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Original Article

The Efficacy of Bee Venom Acupuncture Therapy for Bell's Palsy in the Recovery Period with Sleep Disorders: A Randomized Controlled Trial

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Abstract:

Background: More than one-third of patients with moderate to severe Bell's palsy (BP) have residual sequelae of varying degrees. Failure or incomplete recovery of facial nerve function will bring huge social and psychological pressure to patients, seriously affecting social activities and quality of life. Bee venom acupuncture (BVA) therapy is a rapidly developing treatment method and is widely used for patients with BP in East Asia. However, its therapeutic effect on BP during the recovery period accompanied by sleep disorders remains unclear. The feasibility of this innovative method is the focus of this study.

Objective: To explore the clinical efficacy of BVA therapy in BP complicated with sleep disorders during the recovery period.

Method: We conducted a randomized controlled trial. Patients with BP accompanied by sleep disorders were recruited and randomly divided into control group and BVA group at a ratio of 1:1. The control group received conventional acupuncture, while BVA group was treated with bee needle therapy. Both groups were provided with three treatments per week for a total of 4 weeks. The primary outcome measure was the change in the House-Brackmann Facial Paralysis Scale (HB) from baseline to week 8. The secondary outcome measures were the changes in Facial Disability Index (FDI), Pittsburgh Sleep Quality Index(PSQI), Hamilton Anxiety Scale (HAMA), and Hamilton Depression Scale (HAMD) at weeks 4 and 8.

Result: Of the 70 participants enrolled, 64 (91.4%) completed the intervention and were included in the analysis. In the 8th week, the HB score of BVA group was 2.0 (0.5), which was 2.2 scores lower than the baseline ([95% CI, -2.8 to -1.6]; P<0.001). The HB score of the control group was 2.8 (0.7) scores, with an average decrease of 1.5 scores ([95% CI, -2.3 to -0.7]; P<0.001). There was a statistically significant difference between groups (P=0.002). In addition, compared with the control group, the scores of PSQI, HAMA and HAMD in BVA group were significantly decreased (P<0.05) , and the FDI score was significantly increased (P<0.05) at weeks 4 and 8. No severe adverse event occurred in either group.

Conclusion: BVA therapy is beneficial for improving the facial nerve function, sleep quality and anxiety and depression symptoms of BP patients during the recovery period, and its therapeutic effect can last for up to 4 weeks.

Keywords: bee venom acupuncture therapy, Bell's palsy, sleep disorders, recovery period, randomized controlled trial

1. Introduction

Bell's palsy (BP) is caused by non-specific inflammation of the styloid foramen facial nerve, resulting in facial nerve injury and subsequently presenting symptoms of facial nerve palsy [1]. About 70% of patients can recover spontaneously, but 30% have sequelae [2]. Especially during the recovery period (2 weeks to 6 months after the onset of the disease), patients often experience

symptoms such as sleep disorders, anxiety, and depression, which seriously affect the quality of life [3]. Furthermore, as BP is an exclusive diagnosis, other causes need to be excluded and it should be differentiated from multidisciplinary diseases. Before the condition stabilizes, the degree of facial nerve damage cannot be accurately determined, so the possibility of delayed diagnosis is relatively high, and some patients thus miss the best opportunity for drug treatment [4]. For such patients with moderate to severe BP who were treated or misdiagnosed in the early stage, the symptoms were still severe when they entered the recovery period [5].

At present, the clinical treatment of BP mainly focuses on anti-inflammation, anti-virus and neuronutrition [6]. Studies have shown that the standardized and reasonable use of glucocorticoids in the early stage of facial paralysis can increase the complete recovery rate of facial paralysis and reduce the incidence of sequelae of facial paralysis. However, some patients with BP, such as those with peptic ulcers, diabetes, and pregnant women, are contraindicated for hormone therapy, and the side effects caused by hormone therapy, such as gastrointestinal bleeding, mood changes, and glaucoma, also deserve attention [7]. Surgical treatment is still controversial at present, including surgical indications, timing, decompression range, etc. Moreover, the numerous complications and the high cost of surgical treatment are also among the reasons restricting its clinical promotion [8]. Therefore, seeking safer and more effective treatment methods has become a key issue in the current research on BP.

