

Efficacy of acupuncture and moxibustion in treating Bell's palsy: a multicenter randomized controlled trial in China

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Background Bell's palsy involves acute facial paralysis due to inflammation of the facial nerve. Acupuncture and moxibustion (acu-moxi) is beneficial in treating facial palsy. In order to verify the efficacy of acu-moxi on Bell's palsy, a randomized single-blind, multicenter clinical trial was performed.

Methods A total of 480 patients from four clinical centers were involved in this trial, of whom 439 completed the trial and 41 did not. All patients were randomly assigned to either the control group or to one of two treatment groups. The control group was treated with prednisone, vitamin B₁, vitamin B₁₂, and dibazole; the treatment groups were treated either with acu-moxi alone or in combination with prednisone, Vitamin B₁, vitamin B₁₂, and dibazole. Symptoms and signs, the House-Brackmann scale, and facial disability index (FDI) scores were assessed and determined both pre- and post-treatment to evaluate the effectiveness of the treatment methods.

Results The characteristics of the control and two treatment groups were comparable without statistically significant differences before treatment. There were significant differences between the control and treatment groups after treatment ($\chi^2 = 15.265$, $P = 0.018$). According to evaluations based on the House-Brackmann scale and FDI scores, the effectiveness of treatment in the two treatment groups was better than in the control group and was most effective in patients receiving acu-moxi treatment alone ($Z = -2.827$, $P = 0.005$).

Conclusion The efficacy of acu-moxi treatment for Bell's palsy is verified scientifically.

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Bell's palsy, also known as idiopathic facial paralysis, is a common disease that causes important functional, aesthetic, and psychosocial disturbances in the patients. Because of its unclear etiology, there are a variety of treatment options. Acu-moxi is a traditional method for treating Bell's palsy in China. It has been commonly used in clinical practice for a long time because of its multiple advantages. However, thus far, the efficacy of treatment with acu-moxi according to Evidence Based Medicine (EBM) has not yet been determined clearly due to the lack of a high-quality randomized controlled trial (RCT). In this study, we performed a multi-center randomized single-blind controlled trial for verifying the efficacy of acu-moxi in the treatment of Bell's palsy.

METHODS

Subjects

From September 1, 2001 to July 31, 2003, patients with

Bell's palsy from four clinical centers who met all inclusion criteria were entered consecutively into the trial. The four clinical centers are as follows: the First Affiliated Hospital of

Acupuncture and Tuina College, Chengdu University of TCM, Chengdu 610075, China (Li Y, Liang FR, Yu SG and Xia XH)

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Chengdu University of TCM (center 1); West China Hospital, Sichuan University (center 2); TCM Hospital of Mangyang City (center 3); and People's Hospital of Sichuan Province (center 4). The local institutional review board and ethics committee approved the study protocol, and written informed consent was obtained from all of the individuals before enrollment. Bell's palsy was defined as a peripheral facial paralysis of acute onset.

Inclusion criteria

Patients with Bell's palsy meeting the following inclusion criteria were enrolled in the study: involvement of unilateral facial nerve paralysis only, aged between 16 and 70 years old, period of onset of facial paralysis between 1 and 90 days.

Exclusion criteria

Patients with any of the following were excluded: acute or chronic ear disease, cranial or otologic trauma, known central or peripheral neurological disorders, autoimmune diseases, or herpes zoster oticus (Ramsay Hunt syndrome). Patients could have no contraindications to steroid therapy, including peptic ulcer disease, tuberculosis, diabetes, hypertension, glaucoma, manifest cardiac disease, psychosis, renal or hepatic dysfunction, and pregnancy.

Methods

This study was a multicenter, single-blind, stratified, randomized controlled trial. Stratification factors included the situation and course of disease. A random number table was applied for randomization, and serially numbered, opaque, sealed envelopes were used to ensure adequate concealment of patient identity. The outcome assessors were unaware of the intervention assignments throughout the trial. In total, 480 patients from the four clinical centers were involved, and 439 of these patients completed the study. All patients were randomly assigned to a control group or to one of two treatment groups (treatment groups 1 and 2).

Patients in the control group received muscle injections of vitamin B₁ 100 mg and vitamin B₁₂ 100 µg once daily for 10 days, then three times daily doses of vitamin B₁ 10 mg for 10 days. In addition, they were given prednisone 30 mg once daily for 3 days and dibazole 10 mg three times daily for 2-4 weeks.

