

Compare the efficacy of acupuncture with drugs in the treatment of Bell's palsy

A systematic review and meta-analysis of RCTs

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Abstract

Background: Bell's palsy or idiopathic facial paralysis is an acute facial paralysis caused by the inflammation of facial nerve. Several previous studies showed that acupuncture was beneficial in the treatment of facial paralysis. However, its effectiveness is still controversial compared with drug therapy. Therefore, this systematic review and meta-analysis was performed to assess the efficacy of acupuncture for Bell's palsy.

Methods: This is a systematic review and meta-analysis of clinical studies among patients with Bell's palsy. We did a systematic literature search in PubMed, Embase, and the Cochrane Register of Controlled Trials to identify studies comparing the efficacy of acupuncture and drug treatment in treating facial paralysis. The search was last updated on July 2018.

Results: The study included 11 randomized controlled trials with an overall sample of 1258 individuals. Acupuncture treatment was associated with an increased cure rate [relative risk (RR)=1.77, 95% confidence interval (Cl): 1.41–2.21], with significant heterogeneity in the pooled results ($l^2 = 67\%$, P = .0008). There was a significant difference in total effective rate in acupuncture and drug treatment for Bell's palsy (RR=1.18,95% Cl: 1.07–1.31), with substantial heterogeneity ($l^2 = 90\%$, P < .00001).

Conclusion: Although there was not enough evidence to prove its safety, acupuncture seems to be an effective therapy for Bell's palsy. Results of the present meta-analysis showed that acupuncture was associated with increased cure rate and total effective rate of the treatment of Bell's palsy in comparison with drugs. However, the results should be interpreted cautiously, because of the poor quality and heterogeneity of the included studies. In the future, more and more high quality randomized controlled trials (RCT) are needed to prove the safety and effectiveness of acupuncture.

Abbreviations: CAM = complementary and alternative medicine, CI = confidence interval, RCTs = randomized controlled trials, RR = relative risk, US = the United States.

Keywords: acupuncture, Bell's palsy, meta-analysis, randomized controlled trial, systematic review

1. Introduction

Bell's palsy, also known as acute idiopathic facial paralysis, is an acute peripheral facial neuropathy which is the most common cause of lower motor neuron facial palsy.^[1] The common clinical

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features of Bell's palsy include sudden onset, unilateral, weakness of the facial nerve, auricular pain, headache, hyperacusis, dysgeusia, dry eye, and epiphora.^[2,3] Sometimes, it is accompanied by a subjective change in taste sensation, facial sensation and over activity.^[4] However, some patients recovered with insignificant sequelae, and may had permanent diminished facial function, contracture or synkinesis.^[5] The incidence of Bell's palsy is about 11 to 40 per 100,000 adults each year,^[6] and 1 in 60 people may have a fatal risk.^[7] According to the data of the United States (US), there were more than 60,000 people that developed Bell's palsy in the US each year.^[8] Therefore, the treatment of this disease has received widespread attention around the world.

Because of the unclear etiology of Bell's palsy, there were a variety of treatment options. The treatments usually include antiviral drugs,^[9] Vitamin B drugs,^[10]corticosteroids,^[11] surgery,^[12] physiotherapy, acupuncture treatment and others. In the treatment of facial paralysis, some neurotrophic and neurorestorative drugs are often used. Vitamin B was beneficial for the recovery of peripheral nerve function and can be used orally.^[13] Corticosteroids have long been used in Bell's palsy due to their potent anti-inflammatory effects and have proven to be an effective treatment. Previous studies showed that there were evidences of the presence of the herpes simplex virus in some cases of Bell's palsy.^[14,15] Thus, antiviral agents were applied in some patients with Bell's palsy. As optional treatments for Bell's palsy, surgical decompression of facial nerve or physical therapy has

been suggested in several studies,^[16] but some studies found that surgical therapy was not effective.^[17]

In China, acupuncture, as one of the oldest traditional therapies, has been used to treat various diseases including facial palsy for many years. Meanwhile, acupuncture has been recognized as one of the main therapies for complementary and alternative medicine (CAM) in the United States.^[18] Acupuncture is a practical and low-cost intervention that works well for many diseases with few side effects. In recent years, there were several Cochrane systematic review for the treatment of facial paralysis in which acupuncture interventions had been reported.^[19,20] These studies investigated that there was insufficient evidence to prove that acupuncture had a positive effect on the treatment of facial paralysis.