BVA therapy, as a natural therapy, falls within the category of traditional Chinese acupuncture and moxibustion, combining the combined effects of acupuncture, warm moxibustion and bee venom [9]. Through the synergistic effect of the biological effects of bee venom and the mechanical stimulation of acupuncture, BVA therapy has shown unique advantages in neurological diseases [10]. However, the therapeutic effect of BVA therapy on sleep disorders during the recovery period of BP remains unclear. This study aims to evaluate the feasibility and safety of BVA therapy in the treatment of BP with sleep disorders during the recovery period.

2 Materials and Methods

2.1 Study Design

This study was designed as a randomized controlled trial. This trial recruited subjects with BP accompanied by insomnia in the recovery period who visited the acupuncture department of Sichuan integrative medicine hospital from March 2024 to March 2025. This study has received ethical approval from the Ethics Committee of Sichuan integrative medicine hospital, with the registration number KY-2024-025. Inclusion criteria: (1) Meeting the BP diagnostic criteria for facial paralysis; (2) The age is between 18 and 65; (3) H-B facial nerve grade III - V; (4) The first onset. The course of the disease lasts from 2 weeks to 6 months; (5) PSQI > 7 scores; (6) Voluntarily participate, cooperate with the treatment, accept the observation and evaluation of the researchers, and sign the informed consent form. Exclusion criteria: (1) Non-idiopathic facial paralysis, such as secondary to cerebrovascular diseases, malignant tumors, etc. (2) Patients with severe metabolic diseases such as diabetes and mental illness; (3) Bee needle allergy; (4) Pregnant and lactating women; (5) Patients who are participating in other clinical trials.

2.2 Sample Size

The sample size was calculated through G*Power 3.1 software [11]. To ensure the statistical validity of the research results, this study set up a two-sided test (α=0.05) and a test efficiency of 80% (β=0.2). Based on the previous experiments, we found that the effect size (Cohen's d) of the difference in HB scores between BVA group and the control group was 1.0. The software calculated that the basic sample size of each group was 30 cases. After considering a 15% loss rate, it was finally determined that 35 cases needed to be included in each group, with a total sample size of 70 cases.

2.3 Treatment Procedure

The control group received conventional acupuncture. The acupoints include Yangbai (GB14), Sibai (ST2), Dicang (ST4), Jiache (ST6) and Yifeng (SJ17) on the affected side, as well as Hegu (L14) and Zusanli (ST36) on both sides. The technique of mild reinforcing-reducing method was adopted. The needles were retained for 30 minutes before being discharged. The treatment was conducted three times a week for a

course of 4 weeks

The acupoint positions and treatment courses in BVA group were the same as those in the control group. The operation of the bee needle is as follows: Routine skin disinfection. Use tweezers to take the live bees out of the beehive, hold their bodies, and the stings of the live bees will stick out due to stimulation. Use tweezers to remove the stinger from the tail of the live bee, hold the stinger, and first prick Waiguan (SJ5) to get it out. Prick 1-2 mm in. After 20 minutes, observe whether there is any redness, swelling, pain or other reactions in the forearm. If no severe allergic reaction occurs, insert the remaining acupoints as described above.

2.4 Randomization and Blinding

Researchers identified potential participants and evaluated them through physical examinations and clinical tests. After this screening process, those who are considered eligible are required to provide consent before registration. The information obtained from these participants is confidential. This study designed two groups, including BVA group and the control group. The random number table method was adopted, and SPSS software (version 25.0) was used to generate random numbers and groups. These cards were then placed in random cards, each of which was packed in an opaque envelope to maintain the concealment of the distribution. The subjects were given envelopes in the order of treatment. This study adopted a single-blind method to avoid disclosing relevant grouping information to the subjects, and statistical analysis was conducted by experts.