Treatment group 1 was given acu-moxi treatment. The acupuncture points used were Dicang (ST4), Jiache (ST6), Hegu (LI4), Yangbai (GB14), Xiaguan (ST7), and Yifeng (SI17) on the affected side, and Hegu (LI4) bilaterally.¹ Filiform needles (1-1.5 cun, 0.32 mm) were used with moderate stimulation to get an acupuncture

sensation, and the needles were retained for 30 minutes. Hanging moxibustion was applied for five minutes at each point, once a day, five times a week, for a total of four weeks.

Treatment group 2 received a combination of the treatments received by the control group and treatment group 1.

Outcome assessment

The patients were graded by the facial nerve grading system developed by House and Brackmann (House-Brackmann scale)^{2,3} both pre- and post-treatment. This scale was specifically designed to allow for the reporting of results when evaluating the treatment of facial paralysis disorders. The Facial Disability Index (FDI, including FDIP and FDIS)⁴ was applied to evaluate disabilities of the face and psychosocial status.

Cured: House-Brackmann grade , FDIP 20, FDIS 10.

Obviously improved: House-Brackmann grade , FDIP 15, FDIS 15.

Improved: House-Brackmann grade , FDIP 10 scores, FDIS 20.

No improvement: House-Brackmann grades or or , FDIP < 10, FDIS > 20.

Data analysis

All data were statistically analyzed at the National GCP Center of China in Chengdu. The Chi-square test was used for categorical variables. Analysis of variance (ANOVA) was employed for numerical variables. The Mann-Whitney test was used for the comparison of effectiveness between groups. All statistical tests were bilateral and received the same level of significance ($P = 0.05$).

RESULTS

Group characteristics

Of the 480 patients enrolled in the study, 439 completed the trial and 41 did not for the following reasons: 20 individuals asked to end treatment early for emotional reasons, 4 were excluded for receiving other therapies, and 17 failed to complete the trial for other reasons. There were statistically significant differences between patients completing the trial and those failing to complete the trial ($P = 0.00$). On the other hand, there were no statistically significant differences in allocation to treatment groups between the four centers ($P = 0.971$).

The objective parameters of age, sex, and course of disease prior to treatment are shown in Table 1.

Table 1. Characteristics of the three groups

| Group | n | M/F | Age (y) | Course (d) |
|-------------------|-----|------------------|----------------|---------------|
| Control group | 161 | 82/79 | 39.596 ±14.635 | 6.273 ±12.761 |
| Treatment group 1 | 160 | 85/75 | 40.506 ±15.773 | 6.044 ±11.444 |
| Treatment group 2 | 159 | 82/77 | 40.252 ±14.857 | 6.667 ±12.021 |
| Total | 480 | 249/231 | 40.117 ±15.069 | 6.327 ±12.067 |
| Test value | | $\chi^2 = 0.163$ | F = 0.155 | F = 0.108 |
| P value | | 0.922 | 0.856 | 0.897 |

All patients were graded by the House-Brackmann scale prior to treatment. Gradings 1-3 were defined as mild paralysis, and gradings 4-6 as severe paralysis. An onset of facial paralysis from 1 to 7 days was defined as acute paralysis, and from 8 to 90 days as non-acute paralysis. The objective parameters of mild, severe, acute, and non-acute for the three groups are shown in Table 2.

Table 2. Severity and acuteness of disease in the three groups

| Group | n | Mild | Severe | Acute | Non-acute |
|-------------------|-----|-------|--------|-------|-----------|
| Control group | 161 | 77 | 84 | 129 | 32 |
| Treatment group 1 | 160 | 67 | 93 | 133 | 27 |
| Treatment group 2 | 159 | 62 | 97 | 128 | 31 |
| χ^2 value | | 0.842 | 0.637 | 3.415 | 0.118 |
| P value | | 0.656 | 0.727 | 0.181 | 0.943 |

The House-Brackmann grades for the patients prior to treatment are shown in Table 3.

Table 3. House-Brackmann grades pre-treatment for the three groups

| Groups | House-Brackmann | | | | | χ^2 value | P value |
|-------------------|-----------------|-------|-----|----|---|----------------|---------|
| | | Total | | | | | |
| Control group | 15 | 62 | 55 | 28 | 1 | 161 | |
| Treatment group 1 | 12 | 55 | 63 | 27 | 3 | 160 | 4.916 |
| Treatment group 2 | 8 | 54 | 63 | 31 | 3 | 159 | |
| Total | 35 | 171 | 181 | 86 | 7 | 480 | |

The Facial Disability Index scores (FDIP and FDIS) prior to treatment are shown in Table 4.