As acupuncture is receiving extensive attention, investigating its efficacy and potential modifiers are necessary to better understand and apply this traditional Chinese medical treatment. Nowadays, more and more doctors in Asia choose to use acupuncture to treat facial paralysis. However, the effects of acupuncture and drugs on the treatment of facial paralysis are still controversial. Therefore, we conducted a systematic Review and meta-analysis of randomized controlled trials (RCTs) to investigate whether Bell's palsy patients would benefit from acupuncture treatment comparing with drug therapy.

2. Materials and methods

2.1. Search strategy

This meta-analysis was performed in adherence to PRISMA statement.^[21] A comprehensive literature search with no language restriction was conducted using PubMed, Embase, the Cochrane Register of Controlled Trials. We did not search gray literature, such as conference abstracts and unpublished reports. During the search process, the full-texts of some articles were limited as the problem of copyright in PubMed, and Embase, the Cochrane Register of Controlled Trials. Then we tried to find these full-texts by searching them in China National Knowledge Infrastructure (CNKI), Wanfang Database and the websites of related journals by using the information of PMID, DOI and others. The searching process was independently performed by two investigators (Rongchao Zhang and Tao Wu). We searched terms related to Bell's palsy, acupuncture, and terms related to randomized controlled trials. The detailed search strategy is showed in the Appendix 1: (Search Strategy and detailed records, http://links.lww.com/MD/C967.)

2.2. Study selection

Inclusion criteria of studies:

- 1. study design: randomized controlled trials;
- 2. population: patients with Bell's palsy (Facial paralysis or idiopathic facial paralysis or herpetic facial paralysis);
- intervention: the intervention was acupuncture therapy, the acupuncture therapy refers to needling or needling combined with moxibustion;
- 4. Comparison: oral medication or topical injection without other therapy.

Exclusion criteria of studies:

1. not RCTs;

- 2. trials testing other forms of acupuncture, such as laser acupuncture or electric acupuncture;
- 3. studies of comparison of 2 different forms of acupuncture methods;
- 4. the intervention group of studies combined more than 2 therapies, such as acupuncture plus medication.

2.3. Data extraction and outcome measures

The data extraction process was applied blindly. Two investigators (Rongchao Zhang and Tao Wu) independently extracted the following information from each study: first author, publication year, country, ethnicity, mean age, number of cases and controls, treatment methods for each group. The primary outcome was cure rate, and the secondary outcome was total effective rate. The efficacy criteria for facial paralysis treatment were determined with reference to the House-Brackmann judging and grading system of facial nerve function.^[22] There are 4 levels of the efficacy: cured, markedly effective, effective, and ineffective. The percentage of cured was called cure rate, and the percentage of markedly effective or effective were called total effective rate.

2.4. Assessment of bias risks and methodological quality of included studies

The following aspects of included studies were assessed by 2 authors (Rongchao Zhang and Tao Wu), respectively: random sequence generation; allocation concealment; blinding of participants and personnel; blinding of outcome assessment; incomplete outcome data; selective reporting; other bias. A grade of 'high', 'low', or 'unclear' was given for each item. The risk of bias was assessed using the modified tool for "risk of bias" from the Cochrane Handbook for Systematic Reviews of Interventions.^[23] Any disagreement was resolved by discussion with a third investigator (Ruihui Wang).

2.5. Statistical analysis

Relative risks (RR) with 95% confidence intervals (CI) were evaluated for outcomes. We firstly used the fixed model to pool the effect sizes of the primary and secondary outcomes, and the results showed that the homogeneity among the pooled studies was poor (the I² statistic=67%, Cochrane Q test P=.0008 and the I² statistic = 90%, Cochrane Q test P < .00001, respectively). Then the random effect model was used to pool RRs. Publication bias was assessed using funnel plots and we did not analyze Egger test or Begg test, since there are only 11 included studies. Heterogeneity across studies was assessed using the Q statistic and I² statistic. We defined that the statistical heterogeneity was set at the I² statistic >50% and/or Cochrane Q test P < .10. It was performed by excluding any single study to test the robustness of the pooled results. Subgroup analyses were performed by intervention methods (acupuncture vs acupuncture combine with moxibustion), different methods of medicine (western medicine vs Chinese and western medicine), published year (before 2005 vs after 2005), sample sizes (≥ 90 vs < 90). P value < .05 were considered statistically significant. The sensitivity analysis was analyzed using Stata 14.0 (Stata Corporation, College Station, TX), and the rest of available data were analyzed using RevMan 5.3 (The Nordic Cochrane Centre, Copenhagen, Denmark)

2.6. Ethics statement

This study is a systematic review and meta-analysis, which was a secondary data processing of previously published studies. All contents were not related to human and animal experiments, so no ethical approval was required.

