

Original Research Article

Clinical effectiveness of a combination of oxiracetam and traditional Chinese medicine rehabilitation program in the treatment of early stroke patients with hemiplegia

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Abstract

Purpose: To evaluate the efficacy of a combination of oxiracetam and traditional Chinese medicine rehabilitation program on early stroke patients with hemiplegia.

Methods: 120 patients with early stroke hemiplegia admitted to Wuhu Fifth People's Hospital from March 2019 to July 2020 were recruited. They were equally and randomly assigned to either a control group or a study group, using the random number table method. The control group received oxiracetam, while the study group received oxiracetam plus a traditional Chinese medicine (TCM) rehabilitation program. Outcome measures included treatment effectiveness, motor function, neurological function, TCM symptom scores, and patient satisfaction.

Results: There was significantly higher treatment effectiveness in the study group versus the control group ($p < 0.05$). The Fugl-Meyer score of the control group was lower than that of the study group (52.49 ± 4.73 vs 74.73 ± 5.92 ; $p < 0.001$). After treatment, patients in the study group showed lower neurological function and TCM scores than those in the control group ($p < 0.05$). Furthermore, the study group showed higher satisfaction than the control group ($p < 0.05$).

Conclusion: The combination of oxiracetam and TCM rehabilitation program produce good treatment effectiveness in early stroke hemiplegia patients, and also boosts motor and neurological functions when compared to the use of oxiracetam alone. However, the combination treatment should be subjected to further clinical trials prior to application in clinical practice.

Keywords: Chinese medicine rehabilitation program, Early stroke hemiplegia, Oxiracetam, Motor function, Nerve function

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INTRODUCTION

Stroke is a major cause of mortality and disability worldwide. It poses a substantial threat to the health of patients. Hemiplegia, one of the

common sequelae of stroke patients, impairs motor function and self-care ability, and exerts an immense burden on patients' families and society [1-4]. Consequently, there is the need for an efficient approach to improving the prognosis of

stroke. Oxiracetam is a drug used for the clinical treatment of cognitive dysfunction after stroke. Nevertheless, despite the effectiveness of oxiracetam in enhancing the restoration of brain tissue function in stroke patients, the drug is associated with adverse reactions, leading to poor treatment compliance [5,6].

Previous studies reported favorable outcomes in the use of traditional Chinese medicine (TCM) for the treatment of cognitive dysfunction in elderly stroke patients. To this end, this study investigated the effectiveness of traditional Chinese medicine rehabilitation programs for early stroke hemiplegia patients after symptomatic treatment with western medicine.

METHODS

General information on patients

A total of 168 patients with early stroke hemiplegia treated in the Wuhu Fifth People's Hospital between March 2019 and July 2020 were recruited. They were evenly and randomly assigned to a control group and a study group via random number table method. The study group comprised 34 males and 26 females with average age of 64.39 ± 8.52 years, and the control group consisted of 35 males and 25 females, aged 65.29 ± 9.07 years. The baseline patient characteristics of the two groups were comparable ($p > 0.05$).

Patients who met the diagnostic criteria for stroke and had symptoms of hemiplegia were included, whereas patients with physical disability or paralysis, malignant tumors, gastrointestinal bleeding, cardiac dysfunction, history of mental illness, and congenital mental retardation, were excluded. The experiment was reviewed and ratified by the ethics committee of Tianchang Hospital of traditional Chinese Medicine (approval no. TC20181203). Signed informed consent was collected from the included patients and the study was conducted in strict accordance with the protocols of Helsinki Declaration [7].

Treatments

The control group was intravenously administered a mixture of 4.0 g of oxiracetam at 250 mL of 5 % glucose, and the duration of treatment was 4 weeks [8]. Aside from oxiracetam, the study group received a TCM rehabilitation program which consisted of TCM massage, TCM fumigation and washing, and TCM cupping and acupuncture.

TCM massage

The corresponding acupoints were massaged for 2 min daily with different massage techniques, including acupoints of *Zusanli*, *Shousanli*, *Hegu*, *Taichong*, *Jianqian* and *Quchi*. The massage was performed by professional Chinese medicine nurses using techniques such as kneading, pushing, pressing, and compressing.