2.5 Outcome Assessments

The primary outcome measure was the change in the House-Brackmann Facial Paralysis Scale (HB) from baseline to week 8. HB is used to assess facial nerve function and is divided into 6 grades, ranging from grade I (with completely normal facial muscle function) to grade VI (complete paralysis), reflecting the severity of facial paralysis step by step [12]. The secondary outcome measures were the changes in Facial Disability Index (FDI), Pittsburgh Sleep Quality Index(PSQI), Hamilton Anxiety Scale (HAMA), and Hamilton Depression Scale (HAMD) at weeks 4 and 8. FDI consists of two parts: the Facial Disability Index-Physical (FDIP), and the Facial Disability Index-Social (FDIS). The higher the FDIP score, the better the patient's physical function. Each item is scored in six levels from 0 to 5. The lower the FDIS score is, the better the social function of the patient is. Each item is scored on a six-level scale from 1 to 6 [13]. PSQI judges sleep quality with a total score ranging from 0 to 21. A score of 5 or less is considered good, and a score greater than 5 indicates sleep disorders [14]. HAMA and the HAMD are respectively used to screen for anxiety and depression symptoms. The total score of the former ranges from 0 to 56, covering physical anxiety and mental anxiety. The 17-item version of the latter has a total score of 0 to 52, including items such as low mood and suicidal ideation. Both indicate that the higher the score, the more severe the symptoms [15].

2.6 Statistical Analysis

Data statistical analysis was conducted using SPSS 25.0. Descriptive analysis was used for baseline characteristics of patients in each group. For measurement data that conformed to normal distribution and homogeneity of variance, t-tests or analysis of variance were used. Counting data were tested by chi-square test or Fisher's exact probability method. The rank data were tested by rank sum. To compare the symptom changes between BVA group and the control group, analyses of covariance (ANCOVA) was used. Continuous variables are presented as leastsquares means with 95% Confidence Intervals (95% CI). $P<0.05$ was considered statistically significant.

3 Results

Among the 70 enrolled participants, 64 (91.4%) completed the intervention and were included in the analysis (Figure 1). Among them, there were 32 cases in BVA group and 32 cases in the control group. Table 1 lists the baseline demographic and clinical characteristics of 64 participants. There were no significant differences in age, gender, BMI, educational level and marital status among the groups.