3. Results

3.1. Study selection and characteristics

Detailed steps of the literature search and study selection are summarized in Fig. 1. We identified 323 relative articles: 68



articles in PubMed, 53 articles in Embase, and 202 articles in cochrane database. Of the 323 inferences, 178 repeated studies were excluded by reading titles and abstracts. Finally, only the full texts of 46 articles were obtained for further review. Then 20 articles were excluded: 13 were not RCTs, 4 meta-analyses and 3 reviews. Among the left 26 articles, 15 studies with mixed interventions did not meet our inclusion criteria and were excluded: in 3 articles,^[24-26] the control group combined with non-drug therapy; in 6 articles, non-acupuncture therapy was used in the observation group; in 2 studies, $[2^{7,28}]$ the intervention of the observation group was acupuncture plus electroacupuncture; 1 study,^[29] used light irradiation therapy device; 2 studies^[29,30] used cupping therapy; and the acupuncture group of 1 study^[31] used drug therapy. Four studies^[32–35] compared the effectiveness of different types of acupuncture therapy. The efficacy evaluation of 1 article^[36] is not clear, and 1 article.^[37] was repeated with the previous study. Therefore, of the 46 full-text publications obtained, only 11 RCTs^[38–48] met our inclusion criteria.

Characteristics of the 11 included RCTs were shown in Table 1. All the included studies were based on patients with newly developed facial paralysis, excluding patients with intractable paralysis. The newly developed facial paralysis was defined as the time during which facial paralysis occurs within one month. The observation time points of each study were between 1 to 1.5 months, and the cure rate and total effective rate of the experimental group and the control group were evaluated at the same time. All the included studies were performed in China and published from 1996 to 2015. Nine studies were written in Chinese and 2 in English.^[40-45] A total of 1258 participants were enrolled in this meta-analysis with sample sizes ranging from 28 to 284. The patients were randomly assigned to intervention group (acupuncture group) or control group (drug group), with their age ranging from 8 to 78 years old. In the intervention group, acupuncture treatment only included manual acupuncture or manual acupuncture combined with moxibustion, while the control group only included drugs (oral or injection). In the intervention group, 3^[40,41,47] of the 11 articles used acupuncture combined with moxibustion, and the rest 8 studies used traditional acupuncture. All the included RCTs used drug therapy as control. Only 1 RCT referred to adverse effects and/or complications during acupuncture therapy.^[40] The rest of studies did not report the side effects and/or complications of patients.

3.2. Methodologies bias of selected studies

Details of the quality of included studies were shown in Fig. 2. Randomization was performed in all studies, but only 4 studies reported the details of random sequence generation.^[40,45,47,48] Only 1 study^[45] reported the information of allocation concealment, and none of the other studies mentioned it. Some included studies were assessed as having high risks cause because they did not describe the blinding process. One study reported that the outcome assessment was blinded.^[45] Incomplete outcome data were reported in 7 trails, and 8 trails conducted selective reporting with a low risk of bias. Five trials reported other kinds of bias.^[39,42,43,45,48] In general, the overall risk of bias in included studies is pretty high.

3.3. Primary and secondary outcomes

All the selected 11 studies were used to calculate the pooled estimate for assessing the cure rate and total effective rate.

In summary, 379 individuals were cured in the acupuncture group (n=646) and 199 individuals were cured in the drug group (n=612). The total cure rates for the acupuncture and drug groups were 59.7% and 32.5%, respectively. Acupuncture treatment was associated with an increased cure rate (RR = 1.77, 95% CI: 1.41–2.21, Fig. 3), with significant heterogeneity in the pooled results (I^2 =67%, P=.0008).

There were 626 individuals in the acupuncture group were evaluated as effective in treatment among 646 patients and 508 individuals in the control group were evaluated as effective among 612 patients. The total effective rates in the acupuncture and drug groups were 96.9% and 83.0%, respectively. Acupuncture therapy was associated with an increased total effective rate (RR=1.18, 95% CI: 1.07–1.31, Fig. 4), with significant heterogeneity in the pooled results (I²=90%, P < .00001).

