

Effect of Tiaoshen Kaiqiao acupuncture in the treatment of ischemic post-stroke depression: a randomized controlled trial

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Supported by the State Administration of Traditional Chinese Medicine of the People's Republic of China (201407001-6B)

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Accepted: June 16, 2016

Abstract

OBJECTIVE: To observe the effect of Tiaoshen Kaiqiao acupuncture in the treatment of ischemic post-stroke depression.

METHODS: This research was a single-blind, positive-controlled trial done in a single entity. Totally 58 patients with ischemic post-stroke depression were randomly divided into two groups. The acupuncture group was given Tiaoshen Kaiqiao acupuncture therapy and placebo starch tablets treatment, while the control group was treated with fluoxetine tablets and body acupuncture treatment. Evaluated the clinical efficacy of the two groups with Hamilton Depression Scale (HAMD), Anti Depression Drug Side Effects Rating Scale (SERS), Clinical Global Impression Scale (CGI) respectively before treatment, the fourth weekend of treatment, the eighth weekend of treatment,

the twelfth weekend of treatment. The adverse reactions in two groups were observed and documented.

RESULTS: The HAMD scale scores of the two groups in different treatment period were significantly decreased compared with that before treatment ($P < 0.05$); the score reduction of HAMD scale between the two groups had no significant differences ($P > 0.05$). There was significant difference between the SERS scores of two groups ($P < 0.05$); the control group had more adverse reactions, and the score would be increased with the extension of treatment time. Effect index (EI) of CGI in the acupuncture group is better than that of control group ($P < 0.05$).

CONCLUSION: The effects of Tiaoshen Kaiqiao acupuncture and fluoxetine in the treatment of ischemic post-stroke depression were similar, but the former had no obvious adverse reaction and side effects.

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Keywords: Post-stroke Depression; Acupuncture; Fluoxetine; Randomized controlled trial

INTRODUCTION

Post-stroke depression (PSD) is one of the most common psychoses after stroke whose reported incidence rate is various. A report reveals that the prevalence of PSD reached up to 65%.¹ Antidepressant drugs are usually used by Western medical doctors for treatment. However, the patients can hardly insist on using them for the reason of slow curative effect, long

course of treatment, severe adverse effect, and high prices, etc. It has an obvious advantage to treat PSD with acupuncture. But the deficiency of high quality research on strict design and practice restrains the clinical extend of acupuncture therapy treating PSD.²

The protocol of this research is to carry out Tiaoshen Kaiqiao acupuncture therapy on the treatment of ischemic post-stroke depression with fluoxetine as positive control drug, adopt a randomized parallel controlled clinical trial design with single-center, Single-blind, and positive-treatment, and observe curative effect of acupuncture and drugs on ischemic post-stroke depression. At the same time, adverse effects in the trial were documented.

MATERIALS AND METHODS

Clinical characteristics of patients

Totally 58 ischemic post-stroke depression subjects in line with internalizing criteria were hospitalizing patients of The Acupuncture Department in The First Teaching Hospital of Tianjin University of Traditional Chinese Medicine from February to August, 2014. We divided the patients into acupuncture group and control group randomly, 29 in each group. The patients' ages, courses of diseases, and initial scores of rating scales were analyzed by analysis of variance, gender constitution by χ^2 test, which reveal no statistic variance of inter block distribution ($P > 0.05$, Table 1).

Diagnostic criteria

Western medical diagnostic criteria of cerebral infarction: cerebral infarction as the primary diagnosis of the Western medicine (ICD-10 code: I63) must correspond with the diagnostic criteria of ischemic cerebrovascular disease of the fourth National Academic Conference on cerebrovascular disease,³ or Diagnosis and treatment guide of acute ischemic stroke in China 2010 established by Department of Disease Control in Ministry of Health of China and Neurology branch of Chinese Medical Association in 2010.⁴

Diagnostic criteria of post-stroke depression: Refer to depressive episode diagnostic criteria of the fourth and fifth edition of Diagnostic & Statistical Manual organized by American psychiatric association. "Mood disorder with depression as its feature or combined with depressive like episodes caused by stroke can also mani-

fest as mania or mixing like feature (DSM-4)". "Depressive disorder caused by other medical condition" (DSM-5 ICD-9-CM code 293.83). The main clinical manifestation is persistent depressive mood or obvious reduction of interest or amusement to all or most activities. It is indicated by the evidence of medical history, body or laboratory examination that post-stroke depression is a direct Pathophysiological result of other somatic diseases, and it can't be explained better by other psychonosema. It not only appears during delirium, but there also exist pains with clinical significance or results in social, occupational or other significant damages. Refer to the diagnostic criteria of depressive episode in Chinese Classification and Diagnostic Criteria of Mental Disorders Edition 3.⁵

Symptom criteria: depressed mood is the main symptom including at least four of the following item: (a) lose interest in daily activities and pleasure; (b) vigor reduced apparently and causeless durative lassitude; (c) psychomotor lag or agitation; (d) self-evaluation that are much too low, self-reproach, or feelings of guilt which can reach the degree of delusions; (e) have difficulties in association, or the ability of self-thinking reduces obviously; (f) the thought of dying occurs repeatedly, or there exists suicidal behavior; (g) insomnia, early awakening or hyperhypnosis; (h) inappetence or obvious reducing weight; (i) sexuality reduces obviously.

Severity criteria: social function is damaged and it will bring about distress and harmful consequence to the patients.

Course criteria: (a) Be in line with symptom and severity criteria, and last at least 2 weeks. (b) There exist Schizophrenia symptoms, but it is not in line with the diagnosis of schizophrenia. As to the ones who are in line with the diagnosis of schizophrenia, after the symptoms release, they still need to meet the depression criteria for at least 2 weeks.

Inclusion criteria

(a) Be in line with Traditional and Western Medical diagnostic criteria and depressive episode diagnostic criteria of stroke above; (b) ages between 40 to 80 years old (including 40 and 80 years old); (c) cerebral infarction attacks for the first time and the course is less than 6 months; (d) with clear consciousness, good cooperation in physical examination and without aphasia and severe cognitive disorder; (e) the ones who are informed and consent, and sign the informed consent.

Table 1 Clinical characteristics of the patients ($\bar{x} \pm s$)

Group	n	Gender (n)		Age (years)			Course (days)			Scores of rating scales (scores)		
		Male	Female	Max	Min	Average	Max	Min	Average	MMSE	NIHSS	HAMD
Acupuncture	29	16	13	79	51	69±7	158	19	46±16	23±4	8±3	19±7
Control	29	17	12	78	50	68±7	142	15	49±21	25±5	7±3	20±8

Notes: MMSE: mini-mental state examination; NIHSS: national institutes of health stroke scale; HAMD: Hamilton Depression Scale.

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