RESEARCH ARTICLE

Clinical efficacy study of Buyang Huanwu Decoction combined with regulating spirit and relieving spasms acupuncture in the treatment of post-stroke hemiplegia patients

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Stroke is a leading cause of death and long-term disability worldwide. Post-stroke hemiplegia severely impairs the patients' motor function and quality of life. Buyang Huanwu Decoction, a classic traditional Chinese medicine (TCM) formula, exerts neuroprotective, anti-inflammatory, and antioxidant effects, while "Tiaoshen Jiesu" (regulating the mind and relieving spasms) acupuncture regulates mental activity, unblocks meridians, and relieves muscle spasticity. This research conducted a prospective, randomized, controlled clinical trial to evaluate the clinical efficacy and safety of Buyang Huanwu Decoction combined with "Tiaoshen Jiesu" acupuncture in the treatment of post-stroke hemiplegia defined as qi deficiency and blood stasis syndrome. A total of 91 post-stroke hemiplegia patients including 45 in control group receiving routine rehabilitation and basic medication and 46 in treatment group additionally receiving oral Buyang Huanwu Decoction and "Tiaoshen Jiesu" acupuncture completed the 8-week treatment course. The motor function was evaluated by Fugl-Meyer Assessment (FMA), while Barthel Index (BI), National Institutes of Health Stroke Scale (NIHSS) score, and Modified Ashworth Scale (MAS) grading were also evaluated. Assessments were performed at baseline, 4 weeks of treatment, 8 weeks of treatment, and 1 month after treatment. The results demonstrated that, compared with the control group, the treatment group showed significantly greater improvements in FMA score (from 38.4 ± 8.3 to 99.6 ± 1.3), BI score (from 49.4 ± 7.7 to 87.1 ± 8.0), and NIHSS score (from 12.4 ± 2.3 to 4.7 ± 2.4) ($P < 0.001$). The muscle tone improvement rate was 67.4% in treatment group compared to 62.2% in control group. The total incidence of adverse events was higher in treatment group (34.8%) than that in control group (13.3%), mainly attributable to mild local reactions related to acupuncture (pain/bruising, 17.4%), and no serious adverse events occurred. The combination of Buyang Huanwu Decoction and "Tiaoshen Jiesu" acupuncture on the basis of routine rehabilitation could significantly and comprehensively promote the recovery of motor function, daily living ability, and neurological function in post-stroke hemiplegic patients with acceptable safety, providing an effective integrated Chinese and Western medicine rehabilitation strategy for clinical practice.

Keywords: Buyang Huanwu Decoction; acupuncture; post-stroke hemiplegia; integrated Chinese and Western medicine; clinical efficacy.

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Introduction

Stroke is one of the leading causes of death and long-term disability worldwide [1]. Among its sequelae, hemiplegia severely damages the patients' motor function and daily living ability, imposing a heavy burden on individuals, families, and society [2]. Although conventional

rehabilitation and drug therapy in modern medicine have achieved certain effects, there are still limitations in promoting neural function remodeling, relieving spasticity, and comprehensively improving the quality of life [3].

Comprehensive treatment plans that integrate the characteristics of traditional Chinese medicine (TCM) have shown unique potential in stroke rehabilitation [4]. As a classic formula for treating post-stroke sequelae of qi deficiency and blood stasis type, Buyang Huanwu Decoction has been proven by modern research to exert neuroprotective, anti-inflammatory, and antioxidant effects through multiple targets and pathways [5], and to promote neural function recovery and neurovascular remodeling after cerebral ischemia [6]. Acupuncture, as an important means of TCM rehabilitation, has accumulated rich clinical experience in improving post-stroke limb movement disorders. Among various acupuncture therapies, the "Tiaoshen Jiesu" (spirit-regulating and spasm-relieving) technique combined spirit-regulating acupoints such as Baihui and Shenting with spasm-relieving acupoints located on the affected limb may regulate mental activity, clear the meridians, and alleviate muscle spasms [7]. Clinical studies have demonstrated that this acupuncture method could effectively relieve post-stroke upper-limb spasticity and improve motor function and daily living ability [8]. In recent years, studies have explored the clinical effect of Buyang Huanwu Decoction combined with acupuncture in the treatment of sequelae of cerebral infarction, showing a positive prospect [9]. Other studies have analyzed the effect of the combined treatment from the perspective of inflammation and oxidative stress [10]. In addition, imaging-based studies have attempted to predict the rehabilitation efficacy of TCM in acute ischemic stroke, suggesting potential value for individualized therapeutic decision-making [11]. However, there is currently a lack of high-quality clinical research that systematically evaluates the comprehensive therapeutic effects of Buyang Huanwu Decoction combined with a specific acupuncture regimen aimed at "regulating the mind and relieving spasms" on motor function, daily living ability, neurological deficits, and muscle tone in post-stroke hemiplegic patients through prospective randomized controlled trials.

