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ORIGINAL ARTICLE

Comparison of Efficacy and Safety of Acupuncture and Moxibustion in Acute Phase and Non-acute Phase of Bell's Palsy: a meta-analysis

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Abstract

OBJECTIVE: To evaluate the efficacy and safety of acupuncture and moxibustion for bell's palsy in the acute phase compared with the non-acute phase.
METHODS: Computer retrieval of PubMed, Embase, The Cochrane Library, Web of Science, China National Knowledge Internet (CNKI), Wanfang data, were conducted. According to the inclusion and exclusion criteria, the quality of literature was evaluated, and useful data was extracted. All statistical analyses were performed by RevMan5.3 software.
RESULTS: 17 eligible RCTs with a total of 2644 patients were included in this meta-analysis. The meta-analysis results demonstrated the cure rate of acupuncture and moxibustion for Bell's palsy in the acute phase were lower than that in the non-acute phase ($P<0.05$). The time to cure of acupuncture and moxibustion for Bell's palsy in the acute phase was shorter than that in the non-acute phase ($P<0.05$), and the incidence of sequelae during the treatment period of acupuncture and moxibustion for Bell's palsy in the acute phase were lower than that in non-acute phase ($P<0.05$).
CONCLUSIONS: Acupuncture and moxibustion were safe and effective stimulation for Bell's palsy in the acute phase compared with the non-acute phase, improving the cure rate of Bell's palsy, shorten the time to cure, and reduce the occurrence of sequelae. However, more multicenter RCTs with a large sample number and high quality should verify the conclusion mentioned above.

INTRODUCTION

Bell's palsy, also known as idiopathic facial paralysis, is an acute onset, idiopathic mononeuropathy of the cranial nerves. Bell's palsy is the most common cause of peripheral facial palsy, defined as unexplained, acute unilateral facial palsy occurring within 72 hours (Menchetti *et al.* 2021). Over the years, scholars have obtained consensus on the diagnosis and treatment plan for Bell's palsy (Menchetti *et al.* 2021; de Almeida *et al.* 2014): (1) Corticosteroids are the treatment of choice and can improve the symptoms of patients with Bell's palsy, and hormone therapy given as early as possible after onset will effectively enhance the cure rate of Bell's palsy (within 72 hours); (2) Antiviral drugs have limited effects, which are not recommended alone; The combination of antiviral drugs with steroid hormones improves the prognosis of patients with severe symptoms. (3) Routine clinical examination and imaging examination are not recommended for

the first attack of idiopathic peripheral facial paralysis. In clinical practice, patients with Bell's palsy often present to different disciplines (otorhinolaryngology, neurology, ophthalmology, physiotherapy, rehabilitation, acupuncture, etc.). Therefore, the diagnosis and treatment plan also varies in different disciplines and even the same discipline (Buizert *et al.* 2018). Physical therapy or rehabilitation, such as massage, acupuncture, and electrical stimulation, are widely used to treat Bell's palsy (Albers & Tamang 2014). However, there is still controversy about the efficacy of different treatment methods. Several clinical studies have investigated the effect of physical and rehabilitation treatments such as acupuncture on the efficacy of Bell's palsy, suggesting that acupuncture treatment positively impacts the recovery of facial paralysis and can improve the facial muscle motor function of Bell's palsy (Ferreira *et al.* 2015; Oksuz *et al.* 2019). Still, there is a lack of standardized, controlled studies, and its efficacy has also been questioned. It has also been shown that early acupuncture treatment is an adverse factor in the therapeutic effect of Bell's palsy (Zhang *et al.* 2019a). Hence, the real benefits and effectiveness of acupuncture remain to be further confirmed. The timing and effectiveness of the acupuncture treatment intervention are still one of the urgent problems to be clarified (Heckmann *et al.* 2019). In recent years, the clinical research literature on acupuncture and moxibustion treatment of acute Bell's palsy increased year by year. However, there are few evidence-based studies into the acupuncture and moxibustion for Bell's palsy at different stages. Therefore, the purpose of this meta-analysis is to evaluate the literature regarding the efficacy and safety of acupuncture and moxibustion for Bell's palsy in the acute phase compared with the non-acute phase.