3.4. Publication bias, subgroup analyses and sensitivity analysis

We conducted funnel plots for the primary and secondary outcomes to assess the potential publication bias of the included studies. In regards to the cure rate, we initially found that funnel plot yielded no extreme publication bias (Fig. 5). And for the outcome of total effective rate, there was also no obvious publication bias can be observed based on the funnel plot (Fig. 6).

Subgroup analyses based on intervention methods, different methods of medicine, published year and sample sizes showed similar results across all the analyses (Table 2 and Appendix 2, http://links.lww.com/MD/C967)

Sensitivity analysis was conducted to evaluate the stability of the results. In sensitivity analysis, excluding any single study at each turn did not lead to a remarkable change in the overall RR and 95% CI of cured rate and total effective rate, indicating that the pooled results were stable. (Figs. 7 and 8)

4. Discussion

In this systematic review and meta-analysis, 323 RCTs were found by searching PubMed, Embase and Cochrane Central Register of Controlled, and finally 11 RCTs were included with 1258 patients. The observation group used traditional Chinese acupuncture therapy (acupuncture or acupuncture plus moxibustion), and the control group used drug therapy (oral or injection). Through this study, more evidence can be provided to explore whether acupuncture is beneficial to Bell's palsy and whether it is more effective than drug therapy. The interventions included in the previous studies were complicated, such as acupuncture combined with drug therapy as an intervention group and drug therapy alone as a control group. The studies included in this meta-analysis was acupuncture as an intervention group, and drug treatment as a control group, which is a more direct and accurate comparison of the effects of acupuncture treatment and drug treatment for Bell's facial paralysis.

The results showed that patients in the acupuncture group may associated with increased cure rates and total effective rate (RR = 1.77, 95% CI: 1.41-2.21; RR = 1.18, 95% CI: 1.07-1.31) compared with the drug group. All the RCTs included in this meta-analysis indicate that acupuncture was an effectively treatment for Bell's facial paralysis (peripheral facial paralysis). Bell's palsy is a self-limiting disease, and some patients can recover spontaneously without treatment. Therefore, researches

