A prospective randomised controlled study on efficacies of acupuncture and steroid in treatment of idiopathic peripheral facial paralysis

Fu Man Tong,¹ Shun Kit Chow,¹ Patrick Yiu Bong Chan,¹ Alex Kam Wah Wong,² Sambo Shuk Ying Wan,² Rebecca Ka Wah Ng,² Geoffrey Chan,² Wing Shan Chan,² Angela Ng,² Chi Keung Law³

ABSTRACT

Objective: A randomised controlled trial was undertaken to evaluate the efficacy of acupuncture in comparison with steroid in treatment of idiopathic peripheral facial paralysis (Bell’s palsy).

Methods: A total of 119 patients attending Ear, Nose and Throat Clinic of Pamela Youde Nethersole Eastern Hospital from February 2003 to December 2005 were randomly allocated to groups of acupuncture, steroid and control (conventional expectant treatment). There were 53 in the steroid group, 28 in the acupuncture group and 38 in the control group. Patients were assessed weekly by blinded assessors, using the House–Brackmann facial nerve grading system.

Results: The efficacy of treatment in three groups was compared, in terms of degree of recovery and speed of recovery. Intention-to-treat analyses were performed. Results were analysed with SPSS software. Distribution of initial grade on presentation was analysed with the Pearson chi-square test and showed uneven distribution in the three groups in the intention-to-treat analysis. The overall improvement (grade 3 or better) was 86.9% in the steroid group, 89.5% in the acupuncture group and 89.5% in the control group respectively. However, the difference in degree of recovery and speed of recovery in the three groups was not statistically significant.

Conclusion: The efficacies of acupuncture, steroid and conventional expectant treatment (natural course of recovery) in idiopathic peripheral facial palsy (Bell’s palsy) in the study were the same with respect to the degree of recovery and speed of recovery.

Idiopathic peripheral facial paralysis (Bell’s palsy) refers to an acute lower motor neuron type of facial paralysis without any obvious cause on presentation. Usually one side of the face is affected. The incidence is about 20 to 30 per 100 000 adults.¹–³ Both sides of the face and both sexes are affected equally.⁴–⁶ There is no seasonal variation, and the incidence is less common before the age of 15 and after 60 years of age. Additional symptoms include postaural pain, hyperacusis, dysgeusia, dry eye or epiphora.⁴–⁶

Histologically, there are acute demyelinisation and acute inflammatory changes along the entire facial nerve, including the chorda tympani. Vascular occlusion is not evident.⁷

The cause of idiopathic peripheral facial paralysis is still debatable. There have been two prevailing theories on the pathophysiology: vascular congestion with secondary ischaemia and viral polycranial neuropathy. McGovern, Hansel and Kettel postulated autonomic vascular instability with subsequent spasm of nutrient arterioles.⁸–⁹ In their view, the vasospasm led to ischaemia and capillary injury, resulting in transudation of fluid, nerve oedema and secondary compression within the bony confines of the Fallopian canal. An alternative theory, first proposed in 1919, was that of a viral polycranial neuropathy. McCormick in 1972 proposed that the likely infectious agent was herpes simplex virus.¹⁰ Viral aetiology has gained popularity since the isolation of the herpes simplex I genome from facial nerve endoneurial fluid and postaural muscle.¹¹ However, there were still arguments against a viral cause, as herpes-simplex-virus-specific DNA could be identified at autopsy in the geniculate ganglion of 56% unaffected patients.¹² There was no associated cutaneous lesion like Ramsay Hunt syndrome, recurrence was rare, and the incidence was not more common or severe with immunosuppression.¹³

The natural course of idiopathic peripheral facial paralysis has been well studied. Peitersen suggested a favourable prognosis of spontaneous recovery in the vast majority of patients. In his collection of 2255 cases, 71% had complete recovery, 13% recovered with insignificant sequelae, and 16% had permanent diminished facial function, contracture or synkinesis. All patients showed improvement compared with their initial status. There was no complete palsy on final assessment. Eighty-five per cent of patients showed improvement within 3 weeks of onset. All patients developed sequelae if they showed improvement only after 3 months.¹⁴ ¹⁵

The poor prognostic factors were old age, poor initial grade, late onset of recovery, dry eye, abolished acoustic reflex, postaural pain, diabetes mellitus and hypertension.¹⁴ ¹⁵ May et al also showed that 79% of patients would have an unsatisfactory outcome if electroneuronography showed less than 10% residual facial function within 2 weeks of onset.¹⁴ ¹⁵

The Western management of Bell’s palsy remains controversial. The treatment is mainly expectant, consisting of explanation of the disease to the patient, reassurance on the fairly good prognosis of spontaneous recovery, and eye care with eye protection, eye-drops and ointment.