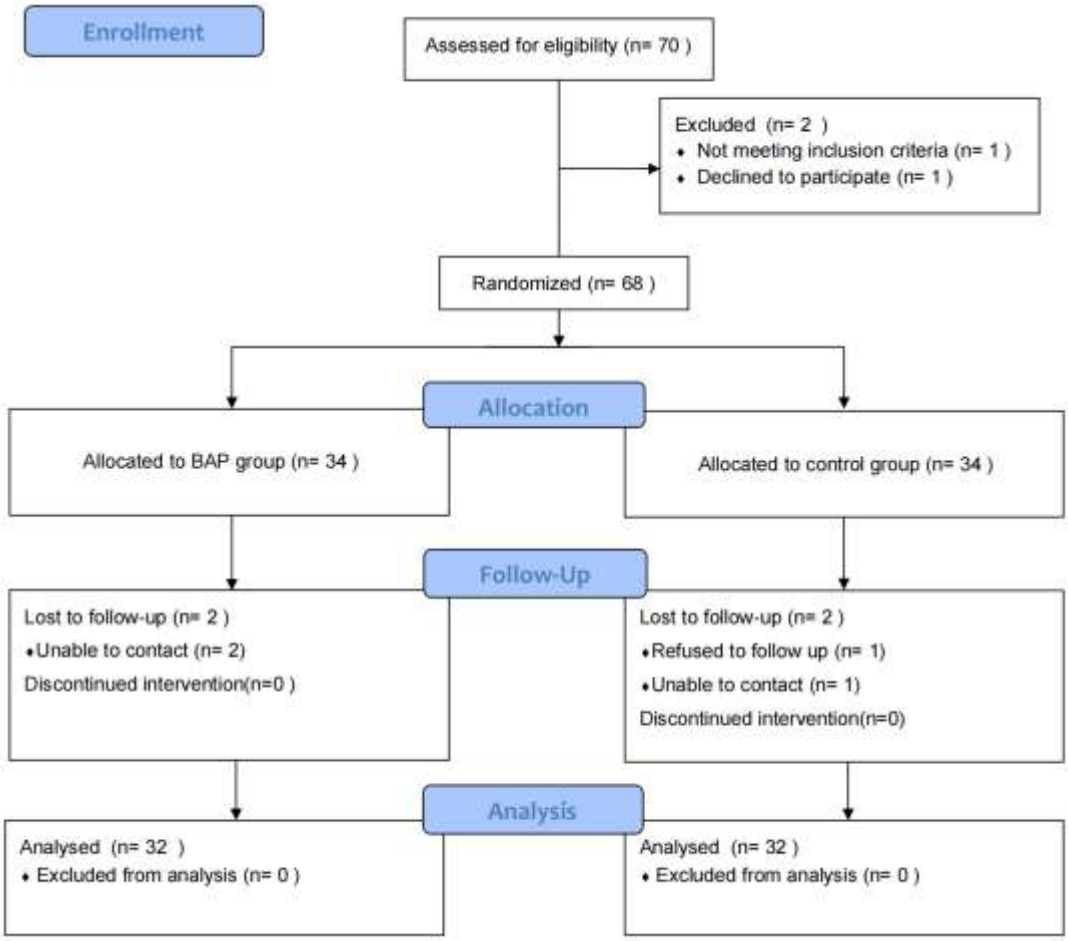

Figure 1. Study Flowchart According to CONSORT 2010.

Table 1 Baseline characteristics of participants

Characteristic	BVA group	Control group	P value
Age, mean (SD)	44.8 (7.2)	45.1(6.9)	0.83
Sex, No. (%)			0.62
Male	14 (43.8)	16 (50.0)	
Female	18 (56.3)	16 (50.0)	
Body mass index, mean (SD), kg/m2	23.5 (3.1)	23.8 (2.9)	0.68
Educational level, n (%)			0.90
Primary education or less	5 (15.6)	4 (12.5)	
Secondary education	10 (31.3)	12 (37.5)	
Tertiary education	17 (53.1)	16 (50)	
Marital status, n (%)			0.78
Married/cohabiting	25 (78.1)	24 (75)	
Never married	5 (15.6)	6 (18.8)	
Divorced	1 (3.1)	2 (6.3)	
Widowed	1 (3.1)	0 (0)	
Score on outcome measure, mean (SD)			
HB	4.2 (0.8)	4.3 (0.7)	0.73
FDIP	35.2 (6.8)	34.7 (7.1)	0.76
FDIS	28.4 (5.9)	27.9 (6.2)	0.78
PSQI	10.3 (1.2)	10.1 (1.0)	0.45
HAMA	18.6 (3.1)	18.2 (2.9)	0.58
HAMD	16.9 (2.8)	16.5 (2.6)	0.51

Abbreviation: SD, standard deviation; HB, House-Brackmann Facial Paralysis Scale; FDIP, Facial Disability Index-Physical; FDIS, Facial Disability Index-Social; PSQI, Pittsburgh Sleep Quality Index; HAMA, Hamilton Anxiety Scale; HAMD, Hamilton Depression Scale.

3.1 Primary Outcome

In the 4th week, the HB score of BVA group was 3.1±0.6, which was 1.1 scores lower than the baseline ([95% CI, -1.9 to -0.3]; P < 0.001). The control group was 3.8±0.9 scores, with an average decrease of 0.5 scores ([95% CI, -2.3 to -0.7]; P=0.083), and there was a statistically significant difference between groups (P=0.02). In the 8th week, the HB score of BVA group was 2.0±0.5, which was 2.2 scores lower than the baseline ([95% CI, -2.8 to -1.6]; P < 0.001). The control group was 2.8±0.7 scores, with an average decrease of 1.5 scores ([95% CI, -2.3 to -0.7]; P < 0.001). There was a statistically significant difference between groups (P=0.002). Tables 2 and 3 show the changes in HB scores between the two groups.