Table 1

Study	Sample size	Mean age (yr)	Acupuncture type	Intervention group	Control group (Drug group)	Outcome measurement
Liu 1996	130	8–75 (38.5)	Multi-needle shal- low puncture	Needles inserted with manual stimulation till elicited de qi;30 min × 10 treatment sessions:	Prednisone 20 mg 3 times /d, vitamin B	Total effective rate; The cured rate
Yu 1999	50	17-78 (39.3)	Multi-needle shal-	Conventional acupuncture 20	Vitamin B, steroid, traditional Chinese	Total effective rate; The cured rate
Li 2004	284	Intervention group:40.50 \pm 15.7; Control group:39.5 \pm 14.6	Convertional acu- puncture +moxi- bustion	Needles inserted with manual stimulation till elicited de qi and hanging moxibustion was applied for 5 min at each point, once a day, 5 times a week, for a total of 4 weeks.	Vitamin B1 100 mg (im), vitamin B12 100 µg (im) once daily for 10 days, then vitamin B1 10 mg (po, 3 times/d) 3 times a day for 10 days. In addition, prednisone (po) 30 mg once daily for 3 days and dibazole (po) 10 mg three times daily for 2–4 weeks	Total effective rate; The cured rate
Ma 2004	95	Intervention group 16–48; Control group 15–44	Multi-needle shal- low puncture +moxibustion	Needles inserted with manual stimulation till elicited de qi; 30 min \times 30 treatment sessions:	VitaminB1 (100 mg, im), B12 (0.25 mg, im) 5 times a week, rest for 2 days, a total of 5 weeks of treatment.	Total effective rate; The cured rate
Zhao 2005	28	20–72	Multi-needle shal- low puncture	Needles inserted with manual stimulation till elicited de qi; 20 min \times 10 treatment sessions:	Stellate ganglion block (SGB) injection: 10 g/L lidocaine, 6–8 ml in one dose, and the injection site is the base of the sixth cervical transverse process.	Total effective rate; The cured rate
Yang 2006	214	Intervention group: 35.95 ± 11.18 Con- trol group: 36.79 ± 11.45	Multi-needle shal- low puncture	Horizontal and shallow nee- dles inserted, 30 min/d × 10 treatment sessions, rested for 2 days,2 cycles;	 Steriod: prednisone (po), 20–40 mg daily × 4 weeks, descending dose; or dex-amethasone (iv), 5–10 mg daily × 2 weeks then prednisone for 4 weeks; antiviral: aciclovir (iv), 0.75–1g daily × 7–10d; or virazole (iv), 0.4g daily × 10d; neurotrophy medicine: vitamin B + nicotinic acid. 	Total effective rate; The cured rate
Zhu 2006	75	15–69	Multi-needle shal- low puncture	Shallow needles inserted, 30 min/d \times 5 treatment sessions for acute stage, 30min/d \times 10 treatment sessions, rested for 2–3 days, 2 cycles for resting stage and restora- tion stage	Prednisone 5 mg three times/d	Total effective rate; The cured rate
Tong 2009	119	12–95	Multi-needle shal- low puncture	Needles inserted with manual stimulation till elicited de qi; 20min × 5–10 treatment sessions/ week for inpatients, 20 min × 2–5 treatment ses- sions/week for outpatients.	Prednisolone 30 mg twice daily × 1 week + pepcidine 20 mg twice daily × 1 week	Total effective rate; The cured rate
Duan 2014	96	Intervention group:20–54 (33. 4 ±1. 3); Control group:22–55 (34.2± 1.8)	Multi-needle shal- low puncture	Needles inserted with manual stimulation till elicited de qi;30 min × 20 treatment sessions;	Prednisone (20 mg, 3 times /d, po), after 3 days reduction of 10 mg / time, gradually reduced; Dibazole (20 mg, 1 time/day, po); Mecobalamin (0. 5 mg /time, po, 3 times/day); Vitamin B1 and vitamin B6 each 10 mg, 3 times / d; Vitamin B12 (0.1 mg, 1 time/d, im), ribavirin as appropriate	Total effective rate; The cured rate
Bao 2015	130	Intervention group:11–72 (45.2 ± 17.8) Control group:12–69 (44.8 ± 18.2)	Multi-needle acu- puncture	Manual acupuncture at Feng- chi, Yingxiang, Shuigou, Chengzhu, Qizhu, Taichong, etc., 30 minutes/time, 1 time/2d, 10 times/treatment, each treatment interval is 3~5 days, A total of 3 courses.	 Prednisone (po, 10 mg/time, 2 times/ day), vitarnin C (po,5 mg/tablet, 1 tablet/time, 1 time/day), multivitamin B (po, 5 mg/tablet, 1 tablet/time, 3 times / day), dibazole (po, 10 mg/tablet, 10 mg/time, 3 times/day). 2, Shuxuening injection (Batch No: Z20043734, size 50 ml/support, 1 time/d, iv). 3, Angelica injection (Batch No: Z20026200, 2 ml/ support, 1/d, im); inosine injection (Batch No: H23021450, 500 mg: 100 ml/support, 1/d, im). 4, topical medica- tion: Xiongdan eye drops, ofloxacin eye ointment. 	Total effective rate; The cured rate
Yu 2015	90	Intervention group:38.9±6.5; Control group:38.1± 6.47	Conventional acu- puncture +moxi- bustion	Conventional acupuncture, leaving the needles for 30 min. At the same time, the acupuncture point between the moxibustion Xiaguan and the Dianzheng point is ignited at 8 cm, moxibustion for 30 min, once/day. After a course of treatment, rest for 3 days and treat a total of 3 courses.	Dexamethasone (10 mg/d, intravenous drip), acyclovir (2400 mg / d, 3 times orally), intramuscular (vitamin B1 0.2 g/ d, vitamin B12 0.5 g / d), 7 d/ course of treatment, a total of 3 courses of treatment.	Total effective rate; The cured rate

im = intramuscular injection, iv = intravenous injection, po = oral administration.