MATERIALS AND METHODS

Inclusion Criteria

(1) Randomized controlled trial (RCT) study, regardless of whether the blind method is used; (2) patients diagnosed with Bell's palsy, regardless of sex, race, and nationality; (3) the treatment group was given acupuncture and moxibustion (acupoints on the affected side) combined with conventional treatment (hormone therapy and other rehabilitation training). The intervention timing is the acute phase (within seven days of onset), regardless of the type and manipulation of acupuncture and moxibustion. The control group was assigned conventional treatment or blank control except for acupuncture in the acute phase. The intervention measures were the same as those in the treatment group in the non-acute phase (after seven days of onset).

Exclusion Criteria

(1) Literature reviews, conference abstract, retrospective or cross-sectional studies, meta-analysis studies; (2) literature on acupuncture and moxibustion as a non-primary treatment or comparison between various acupuncture and moxibustion related therapies; (3) studies that failed to extract original data for analysis; (4) studies that used different staging criteria than this study.

Endpoints

Endpoints after treatment period: (1) Cure rate; (2) time to cure; (3) incidence of sequelae during the treatment period.

Literature Search Strategy

The combination of subject terms and free-text terms were mainly used to search the database. The English terms acupuncture, Bell's palsy, peripheral facial palsy, facial neuritis, idiopathic facial nerve paralysis, randomized controlled trials were searched in PubMed, Embase, The Cochrane Library (2021, Issue 1), and Web of Science. And the same terms in Chinese were searched in China National Knowledge Internet (CNKI) and Wanfang data, with the date range set from January 2000 to January 2021. Search engines, including Google Scholar, Baidu Wenku, were also applied for manual searching of related literature.

Literature Selection and Data Extraction

In accordance with the pre-determined inclusion and exclusion criteria, two reviewers read the titles and abstracts of the literatures respectively and independently excluded articles that failed to meet the criteria, and conducted full-text reading and data extraction on articles that meet the criteria. Discussion was adopted in the case of disagreements, and a third reviewer was introduced when necessary. Data extraction includes: (1) general data: title, authors, published date; (2) basic features of the included literature: research object, interventions, number of cases, basic information of the patients; (3) endpoints mentioned above.

Quality Assessment

Cochrane collaboration's tool for assessing the risk of bias for Systematic Reviews of Interventions 6.0 was used for evaluating randomized controlled trials.

Statistical Analysis

All statistical analyses were performed by RevMan 5.3 Software(Review Manager Version 5.3; The Cochrane Collaboration, Copenhagen, Denmark). Binary data took odds ratio (OR), whereas continuous data took a mean difference (MD) or standard mean difference (SMD) as effect sizes, each with 95% CI results. Chi-square test was applied for heterogeneity analysis (I^2 values <25% are considered of low heterogeneity, between 25% to 50% moderate heterogeneity, and more than 50% are considered of high heterogeneity). If $P>0.10$, I^2 <50%, the heterogeneity level was low, and fixed-effects model analysis was adopted, whereas

