

## Original Article

# Assessment of the clinical efficacy and safety of acupuncture combined with conventional therapy for patients with oculomotor nerve palsy

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**Abstract:** Objective: The aim of the current study was to evaluate the clinical efficacy and safety of acupuncture combined with conventional therapy for patients with oculomotor nerve palsy. Methods: Retrospective analysis was performed on 79 patients with oculomotor nerve paralysis. A total of 38 patients receiving conventional treatment were enrolled in the control group. A total of 41 patients undergoing acupuncture treatment were enrolled in the experimental group. All patients were treated with conventional treatment. However, the experimental group additionally received acupuncture treatment, for a total of three courses. Efficacy, Traditional Chinese Medicine (TCM) syndrome scores of oculomotor nerve palsy, quality of life scores, and pupil sizes were determined before and after treatment. Incidence of adverse reactions was also compared between the groups. Results: Pupil sizes, after treatment, were significantly lower than those before treatment in both groups ( $P < 0.05$ ). Total response rates and quality of life scores in the experimental group were significantly higher than those in the control group (60.53%,  $P < 0.05$ ). However, TCM symptom scores in the experimental group were significantly lower than those in the control group ( $P < 0.05$ ). There were no significant differences in occurrence of adverse reactions ( $P > 0.05$ ). Conclusion: Acupuncture combined with conventional therapy showed better curative effects than simple conventional treatment, with no obvious adverse reactions. This method can improve quality of life scores for patients. Thus, it is worthy of promotion.

**Keywords:** Acupuncture, conventional treatment, oculomotor nerve palsy, safety assessment

## Introduction

Oculomotor, abducens, and trochlear nerves dominate and control the movement of the eyeball [1]. The pathogenesis of oculomotor nerve palsy is quite complicated, mainly resulting from dysfunction of oculomotor nerves and their dominating tissues. The common etiology include diabetes [2] and tumors [3]. Any lesions or abnormalities affecting ocular nerves from the nerve-corpuscle of eye movement to the end of the extraocular muscle may eventually lead to oculomotor nerve palsy [4]. With recent changes in living environments and lifestyles, incidence of oculomotor nerve palsy has increased [5]. Main manifestations of oculomotor nerve palsy include blepharoptosis, pupillary changes, light-regulating reactions, and areflexia, possibly accompanied by strabismus or headaches. These negatively affect the daily

lives of patients [6]. At present, the aim of clinical treatment for oculomotor nerve palsy is to improve the neurological function of patients using nutrient nerve drugs, hormones, and vasodilators. However, outcomes are generally unfavorable and surgery is often a necessity [7, 8].

In Chinese Medicine, the pathogenesis of oculomotor nerve palsy is attributed to Xu and Yu, the essence of the viscera and blood. When blood loss or stiltation occurs, the eyes will become uncomfortable [9]. If the viscera are full of blood, the eyes will remain normal. Body weakness can also lead to blood stasis, making it difficult for blood to replenish the eyes and further increasing blood deficiencies. This may eventually block the blood from reaching the eyes, causing the eye meridian to slow down and triggering oculomotor nerve palsy. Thus,

Chinese Medicine's treatment for oculomotor nerve palsy focuses on improving blood circulation, reinforcing qi, and nourishing the blood [10]. In recent years, acupuncture, a major Traditional Chinese Medicine treatment method, has been widely used for treatment of oculomotor nerve palsy [11]. Research on oculomotor nerve palsy has a long history in Traditional Chinese Medicine (TCM), mainly focusing on the differentiation of TCM supplemented by acupuncture treatment [12]. In clinical practice, acupuncture treatment not only clear meridians, but also improves blood circulation and collaterals. Along with treatment of the disease, it can also reduce treatment side effects and patient suffering [13].

At present, there are few studies concerning treatment of oculomotor nerve palsy. Exploring a better treatment plan, the current study evaluated the clinical efficacy and safety of acupuncture combined with conventional therapy in patients with oculomotor nerve palsy.

### Materials and methods

#### *General information*

Retrospective analysis of 79 patients (42 males, 37 females; average age  $45.70 \pm 11.52$  years) with oculomotor nerve paralysis was performed. All patients contracted the disease for the first time. A total of 38 patients undergoing conventional treatment were enrolled in the control group, while 41 patients receiving acupuncture treatment were enrolled in the experimental group.