This study adopted a prospective, randomized, controlled clinical trial design to evaluate the clinical efficacy and safety of Buyang Huanwu Decoction combined with "Tiaoshen Jiesu" acupuncture in the treatment of post-stroke hemiplegia with the aim to provide an effective integrated Chinese and Western medicine rehabilitation plan for clinical practice.

Materials and methods

Recruitment of patients

A total of 91 post-stroke hemiplegic patients were recruited from the inpatient and outpatient departments of the neurology or rehabilitation department of Xinzheng People's Hospital (Zhengzhou, Henan, China). All subjects were diagnosed through Western medicine criteria of "Diagnostic Key Points for Major Cerebrovascular Diseases in China" (Chinese Society of Neurology of the Chinese Medical Association) and were confirmed through head computed tomography (CT) or magnetic resonance imaging (MRI) imaging examination with the disease stage in the recovery period (2 weeks to 6 months after onset) [12]. The patients were further differentiated using TCM syndrome differentiation standards of "Diagnosis and Efficacy Evaluation Standards for Stroke" (State Administration of Traditional Chinese Medicine) and were clearly defined as qi deficiency and blood stasis syndrome, which included primary symptoms of hemiplegia and limb numbness and the secondary symptoms of shortness of breath and weakness, pale complexion, pale tongue texture or bruising, and fine and astringent pulse [13]. The inclusion criteria included age between 40 and 75 years, meeting the diagnostic criteria of TCM and Western medicine, first onset or previous stroke without significant functional impairment, stable vital signs, consciousness,

and ability to cooperate in completing the assessments and treatments. The exclusion criteria included hemiplegia caused by brain tumors, trauma, or metabolic disorders, severe dysfunction of the heart, liver, kidney, or other important organs, coagulation dysfunction or infection at the acupuncture site, allergy to the TCM components involved in the research, and participation in other clinical trials that might affect this study. All procedures of this research were approved by Ethics Committee of Zhengzhou University of Industrial Technology (Zhengzhou, Henan, China) with the approval number of 202501092231. In addition, this study was registered on the international clinical trial registration platform (https://clinicaltrials.gov/) with the registration number of X20220012391.

Grouping and intervention

Patients with post-stroke hemiplegia were randomly divided into control (45 patients) and treatment (46 patients) groups and completed the 8-week treatment course. The control group received a combination of conventional rehabilitation therapy and basic medication treatment, which included physical therapy and occupational therapy for the hemiplegic limbs such as Bobath technique, Brunnstrom technique, and motor relearning 5 times a week for 40 minutes each time. According to the "Chinese Guidelines for the Prevention and Treatment of Cerebrovascular Disease" issued by the Ministry of Health of China [14], standardized secondary preventive drugs such as blood pressure control, blood glucose control, blood lipid control, and antiplatelet aggregation were administered for basic drug therapy. The treatment group received Buyang Huanwu Decoction combined with "Tiaoshen Jiesu" acupuncture in addition to the routine rehabilitation and basic drug treatment. Buyang Huanwu Decoction was administered orally, one dose per day, prepared as 300 mL of decoction juice and taken in two divided doses in the morning and evening for 8 consecutive weeks. The "Tiaoshen Jiesu" acupuncture selected acupoints such as Baihui, Shenting, and Yintang, as well as main acupoints such as Jiquan, Chize, and Neiguan on the affected upper limb and Weizhong, Sanyinjiao, and Taichong on the lower limb, combined with acupoints on the side where the spasmodic muscle group antagonizes, using the technique of tonifying and purging to obtain qi. The focus was on guiding the patient's mind to pay attention to the affected limb during acupuncture. The needles were retained for 30 minutes each time, and the treatment was given 5 times a week for a total of 8 weeks.

