (PD) Group of the Chinese Medical Association Neurology Chapter. Meanwhile, the criteria for diagnosis and curative effect evaluation of senile tremor syndrome in TCM made by China Association of Chinese Medicine were taken as reference for diagnosis in chinese medicine^[6,7]. Patients were randomized into the research group and the control group, each containing 90 patients. The research group contained 50 males and 40 females, age ranging from 52 to 79 y with a median age of 67.4±3.3 y. The average course of disease in the research group was 8.6±0.9 y, ranging from 1 to 14 y. In contrast, the control group contained 56 males and 34 females, their age ranging from 54 to 80 with a median age of 68.2±3.6 y. The average course of disease in the control group was 7.2±0.5 y, ranging from 1 to 6 y. Data obtained from both groups were comparable.

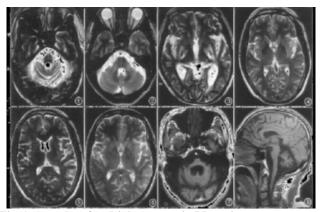


Fig. 1: Atrophy of multiple systems in PD patients

The patients in the control group were treated with Madopar at a dosage of 100/1500 mg, 3-4 times a day. Based on that regimen, patients in the research group were treated with combined therapy of *Bushenzhichan* formula and needle embedding.

Of those, Bushenzhichan formula is a modified combination of GuiluErxian ointment and DadingFengzhu. The constituents of Bushenzhichan formula are as follow up 9 g deer antler glue, 9 g Zhigancao, 20 g raw tortoise plastron, 20 g fructus cannabis, 20 g codonopsis, 20 g raw turtle shell, 12 g gelatin, 12 g gastrodiaelata, 12 g pulp of cornus, 30 g Fructus Lycii, 30 g Radix Paeoniae alba, 30 g dries Radix Rehmanniae, 30 g cistanche, 30 g uncaria, 15 g Radix Ophiopogonis, 10 g polygonatum. It is considered as a single Chinese herb free from decoction, which could be dissolved in 400 ml boiled water, once a day, and used as tea after lunch and dinner while warm.

The prescription of needle embedding is listed as follows: Baihui, Sishencong, Fengchi, Taichong, Yanglingquan, Sanyinjiao, Hegu, Ganshu, Shenshu and the chorea-trembling controlled area. The needle embedding procedure is listed as follows: Pushpintype sterile sputum needles were used (Suzhou Hualun Medical Products Co., Ltd., Batch number: 11101). The skin of the embedding area and forceps wee disinfected, the needle ring clamped with forceps and puncture the needle tip at each acupuncture point. The annular needle handle is placed nicely on the skin and fixed with a tape. If it is summer, leave it for one day. If it is winter, leave it for three days. During the indwelling process, press the needle for 2 min every day to enhance stimulation and increase therapeutic efficacy. Moreover, Madopar (Shanghai Roche Pharmaceutical Company, Batch number: SH1324) was administered at a dosage of 125-1500 mg/d in divided doses 3-4 times a day. Both groups were treated continuously for 4 was a course of treatment and the therapeutic effects after 3 complete courses of treatment were statistically analyzed.

The total therapeutic efficacy was observed and compared between both groups. According to Unified (PD) Rating Scale (UPDRS), if the total scores decreased more than 30 % after treatment, it was recorded as excellent; if the total scores decreased within a range from 5 % to 29 % after treatment, it was recorded as valid; if the total scores decreased less than 5 % after treatment, it was recorded as invalid. Moreover, UPDRS I, UPDRS II and UPDRS III scores were recorded.

SPSS21.0 software was used to carry out statistical analyses. The quantitative data were expressed as mean±standard deviation, with t-test for intergroup comparison. Enumeration data are expressed as natural number (n) and percent (%), with chi-square test for intergroup comparison. The difference was considered statistically significant when p<0.05.

It can be seen from Table 1 that the total therapeutic efficacy of the research group was significantly higher than that of control group (p<0.05). Comparison of the UPDRS I scores between the 2 groups, compared to the control group the UPDRS I scores of the research group were significantly decreased after each course of treatment (p< 0.05) as shown in Table 2. Comparison of the UPDRS II, UPDRS III scores and total scores between both groups, compared with the control group, the II scores, UPDRS III scores and total scores of the research group were significantly decreased after treatment (p<0.05, Table 3). Comparison of the volume of patients' red nucleus and substantia nigra between both groups, as shown in fig. 2, MRI test showed clearly low signal intensity in the red nucleus and substantia nigra, which were shown in layer 12-22 and layer 25-34, respectively. No significant difference was observed regarding the volume and standardizes volume of red nucleus and substantia nigra between both groups (p>0.05).