Facial physiotherapy is sometimes prescribed, but there is little scientific evidence.¹⁶ Steroid and antiviral drugs are also given in some centres. Regular follow-up for assessment and exclusion of
other possible causes are required, since idiopathic peripheral facial paralysis (Bell’s palsy) should be a diagnosis of exclusion. Ramsay Hunt syndrome, parotid tumour and facial neurona may mimic Bell’s palsy initially.

Nevertheless, there is no firm evidence that the Western medication yields good results. The Cochrane database of systematic reviews showed that the available evidence from randomised controlled trials did not show a significant benefit from treating Bell’s palsy with corticosteroids.

More randomised controlled trials with a greater number of patients are needed to determine reliably whether there is real benefit (or harm) from the use of corticosteroid therapy in patients with Bell’s palsy.17

The effect of antiviral drugs was also inconclusive. The Cochrane database of systematic reviews found only limited evidence. More data are needed from a large multicentre randomised controlled and blinded study with at least 12 months’ follow-up before a definitive recommendation can be made regarding the effect of aciclovir or valaciclovir on Bell’s palsy.18 19

Surgical decompression of facial nerve has been suggested, but it was only beneficial for those with electroneurography showing more than 98% degeneration within 2 weeks of onset.20 Other studies found that surgical decompression was not beneficial.14 15 21

The concept of facial palsy in Chinese Medicine is different. It is believed that in facial palsy, owing to lowered body resistance, Cold and Wind of external origin invade the channels traversing the face and disrupt the flow of Qi and Blood, preventing the vessels and muscles from receiving the necessary moistening and nourishment. Treatment of facial palsy by Chinese Medicine consists of herbal formula and acupuncture, with the latter being the most commonly employed procedure. It is believed that acupuncture can regulate channels and collaterals, harmonise Qi and Blood, and spread the Qi through the channels of the face, thus eliminating Cold and Wind. In modern medical terms, it may stimulate the nerve receptors, causing acceleration of growth of injured nerve fibres, or secretion of biochemical to hasten nerve regeneration, or improve microcirculation.

Acupuncture has been used to treat various diseases including facial palsy in China for over a thousand years. Published results in China suggest that acupuncture was beneficial for facial palsy, with a success rate ranging from 37.25% to 100%.22–27 but good-quality randomised controlled trials were lacking when we designed this study in 2008. The methodology was often ambiguous, the assessment was not objective, and the selection criteria were not well defined. The Cochrane database of systematic reviews showed that the quality of six included trials was inadequate to allow any conclusion about the efficacy of acupuncture. More research with high-quality trials is needed.20

Since Bell’s palsy is a common condition with significant sequelae in 16% of patients, and there are no good Western Medicine and Chinese Medicine treatments that improve on the natural course of recovery, we decided to conduct this study to compare the efficacies of steroid and acupuncture in treating this condition.

METHODS

Objective

The objective of the study is to evaluate the efficacy of acupuncture in comparison with steroid treatment and conventional expectant treatment (natural course of recovery) in idiopathic peripheral facial palsy (Bell’s palsy).

Definitions

Efficacy of treatment is measured by the degree of recovery and speed of recovery in the three groups. Degree of recovery is defined as the difference between the initial grade and final grade on the last follow-up. Speed of recovery is defined as the amount of time required to achieve the stable grade from onset of treatment. The date to achieve stable grade refers to the date of improvement to either grade 1 or 2, whichever came first, or, if not improved to grade 1 or 2, the date when it first improved to its best status.

Samples

All patients referred to the Ear Nose and Throat (ENT) clinic, Pamela Youde Nethersole Eastern Hospital, with diagnosis of idiopathic peripheral facial palsy made by ENT surgeons within 2 weeks from onset were invited to participate in the study. The study protocol was approved by the Ethics Committee of Pamela Youde Nethersole Eastern Hospital, Hong Kong SAR.