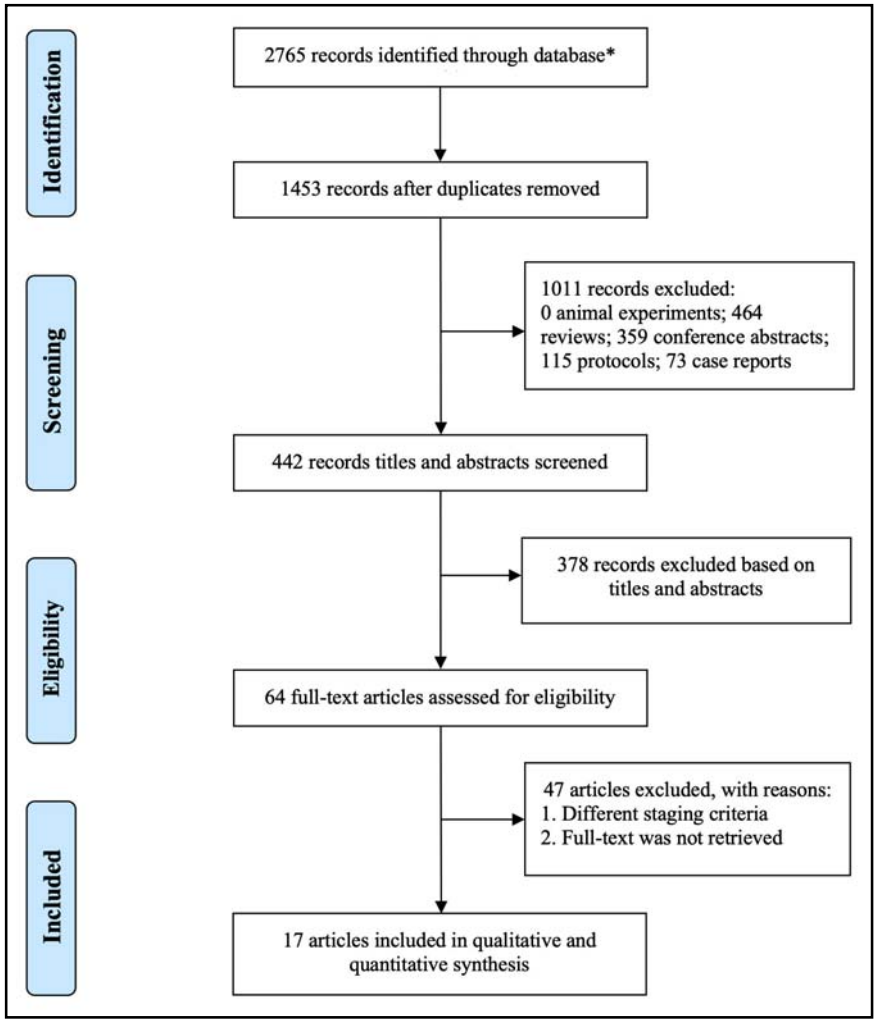

Fig. 1. PRISMA flow diagram
*Literature search results: PubMed (168), Embase (153), Web of Science (126), The Cochrane Library (5), CNKI (1189), Wanfang Data (1124)

$P \leq 0.10$, $I^2 \geq 50\%$ indicated a high level of heterogeneity, and a random-effects model was applied to assess sources of heterogeneity. After excluding studies with evident heterogeneity through analysis, a fixed-effects model analysis was then applied. Small study effects and publication bias was evaluated by visual inspection of respective funnel plots. Funnel plots are plots of the trials' estimated effect sizes (OR) against the standard error of the log-transformed estimates (SE(log[OR])). In the presence of publication or other bias, they may appear to be skewed and asymmetrical. The level of statistical significance was set at $\alpha=0.05$.

RESULTS

Literature Search Results and Basic Features of Included Studies

The title and the abstract of a total of 442 scientific publications were screened for potential inclusion in this meta-analysis. Of those, 378 citations were found not to be relevant, incomplete, or describing duplicate data and were excluded from further analysis. Finally, 17 RCTs were eligible and included in this systematic qualitative review and quantitative data synthesis, comprising 2644 patients. The PRISMA flow diagram presents the search history in Figure 1. In the included studies, patients were randomized to the treatment group (n=1260) or control group (n=1384). All 17 trials were RCTs by design, and their characteristics are outlined in Table 1. Overall, the quality of evidence was low, with a high risk of bias. Most of the studies were inherently not blinded, attrition was universally under-reported or unclear, and information on allocation concealment was missing in most of the cases. The risk of bias summary is shown in Figure 2, and the risk of bias graph is shown in Figure 3.

Publication bias

Visual inspection of the respective funnel plot showed no certain degree of asymmetry, suggesting no publication bias for efficacy with 17 RCTs (Figure 4).

Meta-analysis Results

Level of cure rate

The cure rate after the treatment period was reported in 17 studies. Chi-square test results: $P=0.08$, $I^2=35\%$, indicating moderate heterogeneity. A fixed-effects model was applied: OR=1.96, 95%CI (1.61, 2.40), $P<0.00001$

Tab. 1. Basic Features of Included Studies

Included Studies	Year	Cases (n=)		Age Mean ± SD (years)		Duration of treatment (days)	Endpoints
		T1	T2	T1	T2		
Shen (Shen *et al.* 2009)	2009	74	144	-		60	AB
Feng (Feng & Ma 2013)	2013	144	60	38±33	30±29	30	A
Qu (Qu & Xiong 2005)	2005	15	25	32.5±6.3	34.2±7.38	30	A
Wang (Wang & Yang 2010)	2010	181	250	38.3	36.1	30	A
Zhang (Zhang & Song 2013)	2013	30	30	35±10	36±9	21	A
Zhang (Zhang & Liu 2018)	2018	30	30	46.7±9.9	44.17±12.7	36	AB
Wang (Wang *et al.* 2018)	2018	67	67	37.8±12.6	37.7±12.7	28	AB
Sang (Sang & Sun 2013)	2013	86	62	42±20	48±29	120	AC
Qin (Qin & Huang 2013)	2013	40	80	43.2±12.4	44.6±15.3	28	A
Li (Li 2014)	2014	38	40	-		36	A
Huang (Huang & Hao 2012)	2012	86	171	-		60	AB
Du (Du & Jia 2010)	2010	182	182	-		36	AB
Zhang (Zhang *et al.* 2011)	2011	86	84	45.3±10.2	46.4±12.3	36	AB
Zhang (Zhang 2008)	2008	54	50	40.2±17.4	41±16.4	<180	ABC
Wu (Wu *et al.* 2006)	2006	50	50	41.5±15.5	43.3±16.7	60	ABC
Jiang (Jiang *et al.* 2020)	2020	75	37	51.6±5.3	52.1±5.8	30	A
Li (Li 2019)	2019	22	22	35.3±14.7	34.1±16.7	28	A

