


A retrospective study of Yiqi-Huoxue Decoction on blood pressure in patients with acute ischemic stroke

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Abstract

This retrospective study investigated the effect of Yiqi-Huoxue Decoction (YQHxD) on blood pressure (BP) in patients with acute ischemic stroke (AIS).

A total of 72 patients with BP following AIS who received routine treatment were included in this retrospective study. Of those, 36 patients received YQHxD and were assigned to a treatment group. The other 36 patients were allocated to a control group. All patients were treated for a total of 4 months. The outcomes were assessed by systolic blood pressure (SBP), diastolic blood pressure (DBP), National Institutes of Health Stroke Scale (NIHSS) score and Barthel index scale (BIS). All outcomes were measured after 4-month treatment.

After treatment, all subjects in the treatment group showed greater improvements in SBP ($P < .05$), DBP ($P < .05$), NIHSS ($P < .05$) score, and BIS ($P < .05$) than those of patients in the control group. In addition, the safety profile is similar in both groups.

The findings of this study demonstrated that YQHxD may benefit on BP in patients with AIS. Future studies should focus on warranting the current results.

Abbreviations: AIS = acute ischemic stroke, BP = blood pressure, BIS = Barthel index scale, DBP = diastolic blood pressure, NIHSS = National Institutes of Health Stroke Scale, SBP = systolic blood pressure, YQHxD = Yiqi-Huoxue Decoction.

Keywords: acute ischemic stroke, Yiqihuoxue Formula, blood pressure, effect

1. Introduction

Acute ischemic stroke (AIS) is a very common acute cerebrovascular event resulted from decreased blood flow to the brain.^[1,2] It is also the leading cause of high mortality and morbidity.^[3–5] It is estimated that about 13 million cases occur annually worldwide.^[6] Study reports that its incidence rate is about 2.47/1000 people in China, and its mortality rate is about 1.15/1000 people around the world.^[7] A variety of risk factors and plasma

neuroendocrine biomarkers are associated with AIS, such as high blood pressure (BP), diabetes, heart and blood vessel diseases, high low-density lipoproteins, smoking, brain aneurysms, age, gender, race and ethnicity, family history and genetics.^[8–15] Of those, BP is the most important risk factor for AIS.^[10,16]

Antihypertensive treatments are very important to manage patients with such condition.^[17] Of those, Yiqi-Huoxue Decoction (YQHxD), a type of Chinese herbal medicine, has been

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widely used for a variety of diseases, including spinal cord injury, ischemic stroke, diabetic nephropathy, coronary heart disease, acute cerebral infarction, superficial thrombophlebitis, thoracic obstruction, and ischemic stroke.^[18–28] It is tailored for AIS survivors, who are also featured with BP.^[29,30] Its mechanism is still poorly understood. Additionally, there is still lacking rigorous study specifically focusing on the YQHxD for BP in AIS survivors. Thus, this retrospective study investigated the efficacy and safety of YQHxD for BP management in patients with AIS.

2. Patients and methods

2.1. Ethical consideration

The ethical approval of this study was approved by the Ethics Medical Committee of Longhua Hospital Shanghai University of Traditional Chinese Medicine. The written informed consent of all patients is available.

2.2. Study design

This study included a total of 72 patients with AIS, and all of them were performed at Longhua Hospital Shanghai University of Traditional Chinese Medicine between March 2017 and December 2018. All patients in both groups received routine treatment for a total of 4 months. Of those, 36 patients who received YQHxD were assigned to the treatment group, while the other 36 patients who did not administrate YQHxD were assigned to the control group. All outcomes were measured after 4 months treatment. We employed blind approach to data analyst in this study. However, we did not use randomization and concealment allocation to patients and investigators, because this is a retrospective study and all data were collected from completed case records.