All the above tables show that the characteristics of the three groups were comparable according to the objective parameters of sex, age, period of onset, severity and acuteness of disease, House-Brackmann grade pre-treatment, and FDI score pre-treatment. Thus, there were no statistically significant differences between the control and the two treatment groups prior to the initiation of treatment ($P > 0.05$).

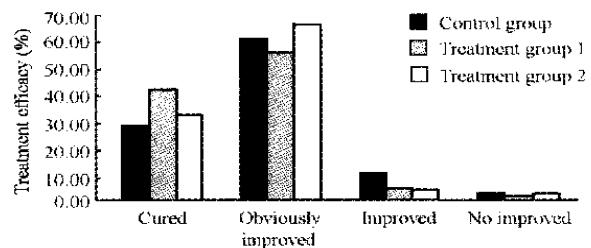
Treatment outcome

The results show that there were no differences in efficacy

Table 4. FDI scores pre-treatment for the three groups

| Group | n | FDIP | FDIS |
|-------------------|-----|---------------|---------------|
| Control group | 161 | 18.075 ±3.006 | 13.638 ±3.599 |
| Treatment group 1 | 160 | 17.763 ±3.175 | 13.569 ±3.305 |
| Treatment group 2 | 159 | 17.579 ±3.072 | 13.887 ±3.623 |
| Total | 480 | 17.806 ±3.086 | 13.697 ±3.507 |
| F value | | 1.056 | 0.362 |
| P value | | 0.349 | 0.697 |

between patients from the four clinical centers ($\chi^2 = 12.854$, $P = 0.170$). The effectiveness of treatment in the three groups, determined at the end of the trial, is shown in Fig. 1.

**Fig. 1.** Effectiveness of treatment in the three groups

The differences in efficacy of treatment between the three groups were statistically significant ($\chi^2 = 15.265$, $P = 0.018$). There were also statistically significant differences between treatment group 1 and the control group ($Z = -2.827$, $P = 0.005$).

The rates of patients from each group who were cured, obviously improved, or improved at the end of the trial (Table 5).

Table 5. Effectiveness of treatment in the three groups

| Group | n | Cured (%) | Obviously improved (%) | Improved (%) |
|-------------------|-----|-------------|------------------------|--------------|
| Control group | 128 | 36 (28.1) | 112 (87.5) | 125 (97.7) |
| Treatment group 1 | 156 | 64 (41.0) * | 149 (95.5) | 156 (100) |
| Treatment group 2 | 135 | 48 (31.0) | 148 (95.5) # | 154 (99.4) |
| Total | 439 | 148 (33.7) | 409 (93.2) | 435 (99.1) |

Compared with control group * $Z = -2.490$, $P = 0.013$; # $Z = -2.261$, $P = 0.024$; # $Z = -2.449$, $P = 0.014$.

A comparison of treatment efficacies among mild, severe, acute, and non-acute cases of facial paralysis is shown in Fig. 2.

The rate of patients whose conditions were obviously improved among mild paralysis patients was statistically significantly different from the rate for patients with severe paralysis ($\chi^2 = 21.166$, $P = 0.000$). The rates of patients whose conditions were obviously improved or improved among acute paralysis patients were statistically significantly

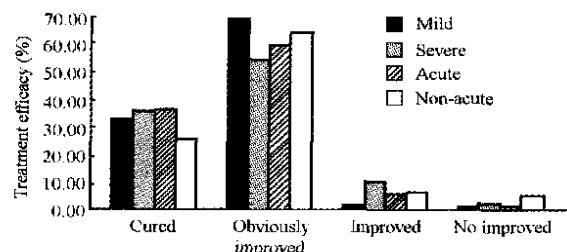


Fig. 2. Severity and acuteness of disease and treatment efficacy.

different from the rates for patients with non-acute paralysis ($\chi^2 = 18.470$, $P = 0.000$, $\chi^2 = 18.395$, $P = 0.000$).

A comparison of post-treatment House-Brackmann, FDIP, and FDIS scores for the three groups is shown in Table 6.