Observation indicators and evaluation

Multidimensional and standardized observation indicators were applied to comprehensively evaluate the efficacy. The primary efficacy indicator was motor function evaluated by using the internationally recognized Fugl-Meyer Assessment Scale (FMA) [15], which included upper and lower limbs, balance, sensation, and joint mobility in a total score of 100 points with high score indicating better motor function. The secondary efficacy indicators included daily living ability evaluated by using the Barthel Index (BI) in a total score of 100 points with high score indicating stronger independence [16], neurological deficit scored by using the National Institutes of Health Stroke Scale (NIHSS) with low score indicating better neurological function [17], and muscle tone graded by using the Modified Ashworth Scale (MAS) to assess the muscle tone of major joints such as the elbow, wrist, knee, and ankle on the affected side to objectively reflect the improvement of spasticity [18]. All scale assessments were conducted by professional assessors before the start of treatment (baseline), 4 weeks of the treatment, 8 weeks of the treatment (treatment endpoint), and 1 month after treatment (follow-up period). The adverse reacts were monitored and recorded through the entire process including the occurrence time, manifestations, treatment, and outcomes such as needle bleeding, hematoma, needle sickness, or gastrointestinal discomfort and allergies caused by TCM. The patients' vital signs, blood routine, liver and kidney function, and other laboratory test indicators were also regularly monitored.

Statistical analysis

SPSS 26.0 (IBM, Armonk, NY, USA) was employed for statistical analysis of this research. The quantitative data conformed to a normal distribution were expressed as mean ± standard deviation (x ± s). Paired sample t-test was used for the intra-group comparison before and after treatment, while the two independent sample t-test was used for the inter-group comparison. Non-normal distribution data were represented by the median and interquartile range, and non-parametric tests such as Mann-Whitney U test were used. Counting data were presented as cases or percentages, and between-group comparisons were conducted using the chi-square test or Fisher's exact probability method. The non-parametric rank sum test was used for the inter-group comparison of grade data. For repeated measures scale scores, repeated measures ANOVA was used for the overall comparison. P value less than 0.05 was defined as statistically significant difference.

Results

Comparison of motor function (FMA) between the two groups

There were no statistically significant differences in the demographic characteristics of age, sex, stroke type, hemiplegic side, and disease duration or the baseline clinical scores of FMA, BI, and NIHSS between the two groups, indicating that the baseline conditions of the two groups were comparable. The treatment group showed significant improvement in motor function (FMA) compared with the control group. During the 4 weeks of treatment, the mean FMA score of 64.90 in the treatment group was significantly higher than 50.26 in the control group ($P < 0.001$). At the end of 8 weeks of treatment and during the follow-up period of 12 weeks, the scores of the treatment group were 90.68 and 99.63, respectively, which remained significantly ahead of 64.11 and 75.87 in the control group ($P < 0.001$). The results indicated that the combined therapy could promote faster and greater recovery of the patients' motor function with sustainable efficacy. The trajectory of the FMA scores of the two groups over time showed that the line representing the treatment group started to rise at a steeper slope from week 4, quickly distancing itself from the line representing the control group, and maintained a significant height difference at week 8 and during the follow-up period (Figure 1).

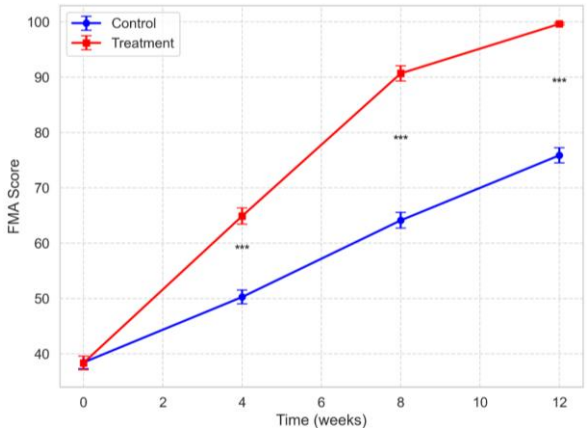


Figure 1. Trend of Fugl-Meyer assessment (FMA) scores over time.