2.3. Patients

We included patients if they fulfilled all inclusion criteria:

- (1) diagnosed as hypertension based on the Revised Guidelines for Prevention and Treatment of Hypertension in China,^[31] and AIS according to the Chinese Cerebrovascular Disease Prevention and Treatment Guideline^[32];
- (2) age between 20 and 75 years old;
- (3) blood pressure (BP) $\geq 140/90$ mm Hg, systolic BP (SBP) ≥ 140 mm Hg or diastolic BP (DBP) ≥ 90 mm Hg; and
- (4) provided written informed consent.

The exclusion criteria were as follows:

- (1) pregnant or lactation;
- (2) cerebral hemorrhage;
- (3) severe or critical organ diseases, such as heart failure, and cancers;
- (4) BP $< 140/90$ mm Hg, SBP < 130 mm Hg or DBP < 90 mm Hg;
- (5) incomplete patient information; and
- (6) written informed consent was not provided.

2.4. Treatment approach

All patients with hypertension following AIS in both groups received routine treatment according to the Revised Guidelines for Prevention and Treatment of Hypertension in China^[31] and

Table 1

General characteristic of included patients in both groups.

Characteristics	Treatment group (n=36)	Control group (n=36)	P
Age (yr)	64.5 (9.1)	66.7 (10.0)	.33
Gender			
Males	17 (47.2)	21 (58.3)	.35
Females	19 (52.8)	15 (41.7)	.35
Race (Chinese Han)	36 (100.0)	36 (100.0)	-
BMI (kg/m ²)	23.8 (2.2)	23.1 (2.5)	.21
Duration of post stroke (month)	3.2 (2.4)	3.6 (2.1)	.45
Duration of BP (yr)	38.7 (11.2)	34.5 (13.1)	.14
Co-morbidities			
Hypertension	36 (100.0)	36 (100.0)	-
High cholesterol	16 (44.4)	14 (38.9)	.63
Diabetes	11 (30.6)	13 (36.1)	.62
Heart disease	7 (19.4)	9 (25.0)	.57
Angina	8 (22.2)	6 (16.7)	.55
Heart attack	5 (13.9)	3 (8.3)	.46
Current smoking	15 (41.7)	17 (47.2)	.64
Other	6 (16.7)	7 (19.4)	.76
SBP (mm Hg)	155.5 (6.8)	157.2 (7.3)	.31
DBP (mm Hg)	95.3 (4.4)	96.1 (3.9)	.41
NIHSS	11.7 (2.1)	12.1 (2.4)	.45
BIS	65.9 (18.0)	62.5 (16.3)	.40

Data are present as mean \pm standard deviation or number (%).

BMI = body mass index, BIS = Barthel index scale, BP = blood pressure, DBP = diastolic blood pressure, NIHSS = National Institute of Health Stroke Scale, SBP = systolic blood pressure.

Chinese Cerebrovascular Disease Prevention and Treatment Guideline.^[32] Additionally, patients in the treatment group administered YQHxD. It comprises of Astragalus 60g, Angelica tail 15g, Chuanxiong Rhizome 12g, Red Peony Root 12g, Geosaurus 20g, Peach Kernel 6g, Safflower 6g, Salvia Miltiorrhiza 12g, Heliotrope 12g, and Cinnamomum Cassia Presl 6g. All patients administered orally twice daily at morning and evening before meals for a total of 4 months.

2.5. Outcome measurements

Primary outcomes were changes of SBP and DBP.^[33–36] Secondary outcomes were National Institutes of Health Stroke Scale (NIHSS),^[37] Barthel index scale (BIS),^[38] and adverse events. NIHSS is utilized to objectively appraise neurological impairment for stroke survivors.^[37] Its total score ranges from 0 to 42, with higher score indicating poorer dysfunction.^[37] BIS score is used to assess quality of daily life in stroke survivors.^[38] Its total score varies from 0 to 100, with lower score meaning poorer disability.^[38] In addition, we also analyzed adverse events in both groups. All outcomes were analyzed after 4-month treatment.

