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Comparison of Acupuncture and Sham Acupuncture in Migraine Treatment

An Overview of Systematic Reviews

Mao Li, MD, Weijun Wang, MD, Wen Gao, MD, and Dongdong Yang, MD

Background: Acupuncture is widely used for treating migraine; however, evidence of its efficacy when compared with sham acupuncture is equivocal. This study aimed to compare the evaluate efficacy of acupuncture versus sham acupuncture in migraine treatment.

Methods: We searched PubMed, the Cochrane Library, Web of Science, and EMBASE databases from their inception to April 25, 2021, for randomized controlled trials. The outcome measurement included response rate, migraine days, intensity, and frequency.

Results: Twenty randomized controlled trials involving 2725 patients were included. Pooled data suggested that acupuncture was superior to sham acupuncture [mean difference (MD) = −0.52, 95% confidence interval (CI): −0.71 to −0.34, $P < 0.00001$] in reducing the migraine frequency after treatment and follow-up (MD = −0.51, 95% CI: −0.70 to −0.32, $P < 0.00001$). In reducing Visual Analog Scale, acupuncture was superior to sham acupuncture (MD = −0.72, 95% CI: −1.17 to −0.27, $P = 0.002$) after treatment, and also superior to sham acupuncture (MD = −0.82, 95% CI: −1.31 to −0.33, $P = 0.001$) on the follow-up. As for responder rate, acupuncture's efficacy was better than sham acupuncture (relative risk = 1.28, 95% CI: 1.00-1.64, $P = 0.05$). However, the reduction of migraine days in the acupuncture group was not significantly different from that in the sham acupuncture group after treatment (MD = −0.62; 95% CI: −1.31 to 0.08; $P = 0.08$) and on the follow-up (MD = −0.68; 95% CI: −1.52 to 0.17; $P = 0.12$).

Conclusions: Acupuncture appears to be an effective treatment modality for migraine. Compared with sham acupuncture, acupuncture had greater improvements in migraine frequency, Visual Analog Scale, and responder rate, but there was no statistically significant difference for the number of migraine days.

Key Words: acupuncture, sham acupuncture, migraine, efficacy and safety, systematic review, meta-analysis

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Migraine is a common disabling primary headache disorder characterized by recurrent moderate to severe throbbing unilateral headache, which is often accompanied by photophobia, phonophobia, nausea, and vomiting. It affects around 1 billion people worldwide.[1] According to the epidemiological statistics, the prevalence of migraine is ~14.9% in the United States,[2] and 9.3% in China,[3] and it ranks as the sixth most disabling disease in the Global Burden of Diseases,[1] Moreover, migraine imposes an enormous financial burden on the sufferers, their families, and society. In Europe, the estimated annual costs of migraine treatment and management range from €18 to €111 billion, of which about 77% to 93% are attributable to reduced productivity.[4,5]

The major classes of medications for migraine treatment include nonsteroidal anti-inflammatory drugs, antiepileptic drugs, ergots, triptans, and anticalcitonin gene-related peptide monoclonal antibodies. However, these drugs may induce side effects and adverse events, such as gastrointestinal dysfunction and cardiovascular damage,[6,7] even though they could relieve migraine to some extent. Also, patients with chronic migraine who overuse symptomatic drugs persistently could greatly increase the risk of developing medication overuse headache.[8] Therefore, an increasing number of people suffering with migraine are seeking for complementary and alternative therapies that have fewer side effects and superior clinical efficacy to use in their daily lives.[9]

Acupuncture, a key component of Traditional Chinese Medicine originated > 2500 years ago, is widely used for managing migraine in China and some other countries.[10,11] Although some authors have suggested that acupuncture is superior to waiting-list control and similar to or probably more effective than preventive medication for migraine,[12,13] it has yielded controversial results. Therefore, it is currently difficult to determine whether acupuncture is superior to sham acupuncture. In view of that uncertainty and controversy about the efficacy of acupuncture compared with sham acupuncture for migraine, it is vital to perform a systematic review and meta-analysis to provide comprehensive, objective, and evidence-based information for clinicians and patients with migraine.

METHODS

Registration

A predetermined, written protocol of this overview was registered on the PROSPERO platform (www.crd.york.ac.uk/PROSPERO/) with an assigned number CRD42020196474. This overview was performed in accordance with the Cochrane Handbook for Systematic Reviews of Interventions and was reported in compliance with the PRISMA statement (PRISMA 2009 Checklist).

Inclusion Criteria

Types of Studies

To maintain rigorous objectivity, this systematic review and meta-analysis only included randomized control trials

(RCTs) published in English. Quasi-RCTs, cohort studies, and case reports were excluded. The follow-up time was not limited.

Types of Participants

Patients who fulfilled the diagnostic criteria for migraine were included, regardless of age, sex, race, duration of migraine, and migraine aura prevalence.