Eligibility

The inclusion and exclusion criteria are listed in table 1. Eligible patients were invited to take part in the study. An information sheet was provided to patients on the aim of the study and the risks of treatment. Informed consent was taken including consent for acupuncture.22 Patients not consented to the study were given the usual conventional expectant treatment, that is eye care, home facial exercise and education.

Assessment

The initial assessment was performed by the first author using the House–Brackmann facial nerve grading system, which is a widely used system adopted by the American Academy of Otorhinolaryngology Head and Neck Surgery (table 2). A complete ENT and head and neck examination was carried out to rule out any other causes of facial palsy. The date of onset, treatment history and contraindication to steroid or acupuncture were noted.

Randomisation and treatment

Randomisation was carried out by drawing lots. Patients were asked to choose one of three identical opaque envelopes containing labels of the three groups, namely, steroid, acupuncture and control. In the steroid group, prednisolone 30 mg twice daily and pepcidine 20 mg twice daily were prescribed for 1 week. In the acupuncture group, patients were given the standardised uniform acupuncture protocol (box 1) according to standard acupuncture textbooks by our physiotherapists who
were also qualified acupuncturists. In the control group, patients were given the conventional expectant treatment, that is eye care including artificial eye-drops and eye ointment, home facial exercise and education, which were also provided to the steroid and acupuncture group. Participants were not stratified according to the duration of symptoms.

Follow-up

Patients in all three groups were followed up weekly in the ENT clinic, and their facial nerve status was assessed by blinded ENT specialists using the same House–Brackmann facial nerve grading system. Signs of recovery were documented, and complications of treatment were assessed. Patients were followed up until stable and with satisfactory recovery (grade 1 or 2). For patients with incomplete recovery (grade 3 or worse) 3 months from onset, MRI was arranged to detect any facial nerve tumour or occult parotid tumour, and they were followed up monthly until they were stable. Patients who changed the mode of treatment were excluded from the study. All other patients were included for the intention-to-treat analysis.

RESULTS

Patients were recruited from 1 February 2003 to 31 December 2005. The total number of patients who attended for idiopathic peripheral facial paralysis in this period was 373. A total of 254 patients were excluded either because they did not consent to the study or they had been treated before coming to our clinic; 119 patients were recruited into the study for intention-to-treat analysis, with 22 of these defaulted with less than 5 weeks’ follow-up, their latest status showing no clinical improvement. The actual reasons for why they dropped out were not known (table 5).

Out of 119 patients, there were 66 males and 53 females, with ages ranging from 12 to 95; 62 enjoyed good past health, and 57 had various medical diseases such as hypertension, diabetes mellitus, heart disease and history of cancer. The left side of the face was affected in 55 patients, while the right side was affected in 64 patients. The duration from onset of paralysis to first attendance ranged from 0 to 12 days, with an average duration of 2.6 days. Forty-seven patients defaulted during the course of assessment; in particular, 10 patients defaulted after their first attendance.

The baseline facial nerve status is shown in table 4, improvement rate in table 5 and final status in table 6. Sixty-five patients improved to grade 1 or 2 and were discharged. On the final review date of 31 May 2007, there were still seven patients on regular follow-up due to poor recovery and other reasons. Thirty-eight grade 3 or worse patients were followed up from 0 to 1075 days, average 96 days. Nine grade 3 or worse patients were followed up for more than 3 months, and an MRI scan was arranged to detect occult parotid or temporal bone neoplasm, but no positive results were found.

Complications

No complications were encountered in steroid group, and three cases of bruises after acupuncture were documented.

Intention-to-treat analysis

The distribution of initial grade with respect to three treatment groups is not evenly distributed ($\chi^2 = 16.95, df = 8, p<0.05$) for these 119 subjects, with the control group including less severely affected cases. The effect of different treatments on the degree of recovery of facial palsy was analysed by the Kruskal–Wallis test, and no significant difference was found ($\chi^2 = 1.5, df = 2, p>0.05$). The effect of different treatments on

<table>
<thead>
<tr>
<th>Group</th>
<th>No of patients recruited (intention-to-treat analysis)</th>
<th>No of patients remaining</th>
<th>No of patients who defaulted (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Steroid</td>
<td>53</td>
<td>44</td>
<td>9 (17)</td>
</tr>
<tr>
<td>Acupuncture</td>
<td>28</td>
<td>27</td>
<td>1 (4)</td>
</tr>
<tr>
<td>Control</td>
<td>38</td>
<td>26</td>
<td>12 (32)</td>
</tr>
</tbody>
</table>