Comparison of daily living ability (BI) between the two groups

The treatment group demonstrated excellent improvement in daily living ability (BI). Starting from the 4th week, the mean BI score of 69.60 in the treatment group was significantly higher than 58.01 in the control group ($P < 0.001$). By the end of the 8th week of treatment, the BI score of the treatment group was 82.27 and had approached the independent level (> 80 points), while that of the control group was 64.50 points and still in the moderate dependence range ($P < 0.001$). The results indicated that the combined therapy could more effectively help the patients restore their self-care ability and improve their quality of life. Further, the growth curves of the BI scores of the two groups with the progression of the treatment course showed that the treatment group remained above that of the control group, and the gap between the two curves widened over time (Figure 2).

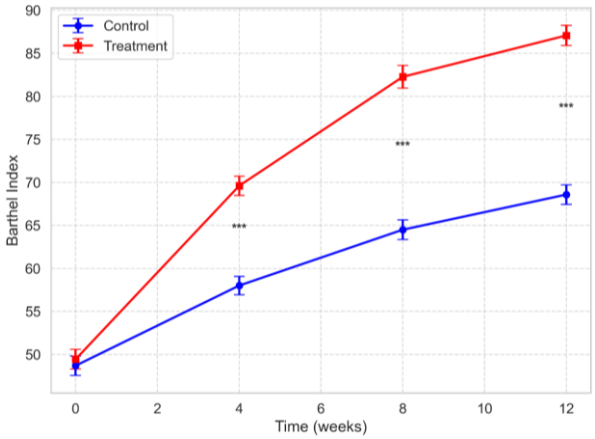


Figure 2. Barthel Index (BI) trends over time.

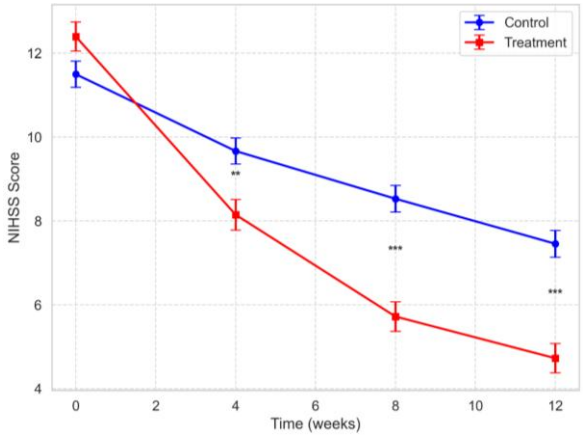


Figure 3. Trend of NIHSS scores over time.

Comparison of NIHSS scores between the two groups

The treatment group demonstrated significant advantages in improving neurological deficits (NIHSS). Although the NIHSS score of the treatment group was slightly higher at baseline, from week 4 onwards, its score was 8.15, which was lower than 9.67 in the control group ($P < 0.01$). By the 8th week and the follow-up period, the scores of the treatment group were 5.72 and 4.73, respectively, which were further lower than 8.53 and 7.45 in the control group ($P < 0.001$). The results indicated that the combined therapy had a clear effect in reducing the severity of neurological deficits and promoting overall neurological recovery. The decreasing trend of the NIHSS score over time, which the lower scores indicated the better conditions, demonstrated that the line representing the treatment group decreased faster from week 4 and remained lower than the line representing the control group (Figure 3).

Comparison of muscle tone improvement (modified Ashworth grading)

The distribution changes and improvement rates of muscle tone (modified Ashworth grading) in the two groups before and after treatment demonstrated that, after treatment, the proportion of patients with muscle tone of grade 0 (no increase in muscle tone) and grade 1 (slight increase in muscle tone) increased in both groups, while the proportion of patients with grade 2 and above (significant increase in muscle tone) decreased. The overall improvement rate of the treatment group defined as the proportion of patients with a decrease in the muscle tone level of at least 1 level was 67.4%, slightly higher than the 62.2% of the control group (Table 1). The results suggested that the combined therapy might have a certain positive effect in alleviating post-stroke limb spasticity.