2.6. Statistical analysis

This study employed SAS package (Version 9.1; SAS Institute Inc., Cary, NC) to statistically analyze all baseline data and outcome values. We analyzed all continuous values using Mann-Whitney *U* test or *t* test, and all categorical values using Chi-square test or Fisher exact test. We defined a 2-side value of *P* $< .05$ as a statistical significance. Considering no study specifically addresses the effects of YQHxD on BP in patients with AIS, the minimum number of patients necessary to appraise

Table 2**Comparison of BP changes at 4 months after treatment (change from baseline).**

BP	Treatment group (n=36)	Control group (n=36)	P
SBP (mm Hg)	-13.4 (-16.9, -9.7)	-7.2 (-10.1, -4.0)	
Difference between 2 groups		-6.3 (-8.0, -4.5)	<.05
DBP (mm Hg)	-5.8 (-7.3, 4.3)	-3.2 (-4.3, -2.0)	
Difference between 2 groups		-2.6 (-3.4, -1.8)	<.05

Data are present as mean (range).

BP = blood pressure, DBP = diastolic BP, SBP = systolic BP.

Table 3**Comparison of NIHSS after treatment between 2 groups.**

NIHSS	Treatment group (n=36)	Control group (n=36)	P
Change from baseline	-7.1 (-8.6, -5.4)	-5.3 (-6.5, -4.0)	
Difference between 2 groups		-1.7 (-2.4, -1.1)	<.05

Data are present as mean (range); NIHSS, National Institute of Health Stroke Scale.

its effects with a total sample size of 72 patients, including assumption of 20% dropout rate,^[39] each group 36 patients.

3. Results

We summarized general characteristics and demographic values of all patients in both groups in Table 1. We compared all those characteristics and demographics in patients between two groups. There are not significant statistical differences regarding those data between two groups (Table 1).

After 4-month treatment, patients in the treatment group showed better outcomes in primary outcome measurements of SBP ($P < .05$, Table 2) and DBP ($P < .05$, Table 2), and secondary outcome measurements of NIHSS ($P < .05$, Table 3), and BIS ($P < .05$, Table 4), than those of patients in the control group. No treatment-related adverse events were reported in both groups after 4-month treatment.

4. Discussion

This retrospective study exerted promising outcomes of YQHxD on BP in AIS survivors after 4-month treatment. To our best knowledge, there is still insufficient available evidence to support the effects of YQHxD on BP management in patients with AIS. Thus, this retrospective study investigated the effects and safety of YQHxD on BP in AIS survivors.

Several studies reported the effects of YQHxD on BP management.^[40–46] Their results are partly consistent with the

findings of this study.^[40–46] However, all of them assessed YQHxD on BP in other diseases, and no study specifically assessed the effects of YQHxD on BP in patients with stroke. In this study, our results showed promising effects of YQHxD on BP in AIS survivors.

The results of this study showed that patients in the treatment group exerted better outcomes of SBP ($P < .05$), DBP ($P < .05$), NIHSS ($P < .05$), and BIS ($P < .05$), than those of patients in the control group. It indicates that YQHxD may benefit BP in patients with AIS. In addition, both groups had similar safety profile.

There are several limitations in this retrospective study. First, this study has an intrinsic restriction. Second, this study did not apply randomization allocation and blinding to both patients and practitioners, which may result in high risk of selection. Third, this study only conducted at one center of Longhua Hospital Shanghai University of Traditional Chinese Medicine, which may affect its generalization to other hospitals. Fourth, the sample size of this study is pretty small, which impact its power. Finally, this study only measured outcomes after treatment, and no outcomes were measured at other time points. Thus, future studies should avoid those limitations.

5. Conclusion

The results of this study showed that YQHxD may be efficacious and safe for BP management in patients with AIS. Future high quality studies should warrant current findings.

Author contributions

Conceptualization: Chao Jiang, Yong-Cheng Xu, Ying Gao, Bang-Jiang Fang.

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Table 4**Comparison of BIS after treatment between 2 groups.**

BIS	Treatment group (n=36)	Control group (n=36)	P
Change from baseline	16.8 (12.4, 21.7)	8.6 (5.7, 12.1)	
Difference between 2 groups		8.2 (6.4, 9.5)	<.05

Data are present as mean (range).

BIS = Barthel index scale.

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