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Figure 2. Risk of bias summary: review authors' judgments about each risk of bias item for each included study.

related to the treatment of Bell's palsy may be uncommon. As one of the most classic therapy of traditional Chinese medicine, acupuncture is pretty popular in Asian countries such as China and South Korea, but not common in Europe and the America. Significant heterogeneity was observed in studies comparing acupuncture and drug efficacy. Experimental design, methodological deficiencies and operator skill differences may be the main causes of heterogeneity. Meanwhile, the various sample size

	Experimental		Control		RISK RAUO		RISK ROUD
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% CI	M-H, Random, 95% Cl
Bao2015	35	65	23	65	10.0%	1.52 [1.02, 2.27]	
Duan2014	29	48	10	48	7.2%	2.90 [1.60, 5.27]	
Li2004	64	156	36	128	11.0%	1.46 [1.04, 2.04]	
Liu1996	48	65	30	65	11.6%	1.60 [1.19, 2.16]	
Ma2004	30	48	8	47	6.4%	3.67 [1.88, 7.16]	
Tong2009	23	28	24	38	11.6%	1.30 [0.97, 1.75]	-
Yang2006	64	107	18	107	9.2%	3.56 [2.27, 5.57]	
Yu1999	25	30	9	20	8.4%	1.85 [1.11, 3.08]	
Yu2015	25	45	14	45	8.4%	1.79 [1.08, 2.97]	
Zhao2005	6	14	7	14	5.2%	0.86 [0.39, 1.91]	
Zhu2006	30	40	20	35	11.0%	1.31 [0.94, 1.84]	
Total (95% CI)		646		612	100.0%	1.77 [1.41, 2.21]	•
Total events	379		199				10 A 10 A 10
Heterogeneity: Tau ² :	0.09; Chi	² = 30.30), df = 10	(P = 0.1)	0008); I ² =	= 67%	
Test for overall effect: $Z = 4.93$ (P < 0.00001)					~		0.02 0.1 1 10 50



	Experimental		Control		Risk Ratio		Risk Ratio
Study or Subgroup	Events	Total	Events	Total	Weight	M-H, Random, 95% Cl	M-H, Random, 95% CI
Bao2015	62	65	52	65	10.4%	1.19 [1.04, 1.36]	
Duan2014	46	48	42	48	10.7%	1.10 [0.97, 1.24]	
Li2004	156	156	125	128	12.4%	1.02 [0.99, 1.06]	+
Liu1996	63	65	50	65	10.2%	1.26 [1.10, 1.45]	
Ma2004	43	48	20	47	5.2%	2.11 [1.49, 2.98]	
Tong2009	28	28	35	38	11.0%	1.08 [0.97, 1.20]	
Yang2006	106	107	98	107	12.0%	1.08 [1.02, 1.15]	+
Yu1999	30	30	11	20	4.5%	1.80 [1.21, 2.66]	
Yu2015	41	45	32	45	8.3%	1.28 [1.04, 1.58]	
Zhao2005	11	14	10	14	4.0%	1.10 [0.72, 1.69]	
Zhu2006	40	40	33	35	11.3%	1.06 [0.96, 1.17]	
Total (95% CI)		646		612	100.0%	1.18 [1.07, 1.31]	•
Total events	626		508				
Heterogeneity: Tau ² =	0.02; Chi ²	= 100.5	54, df = 10) (P < 0	.00001);	I ² = 90%	
Test for overall effect:	Z = 3.19 (F	P = 0.00	1)				0.2 0.5 1 2 5 Favours [experimental] Favours [control]
	Fig	ure 4.	Meta-ar	nalysis	on acu	puncture for total effe	ective rate of Bell's palsy.

between studies is also a source of heterogeneity. There are some methodological flaws in the included studies. First, in the part of allocation concealment, some studies have not been concealed or not described. Second, some studies did not perform the blinding of participants and personnel, which may cause performance bias. Analysis of the risk of bias indicated that the high-risk bias of the included studies was mainly due to the fact that the study process was not blinded or unreported, and assessment of the results were not blinded or unreported. In further studies, the conditions of the experimental group and the control group should be strictly controlled, and blind grouping and treatment should be strictly applied. Meanwhile, future researches should expand the sample size to obtain more objective and accurate results. There were several meta-analyses about the acupuncture treatment for patients with Bell's palsy. Zhou et $al^{[49]}$ searched for relevant literature before 2009 and included 6 RCTs, including 537 Bell's palsy participants. However, due to the poor quality of the included studies, reliable conclusions cannot be drawn about the efficacy of traditional acupuncture and other treatments. Kim et $al^{[50]}$ searched for relevant literature before June 2010. A total of 8 RCTs were included in their study. The Cochrane bias risk tool was used to assess the quality of these trials. Due to the low quality of the trials, no definitive conclusions were reached. Li et $al^{[51]}$ searched for literature before 2015 and included 14 RCTs, including 1541 Bell palsy patients. Since the data included in the study were incomplete, no complication rate was assessed. They investigated





Table 2

Subgroup analysis.