T1: treatment group; T2: control group; A: Cure rate; B: Time to cure; C: incidence of sequelae during the treatment period

(Figure 5). The results are statistically significant. Analysis results showed that the cure rate of acupuncture and moxibustion for Bell's palsy in the acute phase were higher than that in the non-acute phase.

Level of recovery time

The time to cure was covered in 8 studies (Wu *et al.* 2006; Wang *et al.* 2018; Zhang *et al.* 2011; Zhang & Liu 2018; Shen *et al.* 2009; Zhang 2008; Huang & Hao 2012; Du & Jia 2010). Chi-square test results: P=0.0007, I^2=72%, indicating high heterogeneity. A random-effects model was applied: MD=-6.10, 95%CI (-7.90, -4.29), P<0.00001. After excluding Du 2010 (Du & Jia 2010) through sensitivity analysis, the respective chi-square test results were: P=0.30, I^2=17%, indicating low heterogeneity. A fixed-effects model was applied, and the results were similar to those before exclusion: SMD=-6.99, 95%CI (-7.87, -6.10), P<0.00001 (Figure 6). The results are statistically significant. Analysis results demonstrated that the time to cure of acupuncture and

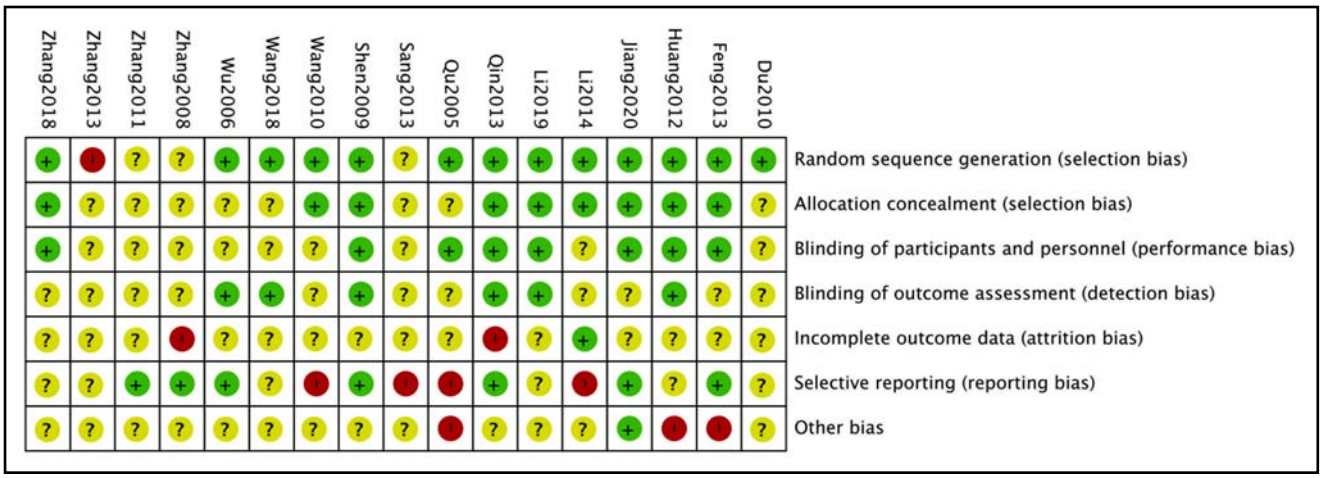

Fig. 2. Risk of bias summary

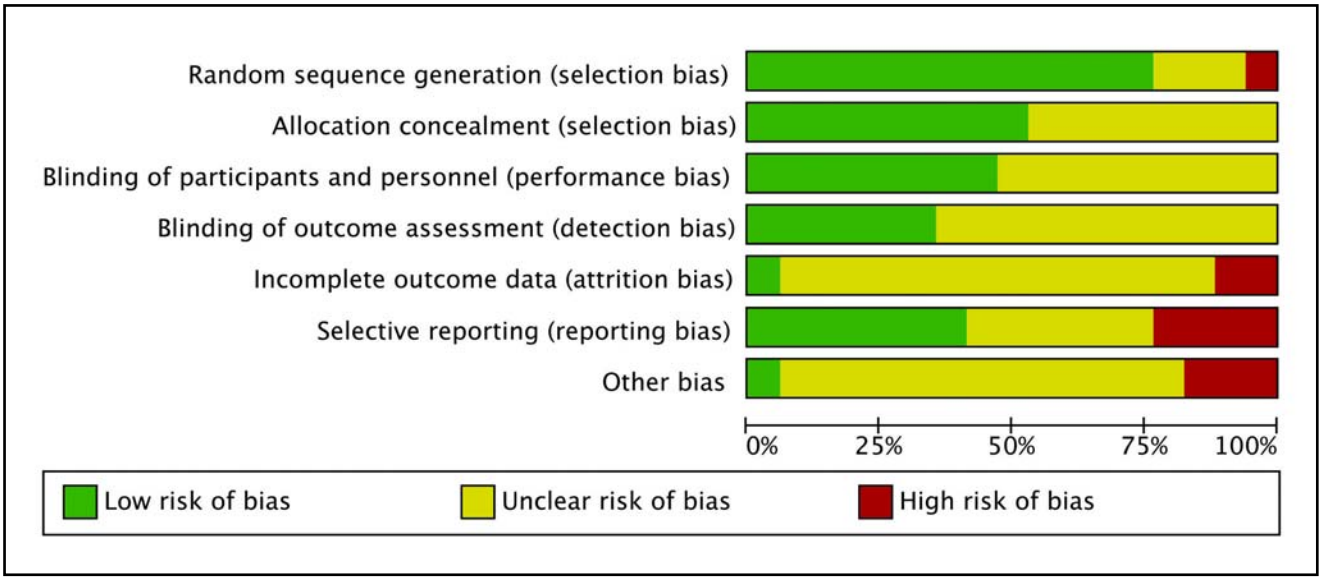

Fig. 3. Risk of bias graph

moxibustion for Bell's palsy in the acute phase were shorter than that in the non-acute phase.

Level of sequelae incidence

The incidence of sequelae during the treatment period was mentioned in 3 studies (Wu *et al.* 2006; Sang & Sun 2013; Zhang 2008). Chi-square test results: P=0.37, I^2=0%, indicating low heterogeneity. A fixed-effects model was applied: OR=0.37, 95%CI (0.17, 0.79), P<0.00001 (Figure 7). The results are statistically significant . Analysis results showed that the incidence of sequelae during the treatment period of acupuncture and moxibustion for Bell's palsy in the acute phase were lower than that in the non-acute phase.

DISCUSSION

At present, there is no uniform standard for the treatment of Bell's palsy, and the main treatment methods are glucocorticoids, antiviral drugs, trophic nerve drugs, acupuncture, traditional Chinese medicine, massage, and surgery. Among them, acupuncture and moxibustion treatment for Bell's palsy is effective and has been widely used in clinical practice (Zhang & Wan 2011). A study (Wang & Zhang 2010) has shown that grasping the timing of acupuncture treatment affects the disease's efficacy, course of the disease, and prognosis. Under the human body's changing physiological and pathological function, selecting different