3.2 Secondary Outcomes

Compared with the baseline, BVA group saw a decrease in scores in the following four outcome measurements after 4 weeks of intervention: FDIS (-10.3 [95% CI, -11.4 to -9.2]), PSQI (-2.5 [95% CI, -3.0 to -2.0]), HAMA (-5.4 [95% CI, -6.2 to -4.6]) and HAMD (-5.5 [95% CI, -6.3 to -4.7]). In the measurement of FDIP results, the score increased by 17.2 scores ([95% CI, 15.6, 18.8]). Compared with the control group, the difference was statistically significant (P < 0.05). In the 8th week, the scores of BVA group decreased significantly in the following four result measurements: FDIS (-18.1 [95% CI, -19.3 to -16.9]), PSQI (-5.2 [95% CI, -5.6 to -4.8]), HAMA (-10.8 [95% CI, -11.7 to -9.9]) and HAMD (-10.4 [95% CI, -11.2 to -9.6]). The scores in the FDIP outcome measurement increased significantly by 32.9 scores ([95% CI, 30.9, 34.9]). There were statistically significant differences between groups (P < 0.001). Tables 2 and 3 show the changes in FDIP, FDIS, PSQI, HAMA and HAMD scores between the two groups.

Table 2. Treatment Effects of BVA group and Control group From Baseline to 4 Weeks Posttreatment and 8 Weeks of Follow-Up

Outcome assessment	BVA group		Control group	
	Change from baseline, mean (95% CI)	P value	Change from baseline, mean (95% CI)	P value
HB				
Posttreatment	-1.1 (-1.9, -0.3)	<0.001	-0.5 (-1.1, 0.1)	0.083
Follow-up	-2.2 (-2.8, -1.6)	<0.001	-1.5 (-2.3, -0.7)	<0.001
FDIP				
Posttreatment	17.2 (15.6, 18.8)	<0.001	10.6 (9.1, 12.1)	0.021
Follow-up	32.9 (30.9, 34.9)	<0.001	24.7 (22.5, 26.9)	<0.001
FDIS				
Posttreatment	-10.3 (-11.4, -9.2)	<0.001	-5.4 (-6.6, -4.2)	0.078
Follow-up	-18.1 (-19.3, -16.9)	<0.001	-12.1 (-13.4, -10.8)	<0.001
PSQI				
Posttreatment	-2.5 (-3.0, -2.0)	<0.001	-0.9 (-1.3, -0.5)	0.04
Follow-up	-5.2 (-5.6, -4.8)	<0.001	-2.0 (-2.4, -1.6)	<0.001
HAMA				
Posttreatment	-5.4 (-6.2, -4.6)	<0.001	-1.7 (-2.4, -1.0)	0.03
Follow-up	-10.8 (-11.7, -9.9)	<0.001	-3.5 (-4.3, -2.7)	<0.001
HAMD				
Posttreatment	-5.5 (-6.3, -4.7)	<0.001	-2.4 (-3.0, -1.8)	0.04
Follow-up	-10.4 (-11.2, -9.6)	<0.001	-3.7 (-4.5, -2.9)	<0.001

Abbreviation: SD, standard deviation; HB, House-Brackmann Facial Paralysis Scale; FDIP, Facial Disability Index-Physical; FDIS, Facial Disability Index-Social; PSQI, Pittsburgh Sleep Quality Index; HAMA, Hamilton Anxiety Scale; HAMD, Hamilton Depression Scale.

Table 3. Treatment Effects of BVA group and Control group at 4 Weeks Posttreatment and 8 Weeks of Follow-Up

Variable	BVA group	Control group	P value
Primary outcome			
HB			
Posttreatment	3.1 (0.6)	3.8 (0.9)	0.02
Follow-up	2.0 (0.5)	2.8 (0.7)	0.002
Secondary outcome			
FDIP			
Posttreatment	52.4 (8.2)	45.3 (9.0)	0.01
Follow-up	68.1 (7.6)	59.4 (8.5)	0.003
FDIS			
Posttreatment	18.1 (4.3)	22.5 (5.0)	0.002
Follow-up	10.3 (3.2)	15.8 (4.1)	0.008
PSQI			
Posttreatment	7.8 (1.6)	9.2 (1.3)	0.004
Follow-up	5.1 (1.0)	8.1 (1.4)	<0.001
HAMA			
Posttreatment	13.2 (2.9)	16.5 (3.2)	<0.001
Follow-up	7.8 (1.8)	14.7 (2.9)	<0.001
HAMD			
Posttreatment	11.4 (2.5)	14.1 (2.7)	<0.001
Follow-up	6.5 (1.6)	12.8 (2.3)	<0.001

Abbreviation: SD, standard deviation; HB, House-Brackmann Facial Paralysis Scale; FDIP, Facial Disability Index-Physical; FDIS, Facial Disability Index-Social; PSQI, Pittsburgh Sleep Quality Index; HAMA, Hamilton Anxiety Scale; HAMD, Hamilton Depression Scale.