Safety evaluation

The comparison of the adverse events observed in the two groups during the treatment period showed that the total incidence of adverse events in the treatment group was 34.8%, which was higher than 13.3% in the control group ($P < 0.05$). This difference was mainly due to the higher incidence of "pain/bruising at the acupuncture site" in the treatment group as 17.4% *vs.* 4.4%, which was a known and common mild adverse reaction of acupuncture therapy. There was no significant difference in the incidence of the other adverse events such as mild gastrointestinal discomfort, dizziness, and rash between the two groups. All reported adverse events were mild or moderate with no serious adverse events occurring or leading to case dropout. The results indicated that the increased risk of the combined therapy was mainly related to the acceptable local reactions associated with the additional acupuncture procedures. A visual comparison of the incidence

Table 1. Distribution and improvement rate of modified Ashworth grading before and after treatment.

MAS Grade	Control group		Treatment group	
	Pre-treatment	Post-treatment	Pre-treatment	Post-treatment
0	3 (6.7%)	18 (40.0%)	4 (8.7%)	14 (30.4%)
1	14 (31.1%)	11 (24.4%)	8 (17.4%)	14 (30.4%)
2	18 (40.0%)	11 (24.4%)	17 (37.0%)	7 (15.2%)
3	9 (20.0%)	5 (11.1%)	14 (30.4%)	10 (21.7%)
4	1 (2.2%)	0 (0.0%)	3 (6.5%)	1 (2.2%)
Improvement rate	62.2%		67.4%	

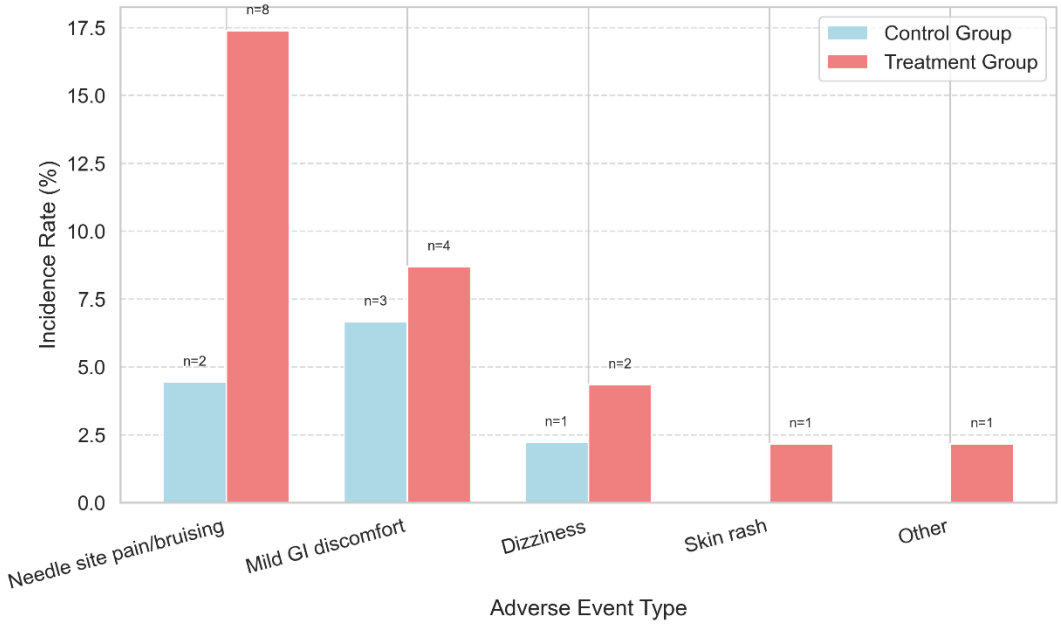


Figure 4. Comparison of adverse event rates between two groups.

rates of various adverse events between the two groups demonstrated that, in the category of "pain/bruising at the acupuncture site", the treatment group was significantly higher than that of the control group (Figure 4), which directly explained the main reason for the higher overall incidence of adverse events in the treatment group.