TABLE 1: COMPARISON OF THERAPEUTIC EFFICACY BETWEEN BOTH GROUPS

Groups	cases	Excellent	Valid	Invalid	Total therapeutic efficacy
Research group	90	66	20	4	86 (95.56)
Control group	90	21	50	19	71 (78.89)
t					12.20
Р					< 0.05

TABLE 2: COMPARISON OF THE UPDRS I SCORES BETWEEN BOTH GROUPS

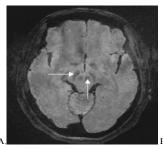
Groups	Before treatment	After 1 course of treatment	After 2 courses of treatment	After 3 courses of treatment
Research group (n = 90)	2.58±1.80	1.66±0.37	1.30±0.93	1.22±0.68
Control group (n = 90)	2.50±1.73	2.25±1.40	2.22±1.02	2.21±1.36
t	0.49	5.21	9.35	6.33
Р	>0.05	< 0.05	< 0.05	< 0.05

UPDRS is unified Parkinson's disease rating scale, data expressed as mean±standard deviation

TABLE 3: COMPARISON OF THE UPDRS II, UPDRS III AND THE TOTAL SCORES BETWEEN TWO GROUPS

Groups	Time	UPDRS II scores	UPDRS III scores	Total scores	
Research group	Before treatment	14.22±5.19	35.50±10.28	52.17±20.15	
(n = 90)	After 3 courses of treatment	10.93±4.92	30.29±11.28	42.18±14.39	
Control group	Before treatment	14.60±6.09	35.26±11.25	52.18±19.04	
(n = 90)	After 3 courses of treatment	13.92±4.39	33.28±10.36	51.07±18.27	

UPDRS is unified Parkinson's disease rating scale, data expressed as mean±standard deviation



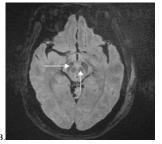


Fig. 2: MRI results of the (A) control and (B) research group

As a common neurodegenerative disease threatening both mental and physical health in the middle-aged and elderly population, (PD) has aroused much concerns. In the respect of Chinese Medicine, (PD) falls into the category of tremor and vibration. It has been clearly elaborated in Su wen that the core of this disease is exhaustion of the essence and blood, water failing to moisten wood...the liver yang is rather high, sometimes with endogenous wind^[8-10]. Therefore, the disease is mostly caused by long-term illness or kidney deficiency in elderly, dysregulation of absorption, compromised kidney essence, or the homogeny of liver and kidney. In this study, the therapeutic effect of combined therapy of Bushenzhichan formula and needle embedding were observed among PD patients, from the theory of liver and kidney[11-14].

Bushenzhichan formula is formed with modified combination of GuiluErxian ointment and DadingFengzhu. Of those, GuiluErxian ointment could generate essence, benefit qi, nourish blood and supplement both yin and yang, while the DadingFengzhu could nourish yin and suppress the excessive yang as well as make the live amiable to stop endogenous wind. The pulp of cornus, polygonatum, gastrodiaelata,

uncaria and the like in the formula could nourish kidney and liver as well as stop endogenous wind and tremor. The needle embedding method is mainly characterized as detention" to form "later meridian inductive effects". The needles were placed in *Baihui, Sishencong, Fengchi, Taichong, Yanglingquan, Sanyinjiao, Hegu, Ganshu, Shenshu* and the chorea-trembling controlled area, which could nourish kidney and liver as well as make the live amiable to stop endogenous wind^[15,16]. By combined therapy of both methods, we could nourish both kidney and liver, supplement body essence and marrow as well as stop endogenous wind and tremor.

Results of this study showed that the total therapeutic efficacy of the research group was higher than that of the control group (p<0.05). After treatment, the UPDRS I, UPDRS II and UPDRS III scores of the research group were significantly higher than that of the control group (p<0.05). The above findings fully indicate that the application of combined therapy of *Bushenzhichan* formula and needle embedding could produce favorable therapeutic efficacy for treatment of PD patients.

In conclusion, the combined therapy of kidney-tonifying antifibrillation and embedding needle is an ideal medical treatment for PD patients. From the perspective of Chinese medicine, PD is caused by a chronic disease or aging of the kidney and less sperm loss, together with malabsorption of nutrients, dark exhaustion of the kidney, or homology of liver, kidney and blood. Therefore, the adoption of TCM treatment scheme can bring in the important effect of TCM syndrome differentiation and treatment to conduct targeted treatment for patients. The results of this study

are consistent with those of many relevant studies published in China, and have strong applicability. Such combined therapy can promote the recovery of patients as soon as possible, which is worth a lot of promotion and application. In the current society, the therapeutic effect is not only should reflect in physical recovery, but also improve the quality of life, including psychological function and social function. Therefore, future studies need to pay attention to the effect of combined therapy of kidney-nourishing antifibrillation formula and embedding needle on the quality of life of PD patients.

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