3.3 Adverse Events

No serious adverse reactions occurred in either group. In BVA group, there was 2 cases of mild local redness and swelling. The incidence of adverse reactions was 6.25%. In the control group, there was 1 case of loss of appetite, and the incidence of adverse reactions was 3.13%. There was no statistically significant difference in the incidence of adverse reactions between the two groups (P>0.05). The above situations were not specially treated and recovered on their own without affecting the treatment. No participant withdrew from the study due to adverse events.

4 Discussion

In the current study, we reported that BVA therapy was more effective than conventional acupuncture in improving facial nerve function, sleep quality and anxiety and depression symptoms in patients with BP during the recovery period. Moreover, the therapeutic effect of BVA therapy can last up to four weeks. Many studies have emphasized the positive role of acupuncture and BVA therapy in the treatment of facial paralysis [16-20]. This study finds that compared with conventional acupuncture, the advantages of BVA therapy are reflected in three aspects. First, it simultaneously acts on the repair of facial nerve injury, the regulation of sleep rhythm and the management of emotions, which is in line with the complex pathological mechanism of BP with sleep disorders. Secondly, the follow-up found that the improvement in HB and FDI scores in the BVA group continued to expand compared with the control group, suggesting that its therapeutic effect might increase with the extension of the treatment cycle. Thirdly, in this study, only 2 cases (6.25%) in BVA group presented with mild local redness and swelling. No severe allergic reactions occurred, verifying the safety of BVA

therapy under standardized operation.

BVA therapy exerts therapeutic effects through the dual effects of bee venom components and acupoint stimulation. The polypeptide substances in bee venom have anti-inflammatory, analgesic and immune-regulating effects, and may accelerate functional recovery by inhibiting the inflammatory response around the facial nerve and promoting myelin sheath repair [21]. In this study, the improvement in the HB score of BVA group was significantly higher than that of the control group, suggesting that the neuroprotective effect of bee venom may shorten the natural course of the disease during the recovery period. In addition, bee needle stimulation of acupoints (such as GB14, ST2 and LI4) can activate the trigeminal neural-facial nerve reflex pathway and promote the functional reorganization of facial muscles through nerve impulse conduction. This is consistent with the conclusion observed in previous animal experiments that "acupoint stimulation promotes the plasticity changes of facial nerve clusters" [22]. The improvement of sleep disorders may be related to the neurotransmitter regulatory effect of bee venom. Phospholipase A2 in bee venom can inhibit the release of pro-inflammatory factors and alleviate the interference of neuroinflammation on the sleep-wake center [23,24]. Meanwhile, BVA therapy indirectly reduces the damage to sleep structure caused by nocturnal discomfort by improving facial blood circulation and alleviating muscle spasms [25,26]. In this study, the total PSQI score of BVA group decreased by 5.2 scores in the 8th week, which was significantly better than that of the control group. Moreover, the HAMA and HAMD scores improved simultaneously, indicating that the improvement in sleep quality might partly result from the relief of anxiety-depression, forming a positive cycle of "recovery of neurological function - improvement of psychological state - improvement of sleep quality".

In terms of limitations, 64 patients were included in this study. Due to the particularity of the bee needle operation, patients cannot achieve complete blinding, which may introduce placebo effect bias. In addition, this study did not detect objective indicators such as serum inflammatory factors and nerve growth factors, and thus could not directly prove the molecular action pathway of bee venom. In the future, it can be further explored in combination with animal experiments or in vitro studies. In conclusion, this study explored the efficacy of BVA therapy in patients with BP during the recovery period accompanied by sleep disorders through a randomized controlled trial. The results showed that BVA group was significantly superior to the conventional acupuncture group in terms of facial nerve function recovery, sleep quality improvement, and psychological state regulation, providing new evidence for the clinical application of BVA therapy in the field of neurorehabilitation.

Conflict of Interest

The authors declare that they have no conflicts of interest.

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Data Availability Statement

The data used for this study are available from the corresponding author upon request.

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