Table 4 Facial palsy grade on first presentation (all participants)

<table>
<thead>
<tr>
<th>Grade on first presentation</th>
<th>Steroid 53</th>
<th>Acupuncture 28</th>
<th>Control 38</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 2</td>
<td>2 (3.8%)</td>
<td>1 (3.6%)</td>
<td>1 (2.6%)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>20 (37.7%)</td>
<td>8 (28.5%)</td>
<td>24 (63.2%)</td>
</tr>
<tr>
<td>Grade 4</td>
<td>9 (17.0%)</td>
<td>11 (39.3%)</td>
<td>2 (5.3%)</td>
</tr>
<tr>
<td>Grade 5</td>
<td>20 (37.7%)</td>
<td>7 (25%)</td>
<td>10 (26.3%)</td>
</tr>
<tr>
<td>Grade 6</td>
<td>2 (3.8%)</td>
<td>1 (3.6%)</td>
<td>1 (2.6%)</td>
</tr>
</tbody>
</table>

Box 1 Acupuncture protocol

Guidelines for Good Clinical Practice in Clinical Research on Chinese Medicine issued by the Hospital Authority, Hong Kong SAR in 2001 were observed. The Hospital Authority Operation Guidelines for Physiotherapists Practising Acupuncture were followed. Sterile disposable stainless steel filiform acupuncture needles 0.25 mm diameter × 25 mm LG were used. One treatment course consists of three treatment sessions per week, each treatment session lasting for 20 min. Needles were left in situ for 20 min after manual stimulation with the intention of eliciting de qi. Electrical stimulation was not used. Treatment was continued until full recovery or for 3 months if no recovery.

The following ipsilateral acupoints according to Traditional Chinese Medicine textbooks were chosen: Quanliao (SI18), Sibai (ST2), Dicang (ST4), Jiache (ST6), Yangbai (GB14), Hegu (LI4), Yifeng (TE17) Taiyang (EX-HN7).
rate of recovery was analysed by one-way ANOVA. There were no significant differences found among these three groups ($F_{2,116} = 0.507, p > 0.05$).

**DISCUSSION**

**Difficulty in recruiting and maintaining patients**

Difficulty in recruiting patients was reflected in the relatively small number of patients recruited; only 119 out of 373 patients were eligible and consented to the study. Most patients wished to receive some form of treatment, some patients selected the mode of treatment for themselves, and they did not like the idea of putting their fate to drawing lots, despite an explanation that no good treatment method has been proven with evidence. Referring doctors were often not familiar with the treatment of facial palsy, and sometimes medication was prescribed before patients came to us, rendering them non-eligible for the study.

There was also difficulty in maintaining patients in the allocated group and persuading them to attend for follow-up. Since some patients might not see an improvement in the first few weeks, they were anxious and requested additional treatment, and some even defaulted follow-up, probably in order to seek treatment in other institutions.

The sample size was therefore small. Only 119 out of 373 patients were recruited in this study of 3 years’ duration. A multicentre study is therefore necessary in order to recruit enough participants to achieve statistical significance.

**Uneven distribution of initial grade**

The uneven distribution of initial grade could not be avoided and could not be controlled, since it was grouped by randomisation. It seemed that more patients in the control group had a less severe grade (65.8% with grade 3 or less), while there were 32.2% and 41.5% of patients with grade 3 or less in the acupuncture and steroid group respectively. As poor initial grade is a poor prognostic indicator of recovery, the uneven distribution of initial grade could not be avoided, since it was grouped by randomisation. The effect of acupuncture showed a trend that was better than the other two treatment modalities as seen in the overall improvement (grade 3 or better); the number of patients who improved after 4 weeks was also largest in the acupuncture group. Larger sample sizes would be needed to show whether these trends in the difference in degree of recovery and speed of recovery in these three groups may be statistically significant. One study found acupuncture superior to prednisolone, a vasodilator (benzodiazol) and vitamin B in 130 patients with Bell’s palsy.$^{31}$

Although statistical calculations showed that steroid, acupuncture and control were equally effective, acupuncture was more costly with respect to the number of treatment sessions and the physiotherapist’s salary, when compared with the cost of steroid and pepsidone or conservative treatment. Because of the uneven distribution of initial grade in the control group, we cannot make a recommendation about conservative treatment. However, it would seem reasonable, with these results, to prefer steroid therapy to acupuncture for economic reasons, unless they have contraindications to its use or when they have a particular preference for acupuncture.