#### *Inclusion and exclusion criteria*

Inclusion criteria: Patients diagnosed with oculomotor nerve palsy with adequate documentation of ocular examinations, neuroimaging, and follow-ups [14]. Exclusion criteria: Patients with severe liver and kidney dysfunction, myasthenia gravis requiring hormone shock therapy, communication disorders, and mental disorders; Patients that were uncooperative. All patients agreed to participate in the experiment, providing informed consent. This experiment was approved by the Ethics Committee.

#### *Experimental methods*

Any primary systemic diseases present were first controlled after admission. For example,

diabetic patients were first treated with hypoglycemic therapy and hypertensive patients were first treated with antihypertensive therapy. Antibiotics, vasodilators, and hormones, as well as conventional treatments, such as neurotrophic agents for treatment of etiology, were administered. Apart from conventional therapy, the experimental group additionally underwent acupuncture treatment: Alveolus of Jingming, Shangming, Hegu, Chengqi; Taking Yangbai, Sizhukong, Sun, Qiuzhu, Zusanli, Fengchi, and Taichong from the affected sides; Disinfecting the skin first and acupuncturing with filiform needles. After Fengchi and Chengqi received qi acupuncturing, there was no needle left. When other acupoints received qi acupuncturing, the needles were kept for 20-30 minutes. When Fengchi was acupunctured, it stimulated the eyeball and the needle was up to the eye. After the procedure, the acupuncture site was pressed to prevent bleeding. Acupuncture treatment is usually done once a day. The course is 10 days. The treatment interval is two days, with a total of three courses.

#### *Outcome measurement*

(1) Efficacy evaluation [15]: Curative effects are divided into three levels: cure, improvement, and ineffectiveness. Criteria for cure: Eye position is correct. The eyeball can move freely, with no symptoms such as ptosis and diplopia. When the patient looks forward, the corneal upper margin of the upper eyelid does not cover more than 2 mm; Criteria for improvement: The distance of ptosis is significantly reduced and eye movement is improved to a certain degree; Criteria for ineffectiveness: Symptoms are not significantly relieved, eye position is still skewed, and ptosis has not improved. Total effective rate of treatment = (number of patients cured + number of patients improved) / total number of patients  $\times 100\%$ ; (2) TCM syndrome assessment scores [16]: Symptom scores of patients, before and after treatment, were evaluated, including headaches, diplopia, eye position, and ptosis. Higher scores indicate more severe symptoms; (3) Pupil sizes, before and after treatment, were measured; (4) Quality of life scores of patients, before and after treatment, were evaluated using the short Form 36-item Health Survey [17]; (5) Occurrence of adverse reactions was recorded and compared.

## Acupuncture combined with conventional therapy

**Table 1.** General information of the participants factor

	Test group n=41	Control group n=38	t/ $\chi^2$	P
Sex			0.008	0.927
Male	22 (53.66)	20 (52.63)		
Female	19 (46.34)	18 (47.37)		
Age (years)			0.059	0.808
$\geq 45$	27 (65.85)	26 (68.42)		
$< 45$	14 (34.15)	12 (31.58)		
Body mass index			0.003	0.954
$\geq 23$	24 (58.54)	22 (57.89)		
$< 23$	17 (41.46)	16 (42.11)		
Pathogeny			0.059	0.999
Diabetes	11 (26.83)	10 (26.32)		
Hypertension	7 (17.07)	7 (18.42)		
Inflammation	9 (21.95)	8 (21.05)		
Trauma	8 (19.51)	7 (18.42)		
Others	6 (14.63)	6 (15.79)		
Coagulation function				
Activated partial thromboplastin time (s)	28.71 $\pm$ 2.43	29.01 $\pm$ 2.51	0.540	0.591
Prothrombin time (s)	11.87 $\pm$ 1.03	11.96 $\pm$ 0.97	0.399	0.691
Fibrinogen (g/l)	3.15 $\pm$ 0.21	3.16 $\pm$ 0.23	0.202	0.840
Thrombin time (s)	14.66 $\pm$ 1.57	14.59 $\pm$ 1.54	0.200	0.842
Liver function index				
Serum total protein g/L	71.55 $\pm$ 2.48	71.62 $\pm$ 2.53	0.124	0.901
Glutamic pyruvic Transaminase ( $\mu\text{mol/L}$ )	26.16 $\pm$ 4.22	26.21 $\pm$ 4.17	0.053	0.958
Total bilirubin $\mu\text{mol/L}$	11.16 $\pm$ 2.12	11.15 $\pm$ 2.14	0.021	0.983
Renal function index ( $\mu\text{mol/L}$ )				
Creatinine	65.41 $\pm$ 4.22	66.01 $\pm$ 4.25	0.629	0.531
Urea	5.69 $\pm$ 0.77	5.70 $\pm$ 0.81	0.056	0.955
Uric acid	305.89 $\pm$ 11.92	304.98 $\pm$ 12.06	0.337	0.737
Course of disease (d)	28.33 $\pm$ 4.56	28.29 $\pm$ 4.41	0.040	0.969