Subgroups	Number of studies	Pooled hazard risk	95% confidence interval	Heterogeneity between studies
1. Cure rate.				
1. 1 Acupuncture and moxibustion Acupuncture	8	1.70	1.29-2.25	P = .001 $ ^2 = 71\%$
Acupuncture and moxibustion	3	1.98	1.22-3.23	P = .005 $l^2 = 66\%$
1.2 Types of medication Western medicine	8	1.84	1.32–2.57	P < .0001
Mixed Chinese and Western medicine	3	1.62	1.30-2.01	P = .0083 $l^2 = 0\%$
1.3. Publication time Before 2005 (including 2005)	5	1.68	1.23–2.31	P=.06
After 2005	6	1.85	1.29-2.64	P = .0004 P = .78%
1.4. sample size Sample size ≤ 90	6	1.65	1.14–2.39	P=.0008
Sample size > 90	5	1.87	1.39–2.52	P = 76% P = 0.05 P = 58%
2. Effective				1 00/0
2.1. Acupuncture and moxibustion Acupuncture	8	1.13	1.06-1.21	P = .02
Acupuncture and moxibustion	3	1.39	0.67–2.89	P < .0001 $l^2 = 98\%$
2.2. Types of medication Western medicine	8	1.13	1.02–1.25	P<.0001
Mixed Chinese and Western medicine	3	1.29	1.10-1.50	P = .12 P = .53%
2.3. Publication time Before 2005 (including 2005)	5	1.39	0.87-2.22	P<.0001
After 2005	6	1.10	1.05–1.15	$ ^{2} = 97\%$ P = .33 $ ^{2} = 14\%$
2.4. sample size Sample size ≤ 90	6	1.13	1.03–1.25	P=.01
Sample size > 90	5	1.25	0.98–1.59	$l^{2} = 65\%$ P = .0001 $l^{2} = 96\%$



that acupuncture seems to be an effective treatment for Bell's palsy, but due to the poor quality and great heterogeneity of the included studies, there is insufficient evidence to support the efficacy and safety of acupuncture. Zhang et al^[52] searched for literature before July 2016 and included 20 RCTs, including 2508 Bell palsy patients. Their results show that due to limited methodological quality and potential biases of studies, it was not possible to conclude that acupuncture was effective against facial paralysis. Although acupuncture therapy shows benefits, the efficacy may be influenced by factors such as patient's compliance and doctor's experience. Because the use of acupuncture is a complex technical process, differences in the depth and strength of the needles penetrated by different operators may also affect the effectiveness of acupuncture treatment, which increases the difficulty of assessing the consistency of each trial. However, acupuncture therapists can achieve constant standards through regular



training and practice. Insufficient information about the side effects or complications of acupuncture treatment means that we cannot further evaluate other meaningful clinical indicators. Therefore, we need more high-quality and large sample randomized controlled studies to explore the effects and side effects of acupuncture treatment.

This study has several limitations. First, the sample size of included studies were small, which may lead to limited generalizability. Second, the experimental design of several studies was not good enough, such as randomization, allocation concealment, and blinding were not performed strictly. Third, information of the side effects and complications of acupuncture were not presented in the trails. This means that there was not enough evidence to prove the safety of acupuncture treatment, so potential risks need to be considered when giving treatment advice.

5. Conclusion

Despite the poor quality of the included studies, our metaanalysis further confirmed the results of previous researches. Despite the high risk of bias and heterogeneity, acupuncture seems to be superior to drug therapy in the treatment of Bell's palsy including cure rate and total effective rate, which may be an effective method of treating Bell's palsy. When treating patients with facial paralysis, Acupuncture can be seen as one of the effective and operational treatment options. However, due to the existence of methodological flaws and potential bias risk in the included studies, more high-quality and large-sample RCTs are needed. Therefore, please carefully refer to the research conclusions of this meta-analysis.

Author contributions

Conceived and designed the experiments: Rongchao Zhang, Ruihui Wang.

- Performed the experiments: Rongchao Zhang, Tao Wu, Dong Wang
- Analyzed the data: Rongchao Zhang, Tao Wu, Dong Wang
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- Wrote the paper: Rongchao Zhang.
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