One may consider research into moxibustion combined with acupuncture: Li and colleagues found that acupuncture with moxibustion, with or without prednisone, was superior to prednisone in a trial of 480 patients.$^{32}$

**Intention-to-treat and per-protocol analysis**

A randomised controlled trial is the best way to minimise bias in ascertaining treatment effects. The intention of randomisation is to establish groups of participants with similar distributions of characteristics. It seems reasonable to exclude those participants who do not adhere to the protocol, forming the per-protocol analysis, but problems may arise because the reasons for non-adherence to the protocol may be related to the outcome of treatment. Empirical evidence suggests that participants who adhere tend to do better than those who do not adhere, even after adjustment for all known prognostic factors and irrespective of assignment to active treatment or placebo. Excluding non-adherent participants from the analysis leaves those who may be destined to have a better outcome and destroys the unbiased comparison afforded by randomisation. Therefore, if randomised controlled trials are to provide unbiased assessments of treatment efficacy, the intention-to-treat principle must be applied. That is why we have performed an intention-to-treat analysis in the study to see the effect of non-adherence, which is obvious in the control group where there was the highest percentage of non-adherence (32%). Nevertheless, it was found that the difference in degree of recovery and speed of recovery in these three groups was statistically not significant.

### Table 5 Number of patients showing at least one grade improvement in the first 4 weeks (intention-to-treat analysis)

<table>
<thead>
<tr>
<th>No of patients with improvement (cumulative)</th>
<th>Steroid 53</th>
<th>Acupuncture 28</th>
<th>Control 38</th>
</tr>
</thead>
<tbody>
<tr>
<td>No who improved after 1 week</td>
<td>25 (47.2%)</td>
<td>9 (32.1%)</td>
<td>10 (26.3%)</td>
</tr>
<tr>
<td>No who improved after 2 weeks</td>
<td>33 (62.3%)</td>
<td>17 (60.7%)</td>
<td>17 (44.7%)</td>
</tr>
<tr>
<td>No who improved after 3 weeks</td>
<td>38 (71.7%)</td>
<td>20 (71.4%)</td>
<td>22 (57.9%)</td>
</tr>
<tr>
<td>No who improved after 4 weeks</td>
<td>41 (77.4%)</td>
<td>23 (82.1%)</td>
<td>24 (63.2%)</td>
</tr>
</tbody>
</table>

### Table 6 Final grade (intention-to-treat analysis)

<table>
<thead>
<tr>
<th>Final grade on last follow-up</th>
<th>Steroid 53</th>
<th>Acupuncture 28</th>
<th>Control 38</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>19 (35.9%)</td>
<td>13 (46.4%)</td>
<td>17 (44.7%)</td>
</tr>
<tr>
<td>Grade 2</td>
<td>17 (32.1%)</td>
<td>9 (32.1%)</td>
<td>6 (15.8%)</td>
</tr>
<tr>
<td>Grade 3</td>
<td>10 (19.9%)</td>
<td>5 (17.9%)</td>
<td>11 (29.0%)</td>
</tr>
<tr>
<td>Grade 4</td>
<td>5 (9.4%)</td>
<td>1 (3.8%)</td>
<td>1 (2.6%)</td>
</tr>
<tr>
<td>Grade 5</td>
<td>2 (3.7%)</td>
<td>0</td>
<td>3 (7.9%)</td>
</tr>
<tr>
<td>Grade 6</td>
<td>0</td>
<td>0</td>
<td>0</td>
</tr>
</tbody>
</table>
CONCLUSION
The efficacies of acupuncture, steroid and conventional expectant treatment (natural course of recovery) in idiopathic peripheral facial palsy (Bell’s palsy) in this study were the same with respect to the degree of recovery and speed of recovery.

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Competing interests: None.

Ethics approval: Ethics approval was provided by Ethics Committee, HKEC, Hospital Authority, Hong Kong.

Patient consent: Obtained.

Provenance and peer review: Not commissioned; externally peer reviewed.

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