TCM fumigation and washing

Every night before going to bed, the patient's limbs were fumigated and washed using Chinese medicine consisting of Chinese medicinal materials such as *Achyranthes bidentata*, salvia, wormwood, cassia twig, and *spatholobi*. An appropriate dose was decocted and used to fumigate and wash the limbs and joints of the patient, or for full fumigation in line with the instructions in the medicine packet.

TCM cupping and acupuncture

Cupping was performed on the back muscles of each patient. For acupuncture irritation, the skin at the acupuncture site was routinely disinfected, and a 75-mm acupuncture needle was used to pierce at *Zusanli*, *Sanyinjiao*, *Baihui*, *Lianquan*, *Quchi*, *Hegu*, *Renzhong*, *Waiguan*, *Xuehai*, *Yanglingquan* and other acupoints. The needles were left at the acupoints for 20 min, once a day, and 7 treatment times formed one treatment cycle. Each patient was subjected to a total of 4 treatment cycles [9,10].

Evaluation of outcomes/indices

Treatment effectiveness

Treatment was considered markedly effective if the patient's limbs moved slightly, and the recovery of muscle strength was satisfactory, while treatment was considered effective if the patient could do simple limb activities, and the strength of the affected limb was improved. However, treatment was deemed ineffective if muscle strength and functional activity were not improved.

Evaluation of motor function

Fugl-Meyer scale was used to evaluate the motor function, with score ranges of 96 - 100, 85 - 95, 50 - 84, and < 50 denoting mild dyskinesia, moderate dyskinesia, obvious movement disorder, and severe movement disorder, respectively. The score was proportional to the degree of motor function.

Neurological function

The National Institutes of Health Stroke Scale (NIHSS) was adopted to assess neurological function. Higher scores indicate more severe neurological deficits.

TCM symptom scores

The Diagnosis and Efficacy Standards for Diseases and Syndromes of Traditional Chinese Medicine was used to evaluate symptoms such as facial palsy, dizziness, fatigue, restlessness and irritability, redness in face and eyes, hemiplegia, and aphasia. The scale was a 4-Likert scale ranging in scores from 0 to 3, with a full score of 21 points. A score of 0 meant asymptomatic, and a score of 3 meant severe symptoms. Higher scores suggest higher severity of the symptoms [11,12].

Patients' satisfaction

A hospital-designed questionnaire was used to evaluate patient satisfaction in an anonymous way [13,14].

Statistical analysis

Data analyses were conducted with SPSS 26.0 statistical software. Measurement data are

expressed as mean \pm standard deviation (SD), and a two-group comparison was done by *t*-test. Count data were analyzed using chi-square test. Statistical significance of difference was assumed at $p < 0.05$.

RESULTS

Clinical treatment efficacy

As shown in Table 1, the study group had higher total treatment effectiveness than the control group ($p < 0.05$).

Motor function

After treatment, patients in the study group had higher Fugl-Meyer scores versus those in the control group (52.49 ± 4.73 vs 74.73 ± 5.92 ; $p < 0.001$) (Table 2).

Neurological function scores and TCM syndrome scores

Before treatment, the two groups showed similar neurological function scores and TCM syndrome scores ($p > 0.05$). After treatment, patients receiving TCM treatment showed lower neurological function and TCM scores than those in the control group ($p < 0.05$; Table 3).