Discussion

This prospective randomized controlled study confirmed that, based on conventional rehabilitation and secondary preventive drug treatment, the combined use of Buyang Huanwu Decoction and "Tiaoshen Jiesu" acupuncture could significantly promote the recovery of motor function, daily living ability, and neurological function in post-stroke hemiplegic patients with efficacy superior to that of conventional rehabilitation alone with a manageable safety profile. The results of this study are consistent with previous meta-analyses, demonstrating that supplementing conventional Western medicine treatment with Buyang Huanwu Decoction significantly improved the neurological function of convalescent stroke patients [19]. As a classic formula for tonifying qi and promoting blood circulation, modern pharmacological research has revealed that Buyang Huanwu Decoction

exerts neuroprotective effects through multiple pathways including anti-inflammation, anti-oxidation, inhibition of cell apoptosis, and promotion of neurovascular remodeling. Studies have indicated that this formula exerts an anti-cerebral ischemia effect by modulating the IRE1α/ASK1/JNK signaling pathway [20], while promotes neurovascular remodeling by modulating astrocyte and microglial polarization [21]. It suppresses ischemia-induced glycolysis and cell apoptosis in brain microvascular endothelial cells [22]. In addition, the combination of Buyang Huanwu Decoction with intravenous thrombolysis has been shown to enhance the Keap1-Nrf2/ARE antioxidant pathway [23]. Mitochondrial injury has also been identified as a key target of TCM intervention in ischemic stroke [24]. These findings provide a potential biological basis for the significant improvements in motor function and neurological deficits observed in this study. The "Tiaoshen Jiesu" acupuncture method adopted in this study emphasized the combination of regulating the mind and unblocking meridians. Acupuncture at Baihui, Shenting, and other acupoints regulates the mind and calms the body, combined with Jiquan, Weizhong, and other acupoints to relieve muscle tension. It may exert its effects through various pathways such as regulating the excitability of the central nervous system, improving local blood circulation, and regulating muscle tone. Previous studies have supported the value of acupuncture and moxibustion in improving limb dyskinesia after stroke. This study further combined this acupuncture concept with the TCM prescription system. The results showed that the treatment group displayed a better trend in improving muscle tone than the control group. Although this difference did not reach statistical significance, the improvements observed in items related to coordination and reflexes on the FMA scale suggested that this comprehensive intervention might offer potential advantages in alleviating spasticity and enhancing the quality of movement. The results of this study were consistent with previous reports showing a positive prospect of Buyang Huanwu Decoction combined with acupuncture in treating sequelae of cerebral infarction. Analyses from the perspective of inflammation and oxidative stress also confirmed that the combined therapy could more effectively regulate relevant biomarkers, which might partially explain why the treatment group performed better in neurological function recovery with a more significant decrease in the NIHSS score. In addition, the rapid improvement in daily living ability of the treatment group patients and their early attainment of nearly independent functional levels were not only direct manifestations of improved motor function, but might also be attributed to the positive effects of "regulating the mind" acupuncture on the patients' attention and participation in rehabilitation, as well as the comprehensive regulation of the patients' physiological and psychological states by the overall treatment, thus, more effectively transforming the gains in motor function into actual living ability. In terms of safety, the higher incidence of adverse events in the treatment group was mainly attributed to the mild local reactions related to acupuncture, which was consistent with the characteristics of acupuncture therapy, and no serious adverse events occurred, indicating that this combination therapy had an acceptable risk-benefit ratio under standardized operation. The combination of Buyang Huanwu Decoction and "Tiaoshen Jiesu" acupuncture formed a multi-level and integrated treatment strategy through the systemic neuroprotection and repair of TCM, the neural regulation and local antispasmodic effects of acupuncture, and complementary modern rehabilitation training. Systems pharmacology analyses have revealed the multi-target mechanisms underlying the therapeutic effects of Buyang Huanwu Decoction in ischemic stroke [25], providing a scientific basis for this integrated strategy. The combination provided an effective and distinctive integrated Chinese and Western medicine approach for the rehabilitation of post-stroke hemiplegia and was worthy of further promotion and application in clinical practice. Future research could further reveal the specific neurophysiological and

molecular mechanisms underlying the effectiveness of this combined approach through imaging, biomarker detection, and other methods [26].

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