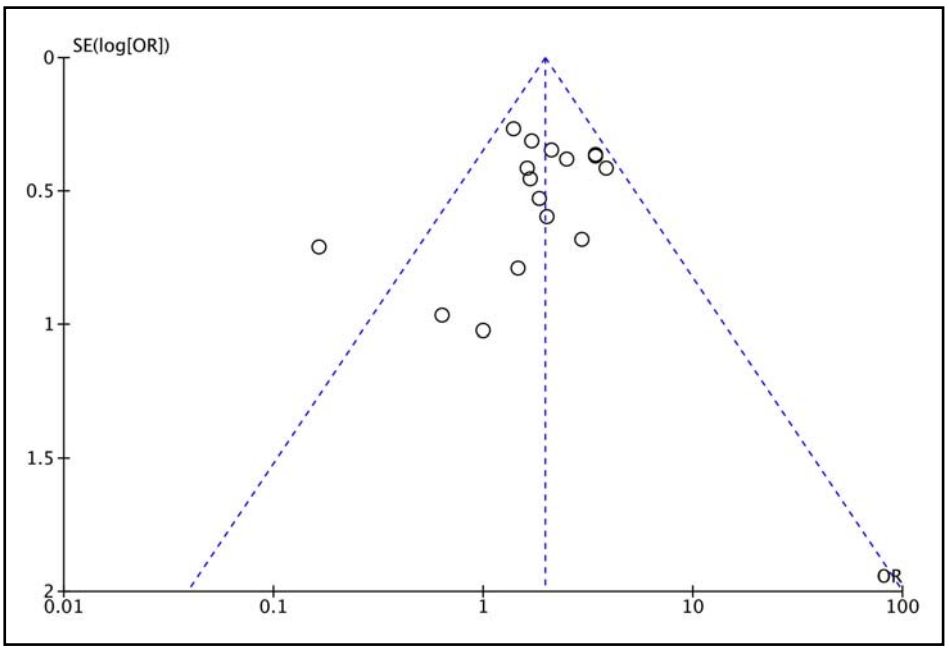

Fig. 4. Funnel plots of the cure rate with 17 RCTs

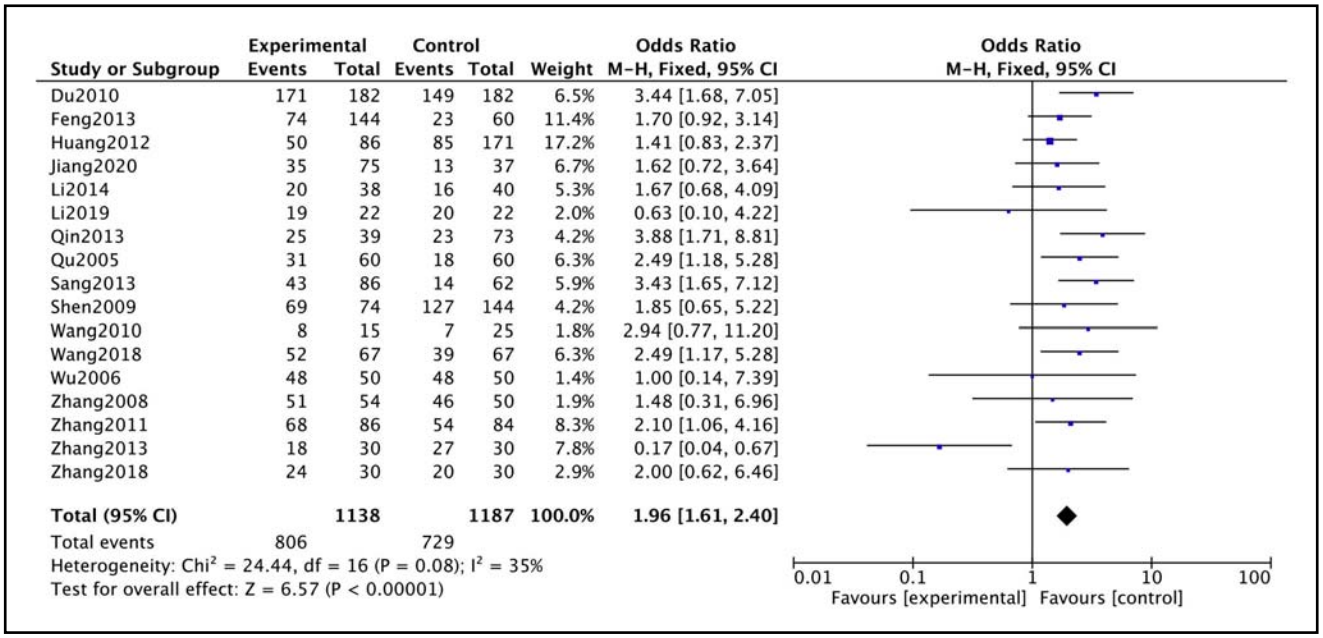

Fig. 5. Comparison between the cure rate of acupuncture and moxibustion for Bell's palsy in the acute phase and non-acute phase

acupuncture intervention time has very different curative effects (Guo & Meng 2015). The acute phase is the key to the treatment of peripheral facial paralysis. The correct treatment of the acute phase can directly affect the disease's efficacy and prognosis (Liu *et al.* 2016).