Table 1: Comparison of clinical efficacy between the two groups (n, %)

| Group | N | Markedly effective | Effective | Ineffective | Total (%) |
|-----------------|----|--------------------|-----------|-------------|------------|
| Control | 60 | 25 | 23 | 12 | 48 (80.00) |
| Study | 60 | 38 | 18 | 4 | 79 (93.33) |
| χ^2 | | | | | 4.615 |
| <i>P</i> -value | | | | | 0.032 |

Table 2: Comparison of motor function using Fugl-Meyer motor function scale (mean \pm SD)

| Group | N | Before treatment | After treatment |
|-----------------|----|------------------|-------------------|
| Control | 60 | 31.49 \pm 3.97 | 52.49 \pm 4.73* |
| Study | 60 | 31.55 \pm 4.15 | 74.73 \pm 5.92* |
| T | | 0.096 | 26.9 |
| <i>P</i> -value | | 0.924 | <0.001 |

* $P < 0.05$, compared with before treatment

Table 3: Comparison of neurological function and TCM syndrome score (mean \pm SD)

| Group | n | NIHSS | | TCM syndrome score | |
|-----------------|----|------------------|------------------|--------------------|------------------|
| | | Before treatment | After treatment | Before treatment | After treatment |
| Control | 60 | 8.73 \pm 1.23 | 4.18 \pm 0.97* | 19.36 \pm 1.45 | 7.24 \pm 1.71* |
| Study | 60 | 8.81 \pm 1.49 | 2.27 \pm 0.61* | 19.55 \pm 1.47 | 4.33 \pm 1.19* |
| T | | 0.379 | 15.277 | 0.843 | 12.802 |
| <i>P</i> -value | | 0.705 | <0.001 | 0.4 | <0.001 |

* $P < 0.05$, compared with before treatment

Table 4: Comparison of patients' satisfaction between the two groups of patients (n, %)

| Group | n | Very satisfied | Satisfied | Unsatisfied | Total (%) |
|----------|----|----------------|-----------|-------------|------------|
| Control | 60 | 22 | 22 | 16 | 44 (73.33) |
| Study | 60 | 37 | 20 | 3 | 57 (95.00) |
| χ^2 | | | | | 10.568 |
| P-value | | | | | 0.001 |

Patient satisfaction

Table 4 shows higher patient satisfaction in the study group versus the control group ($p < 0.05$).

DISCUSSION

The primary aim of treatment of early stroke hemiplegia is to improve patients' ability for independent living, thereby enhancing the quality of life of the subjects. Studies have shown that oxiracetam, an analog of piracetam, increased ATP/ADP ratio by accelerating the synthesis of phosphoryl choline and phosphoryl ethanolamine [14]. Moreover, it facilitated the repair of damaged brain cells and enhanced nerve repair and nerve regeneration, thereby producing beneficial effects on stroke patients with hemiplegia [14]. However, the drug is associated with adverse reactions. Studies have also shown that the rehabilitation program of TCM produced good clinical effects in the treatment of stroke patients with hemiplegia. Traditional Chinese Medicine (TCM) uses acupuncture, massage, fumigation, and other techniques, in conjunction with rehabilitation function training methods, to help restore body functions in stroke patients. It achieves this by stimulating acupuncture points, regulating the balance of *yin* and *yang*, *dredging blocked meridians*, improving blood circulation, and regulating *qi* and blood movement, thereby facilitating recovery. Moreover, TCM fumigation and washing effectively eliminate *dampness and cold* in the body, and relieves pain and *channel qi*, all of which are favorable to patients with hemiplegia [15-17]. In this regard, the present study investigated the effectiveness of the combined use of oxiracetam and a TCM rehabilitation program in the treatment of early stroke hemiplegic patients. Here, the TCM rehabilitation program with oxiracetam resulted in higher treatment effects and motor function in patients versus oxiracetam alone. In addition, milder neurological deficits and higher satisfaction were observed in the study group than in the control group [18].

CONCLUSION

The treatment of early stroke hemiplegia patients with oxiracetam in combination with a TCM

rehabilitation program is effective and it boosts motor and neurological functions, relative to the use of oxiracetam alone. However, the combination treatment should be subjected to further clinical trials prior to application in clinical practice.

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Ethical approval

None provided.

Availability of data and materials

The datasets used and/or analyzed during the current study are available from the corresponding author on reasonable request.

Conflict of Interest

No conflict of interest associated with this work.

Contribution of Authors

The authors declare that this work was done by the authors named in this article and all liabilities pertaining to claims relating to the content of this article will be borne by them.

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