Table 6. House-Brackmann, FDIP, and FDIS scores post-treatment

| Group | n | House-Brackmann grade | FDIP | FDIS |
|-----------------------------|-----|-----------------------|---------------|---------------|
| Control group | 128 | 1.9063 ± .99160 | 5.367 ± 3.119 | 4.586 ± 2.907 |
| Treatment group 1 | 156 | 2.3590 ± .89406 | 6.558 ± 3.175 | 4.141 ± 3.072 |
| Treatment group 2 | 155 | 2.3097 ± .85711 | 6.458 ± 2.996 | 4.432 ± 2.879 |
| F | | 10.127 | 6.194 | 0.843 |
| P | | 0.000 | 0.002 | 0.431 |
| Compared with control group | | $P = .005$ | $P = .009$ | |

From the above tables, we concluded that there was no difference in efficacy between the four clinical centers, while significant differences did exist between the control and the treatment groups. According to the evaluations based on the House-Brackmann scale and FDI scores, the effectiveness of treatment in the two treatment groups was better than in the control group, and acu-moxi treatment alone was most effective. In addition, treatment effectiveness in cases of mild and acute facial paralysis was better than that in cases of severe and non-acute facial paralysis.

Follow up

Three hundred and fourteen and 207 patients, respectively, were evaluated with the House-Brackmann scale and FDI scores at 3 and 6 months post-treatment. Although no differences were found between the three groups, all patients showed improved facial nerve function to some extent, reaching House-Brackmann grade 3 or better. The FDIP scores in treatment group 1 were better than those in the other two groups at 3 and 6 months post-treatment.

DISCUSSION

Although there is much literature on acu-moxi treatment for Bell's palsy, RCTs have rarely been adopted. It is known

that mega-trials and meta-analyses produce the most reliable evidence for clinical studies.^{5,6} Therefore, in order to ensure a reliable outcome, a strict quality control was maintained throughout this study and blind assessment was used in analyzing data. In this study, the efficacy of acu-moxi in treating Bell's palsy was confirmed. Furthermore, severe side effects (such as fainting during acupuncture and scalding during moxibustion) were not encountered in this trial. Consequently, the authors recommend that all patients with Bell's palsy receive acu-moxi treatment.

The House-Brackmann scale is specifically designed to evaluate the results of the treatment of facial paralysis disorders.⁷ Facial nerve function is graded by the House-Brackmann scale into 6 grades: 1, Normal; 2, Mild dysfunction; 3, Moderate dysfunction; 4, Moderately severe dysfunction; 5, Severe dysfunction and 6, Total paralysis. The House-Brackmann scale is generally accepted as effective in evaluating facial nerve function.

The FDI is a disease-specific, self-reporting tool for the assessment of disabilities in patients with facial nerve disorders. It is used in the physical examination of facial movement and the examination of psychological state. There are a total of 10 parameters in the FDI scoring system, 1-5 parameters assessing physical function (FDIP) and 6-10 parameters assessing social function (FDIS). The FDI score is a convenient and reliable measurement for the assessment of disabilities in patients with facial nerve disorders. In this study, there were no statistically significant differences between the treatment groups and the control group ($P = 0.431$). Perhaps, this can be attributed to the subjective factors of psychosocial measurement, which are not assessed by the House-Brackmann scale and the FDIP score.

Treatment for the control group relied on prednisone, vitamin B₁, vitamin B₁₂, and dibazole. The most widely accepted method for treating IFNP is oral steroids.⁸ It has been shown that all patients with Bell's palsy treated at onset with prednisone have a smaller chance of developing denervation and fewer sequelae involving hemifacial spasms.⁹ However, available evidence based on randomized controlled trials does not show a significant benefit from treating Bell's palsy with corticosteroids, according to a recent Cochrane review.¹⁰ Prednisone treatment always has side effects, and the efficacy of vitamin B₁, vitamin B₁₂, and dibazole in the treatment of Bell's palsy is unclear. Acu-moxi therapy has been widely used for a long time in China for the treatment of facial nerve disorders due to its convenience, low cost, and short course of treatment. In this study, the efficacy of acu-moxi in the treatment of Bell's palsy was verified by a randomized, single-blind, multicenter

controlled trial. Therefore, the authors recommend that all patients with Bell's palsy receive acu-moxi treatment. Meanwhile, it needs further research to clarify the mechanism of acu-moxi and prednisone, vitamin B₁, vitamin B₁₂, and dibazole in the treatment of Bell's palsy.

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