However, there has been clinical controversy about the timing of acupuncture intervention for peripheral facial paralysis. A literature (Phan *et al.* 2016) has proposed that it is better not to intervene with acupuncture and moxibustion in the acute phase of Bell's palsy. In the acute phase, facial nerve edema gradually peaks, and early acupuncture stimulation will aggravate inflammatory edema, which is not conducive to the supply of local nutrients and the improvement of microcirculatory status but aggravates the condition (Gilden & Tyler 2007; Calcaterra *et al.* 1976). Hence, frequent acupuncture may cause nerve cell fatigue, reduce the excitability of nerves, and aggravate inflammatory edema of nerves, which is not conducive to improving blood circulation and the recovery of the condition. Li *et al.* (Li *et al.* 2010) and Chen *et al.* (Chen *et al.* 2012) compared the cure rate and efficacy of acupuncture and western medicine in treating acute Bell's palsy through systematic evaluation study, and the results demonstrated no significant statistical difference. Acupuncture and moxibustion treatment should be in the stationary and recovery phases due to the shallow distribution of the facial nerve in the face, nerve edema, and increased fragility after the disease's onset (Yu *et al.* 2020).

However, studies (Zheng *et al.* 2015; Yin 2016) suggested that the aggravation of symptoms that occur with acupuncture in the acute phase of Bell's palsy was the process of disease development and was not caused by acupuncture. They demonstrated that the acute phase was the best time for acupuncture treatment through clinical research. Early acupuncture treatment can reduce neuritic edema and prevent nerve degeneration. Meanwhile, acupuncture treatment can promote the absorption of inflammatory exudate, which blocks the continued development of aseptic inflammation (Li *et al.* 2020). Acupuncture and moxibustion treatment

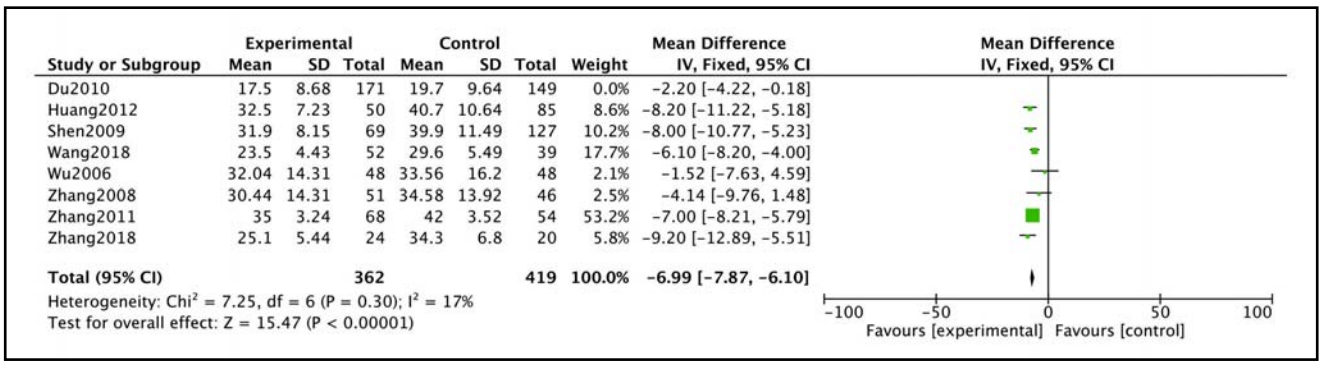

Fig. 6. Comparison between the time to cure of acupuncture and moxibustion for Bell's palsy in the acute phase and non-acute phase

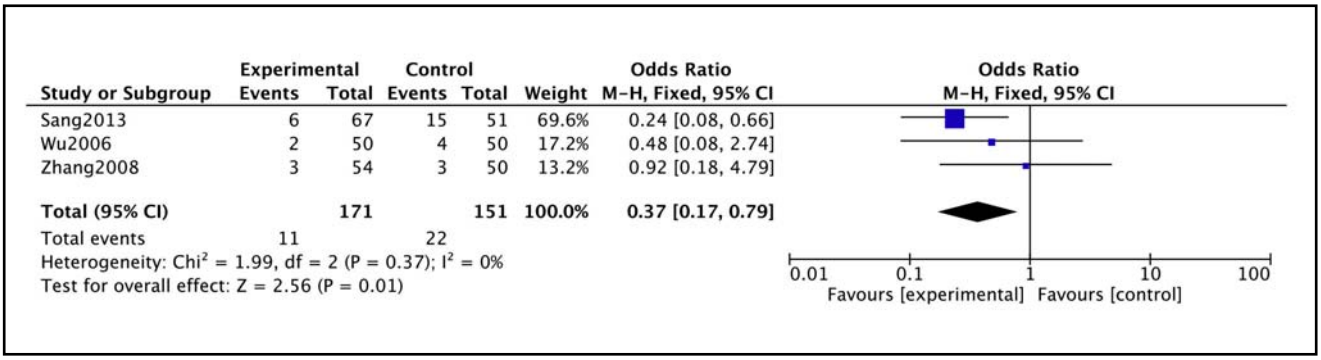

Fig. 7. Comparison between the incidence of sequelae during the treatment period of acupuncture and moxibustion for Bell's palsy in the acute phase and non-acute phase