**Table 2.** Comparison of therapeutic effects between the two groups of patients

Curative effect	Test group n=41	Control group n=38	$\chi^2$	P
Cure	31 (75.61)	11 (28.95)	-	-
To become better	7 (17.07)	12 (31.58)	-	-
Invalid	3 (7.32)	15 (36.59)	-	-
Total effective rate	38 (92.68)	23 (60.53)	11.59	<0.001

Chi-squared test.  $P < 0.05$  indicates statistical differences.

### Results

#### Comparison of general data

There were no significant differences in gender, age, and body-mass-index between the two groups ( $P > 0.05$ ) (**Table 1**).

#### Statistical analysis

SPSS 20.0 software (Bo Yi Zhixun (Beijing) Information Technology Co., Ltd.) was used for statistical analysis. Measurement data are expressed as mean  $\pm$  standard deviation. Student's t-test was used for comparisons between groups. Enumeration data were tested using

#### Acupuncture treatment shows higher effective rates

After three courses of treatment, numbers of patients with cure, improvement, and ineffectiveness in the experimental group were 31, 7, and 3, respectively, with a total effective rate of 92.68%. Numbers of patients with cure,

**Table 3.** Comparison of TCM syndrome scores between the two groups before and after treatment

Time	Test group n=41	Control group n=38	t	P
Before treatment	28.61 ± 4.47*	28.56 ± 4.51*	0.050	0.961
After treatment	11.23 ± 2.02	15.79 ± 2.11	9.813	<0.001

Note: \*compared with that after treatment, P<0.05.

**Table 4.** Comparison of pupil sizes before and after treatment between the two groups of patients

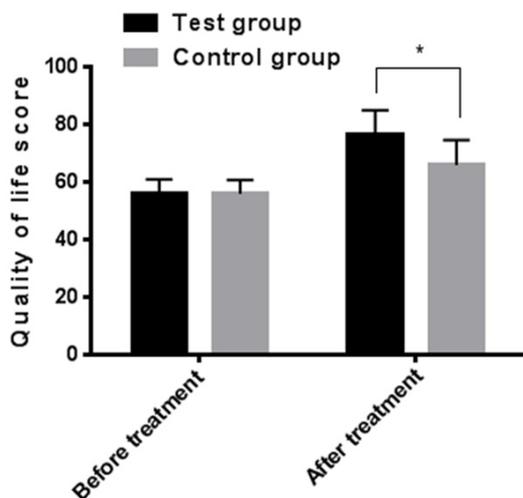
Time	Test group n=41	Control group n=38	t	P
Before treatment	4.48 ± 0.66*	4.51 ± 0.65*	0.203	0.839
After treatment	3.47 ± 0.22	3.48 ± 0.21	0.206	0.837

Note: \*compared with that after treatment, P<0.05.

**Table 5.** Comparison of quality of life scores between the two groups before and after treatment

Time	Test group n=41	Control group n=38	t	P
Before treatment	56.14 ± 4.76*	55.98 ± 4.65*	0.151	0.880
After treatment	76.41 ± 8.57	65.91 ± 8.66	5.414	<0.001

Note: \*compared with that after treatment, P<0.05.



**Figure 1.** Comparison of quality of life between the two groups before and after treatment. There were no significant differences in quality of life scores between the two groups before treatment (P>0.05). After treatment, quality of life scores of the experimental group were significantly higher than those in the control group. Differences were statistically significant (P<0.05). Note: \*indicates P<0.05.

improvement, and ineffectiveness in the control group were 11, 12, and 15, with a total

effective rate of 60.53%. The total effective rate of the experimental group was significantly higher than that in the control group (P<0.05) (Table 2).

*Acupuncture treatment improves symptoms more obviously*

There were no significant differences in TCM symptom scores between the two groups before treatment (P>0.05). However, scores of the experimental group after treatment (11.23 ± 2.02) were significantly lower than those in the control group (15.79 ± 2.11) (P<0.05) (Table 3). This indicates that symptom improvement in the experimental group was more obvious than that in the control group.