of Bell's palsy in the acute phase does not damage the facial nerve but helps shorten the treatment course and improve the cure rate (Zhang *et al.* 2019b). Li *et al.* (Li *et al.* 2011) conducted a large-sample, multicenter randomized controlled trial to evaluate the clinical efficacy of acupuncture and moxibustion in the elective treatment of peripheral facial paralysis, and selected the Houseand Brackman Facial Function GradingSystem (H-B) and the Facial Disability Index (FDI) as the observation indicators. The study found that the period of 1 to 3 weeks after onset was the optimal treatment time point for acupuncture interventional therapy for peripheral facial paralysis, that is, the acute and stationary phases. Besides, acupuncture with a simple filiform needle is recommended mainly in the acute phase, and shallow needling is better for facial acupoints. Simple acupuncture therapy is not recommended in the recovery phase, and moderate stimulation intensity should be given in combination with Zusanli. Qin *et al.*[24] selected 120 patients with peripheral facial paralysis within two days of onset as the study subjects. Acupuncture and moxibustion treatment started in the acute phase (after the onset), the stationary phase (8th day after the onset), and the recovery phase (16th day after the onset). All three groups were treated with western medicine, such as dexamethasone combined with TDP irradiation. The therapeutic effect of staged acupuncture and moxibustion was evaluated by the H-B scale and the modified Portmann scoring standard. The results suggested that the acute phase was the best time for acupuncture and moxibustion interventional therapy for peripheral facial paralysis.

This meta-analysis showed the cure rate of acupuncture and moxibustion for Bell's palsy in the acute phase was higher than that in the non-acute phase. The time to cure of acupuncture and moxibustion for Bell's palsy in the acute phase were shorter than that in the non-acute phase, and the incidence of sequelae during the treatment period of acupuncture and moxibustion for Bell's palsy in the acute phase was lower than that in non-acute phase. The results suggested that acupuncture and moxibustion was a safe and effective stimulation for Bell's palsy in the acute phase. Early acupuncture intervention with appropriate stimulation can reduce facial nerve edema and compression, avoiding further facial nerve injury. It has a positive impact on the course of the disease and prognosis.

Limitations of the present study: (1) In this study, although the main Chinese and English databases were searched in strict accordance with the preset search strategy, the included kinds of literature were all in Chinese, the trial location was in China, and the race of the study subjects was single. Therefore, the generality of the conclusions to the population may be lacking. (2) By definition and study design, the observation indicators are not comprehensive, especially there are few internationally accepted quantitative indicators, affecting the combined analysis of quantitative data. (3) Interventions are not uniform, especially in the acute phase of facial paralysis. Different protocols such as light stimulation (such as shallow needling) and heavy stimulation (such as electroacupuncture) were regarded as the same treatment protocol. (4) There are few high-quality randomized controlled studies, including the small number of subjects, the lack of description of random methods, allocation concealment, and follow-up implementation. (4) This study did not strictly limit the age, course of the disease, the severity of Bell's palsy, which will also cause a risk of bias in evaluating efficacy. Therefore, the results and conclusion should be used with caution.

CONCLUSIONS

Analysis of a limited body of low-quality evidence with a high risk of bias showed that the acupuncture and moxibustion was a safe and effective stimulation for Bell's palsy in the acute phase compared with the non-acute phase, which could improve the cure rate of Bell's palsy, shorten the time to cure, and reduce the occurrence of sequelae. Therefore, clinically, appropriate treatment methods should be selected according to the patient's specific condition. However, more multicenter RCTs with a large sample number and high quality should verify the conclusion mentioned above.

DECLARATIONS

Ethical approval: This meta-analysis was approved by the institutional review board, the need for informed patient consent for inclusion was waived.
Consent for publication: Not applicable.
Availability of data and material: The datasets used or analysed during the current study are available from the corresponding author on reasonable request.
Conflicts of interest: None.
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