*Group differences in pupil size*

Pupil sizes of the two groups, after treatment, were significantly reduced, compared to before treatment (P<0.05). However, there were

no significant differences in pupil sizes between the two groups, before and after treatment (P>0.05). Results further indicated no significant differences in the effects of acupuncture and conventional treatment on pupillary changes (Table 4).

*Acupuncture treatment improves quality of life*

There were no significant differences in quality of life scores between the two groups before treatment (P>0.05). After three courses of treatment, quality of life scores of experimental and control groups were 76.41 ± 8.57 and 65.91 ± 8.66, respectively. Quality of life scores of the two groups were significantly improved, compared to those before treatment. Quality of life scores of the experimental group, after treatment, were significantly higher than those in the control group. Differences were statistically significant (P<0.05) (Table 5 and Figure 1).

*Group differences in adverse reactions*

During treatment, one patient from the experimental group experienced mild nausea, with no

**Table 6.** Incidence of adverse reactions in the two groups of patients

Adverse reaction	Test group n=41	Control group n=38	X <sup>2</sup>	P
Nausea	1 (2.44%)	0	-	-
Vomit	0	0	-	-
Dizzy	0	0	-	-
Adverse reaction rate	1 (2.44%)	0	0.939	0.333

significant effects on the patient. Incidence of adverse reactions was 2.44%. No adverse reactions occurred in the control group. There were no significant differences in adverse reactions between the two groups ( $P>0.05$ ), indicating that the safety of acupuncture treatment was better (Table 6).

**Discussion**

Nutritional nerve drugs are commonly used to treat patients with oculomotor nerve palsy in Western medicine, but the effects are not significant [18]. Severe cases require surgery, which is accompanied with pain and trauma [19]. With the recent promotion of TCM and its remarkable efficacy in the treatment of various diseases, more and more patients with oculomotor nerve palsy have opted for TCM treatment [20]. In Chinese Medicine, oculomotor nerve palsy is mainly caused by a lack of strength of the eye muscles resulting from qi and blood deficiencies, as well as abnormal neurological function caused by blood stasis [21]. Acupuncture treatment is a widely used clinical option, due to less incidence of adverse reactions, high safety, and remarkable curative effects [22]. At present, few studies have focused on the combination of Chinese and Western treatments on oculomotor nerve palsy. Therefore, the current study investigated the clinical efficacy and safety of acupuncture combined with conventional therapy in patients with oculomotor nerve palsy.

Results showed that acupuncture combined with conventional therapy for treatment of oculomotor nerve paralysis was more effective than simple conventional therapy. Symptomatic relief was improved and curative effects were more significant. Currently, many related studies [23] have found that acupuncture has better effects on oculomotor nerve palsy. Reports have suggested that acupuncture mainly promotes blood recovery in the eye by stimulating

acupoints around the eye, thus decreasing the adverse effects of Xu and Yu. In acupuncture treatment, the tonifying method should be used for acupoints such as Jingming, Shangming, Hegu, and Chengqi. This could replenish qi, enrich blood, and reduce discomfort [23, 24]. The current study also compared pupil sizes, quality of life scores, and

adverse reactions between the two groups after treatment. Quality of life score of the experimental group, after treatment, were significantly higher than those in the control group. This shows that acupuncture combined with conventional therapy presents significant improvements in quality of life of patients with oculomotor nerve palsy. This may be attributed to the improvement of patient symptoms. Related studies have explored the impact of Traditional Chinese Medicine combined with acupuncture on the quality of life of patients with oculomotor nerve palsy. They found that acupuncture treatment improved quality of life scores of these patients, confirming present conclusions [25]. In some studies, there was a discussion concerning the safety of acupuncture treatment for patients with oculomotor nerve palsy, in addition to the slight discomfort caused by extreme nervousness in some patients. However, no adverse reactions were reported, in accord with present conclusions [26]. Attention should be paid to the fact that, before using acupuncture treatment, patients should be given a thorough explanation of the procedure, along with appropriate emotional counseling, thereby alleviating nervousness. Patients will then cooperate with treatment and obtain better curative effects. Attention should be paid to the movement of the needle during treatment. It should not be violently manipulated, causing unnecessary pain or injury to the patient.

In summary, acupuncture combined with conventional therapy is preferable to simple conventional therapy for oculomotor nerve palsy. It causes no obvious adverse reactions. It can improve the quality of life of patients, with better safety. Thus, it is worthy of promotion. However, the sample size of this study was relatively small. Large-sample and multi-center experiments should be carried out, providing more evidence for the clinical application of acupuncture for oculomotor nerve palsy.

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**Disclosure of conflict of interest**

None.

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