Types of Interventions

The experimental groups were treated with body acupuncture (including manual acupuncture, balance acupuncture, and electroacupuncture). Other types of acupuncture (eg, laser acupuncture, auricular acupuncture, scalp acupuncture, abdominal acupuncture, dry needling, sticking needling, acupuncture acupoint injecting, bloodletting acupuncture, acupuncture-like electrical stimulation) were excluded.

Types of Comparisons

The control groups were treated with sham acupuncture (minimal insertion into superficial areas with no verum, acupoints unrelated to headache, and the vicinity of elbow and knee joints).

Types of Outcomes

The included studies needed to report changes in at least 1 targeted outcome measurement, including response rate, headache days, headache intensity, or headache frequency.

Exclusion Criteria

Duplicate publications, conference abstracts, comments, narrative reviews, and other reviews were excluded. Studies that combined acupuncture with other adjuvant therapies as the intervention in the experimental group and studies in which the control groups were treated by Chinese herbal medicine or other Chinese patent medicine(s) or medications not recommended by the guideline were also excluded.

Search Strategy

We searched PubMed, the Cochrane Library, Web of Science, and EMBASE from their inception to April 25, 2021 for RCTs. We used the following keywords and MeSH terms: ((((sham acupuncture[MeSH Terms]) OR (sham acupuncture)) AND ((electroacupuncture) OR ((acupuncture[MeSH Terms]) OR ((Acupuncture therapy) OR (Acupuncture Treatment))))) AND ((Migraine[MeSH Terms]) OR ((Migraine Disorder) OR (Migraines) OR (Migraine Headache) OR (Migraine Headaches) OR (Disorder, Migraine)))) AND (((Clinical Trials, Randomized) OR (Trials, Randomized Clinical) OR (Controlled Clinical Trials, Randomized)) OR (randomized controlled trial[MeSH Terms])).

Researchers also searched conference abstracts, reference lists, and gray literature of all available records identified in the initial publications to avoid missing relevant RCTs. Incomplete but useful data for studies were obtained from the contact trial personnel for data synthesis.

Study Selection

The reference management software Endnote X9 was used to remove the duplicate records. Two reviewers (W.W. and W.G.) independently screened studies by reading titles and abstracts based upon the inclusion and exclusion criteria. After obtaining the full-text articles, the reviewers read them once again for thorough screening. If the information in the included articles was incomplete or difficult to be judged during the screening process, the reviewers sent emails to the author(s) to request further information. If it was difficult to receive a response from the original author, the articles that had missing information were excluded. The disagreements were resolved through discussion and arbitrated by a third reviewer (D.Y.).

Data Extraction

Two reviewers (W.W. and W.G.) independently extracted the data. We collected the following information using a standard form: title, author, publication year, country, sample size, age, diagnostic criteria, duration of migraine, intervention type, treatment and follow-up periods, outcome indicators, quality evaluation method, conclusion, and the risk of bias. Disagreements were resolved by the third reviewer (D.Y.).

Risk of Bias Assessment

Two reviewers (W.W. and W.G.) evaluated the quality of the included studies by using a risk-bias assessment tool provided by the Cochrane Collaboration[14] and made judgments of high risk, low risk, and unclear for each item. Disagreement during this procedure was resolved after discussion and consultation with the third researcher (D.Y.). Bias types included the following:

(1) Random sequence generation.
(2) Allocation concealment.
(3) Blinded of outcome assessment.
(4) Incomplete outcome data.
(5) Selective reporting of research results.
(6) Other sources of bias.

Statistical Analysis

Meta-analysis was performed using Cochrane systematic Review software (RevMan 5.3). Continuous data were presented as mean differences (MDs) with a 95% confidence interval (CI), and dichotomous data were presented as relative risk with a 95% CI. Statistical heterogeneity across trials was measured by the Cochrane Q test ($P < 0.1$ for statistical significance) and quantified by the I^2 statistic. An $I^2 < 50\%$ indicated that the interstudy heterogeneity was not statistically significant, in which case the fixed-effect model was adopted. When heterogeneity was high, we used the random-effects model or subgroup analysis to identify the potential sources or for sensitivity analysis. We used sensitivity analysis to enhance the credibility of the results by eliminating studies with a high risk of bias, studies with missing data, and outliers if needed.

Assessment of Reporting Bias

A funnel plot was generated to reveal reporting bias when > 10 trials were included in each meta-analysis.

RESULTS

Study Selection

Figure 1 shows a flow chart of the study selection process according to the PRISMA guideline. The initial search yielded 49 records. Of which, 4 records were removed for duplication. After screening the titles and abstracts, 45 were deemed to be potentially eligible. After reviewing the full text, 24 records were excluded (2 had patients who were not diagnosed as having migraine; 14 were review articles; 5 were conference papers, protocols, or other papers without valid data; 1 was a duplicate publication; and 2 were irrelevant). In total, 20 trials were included for the final analysis.

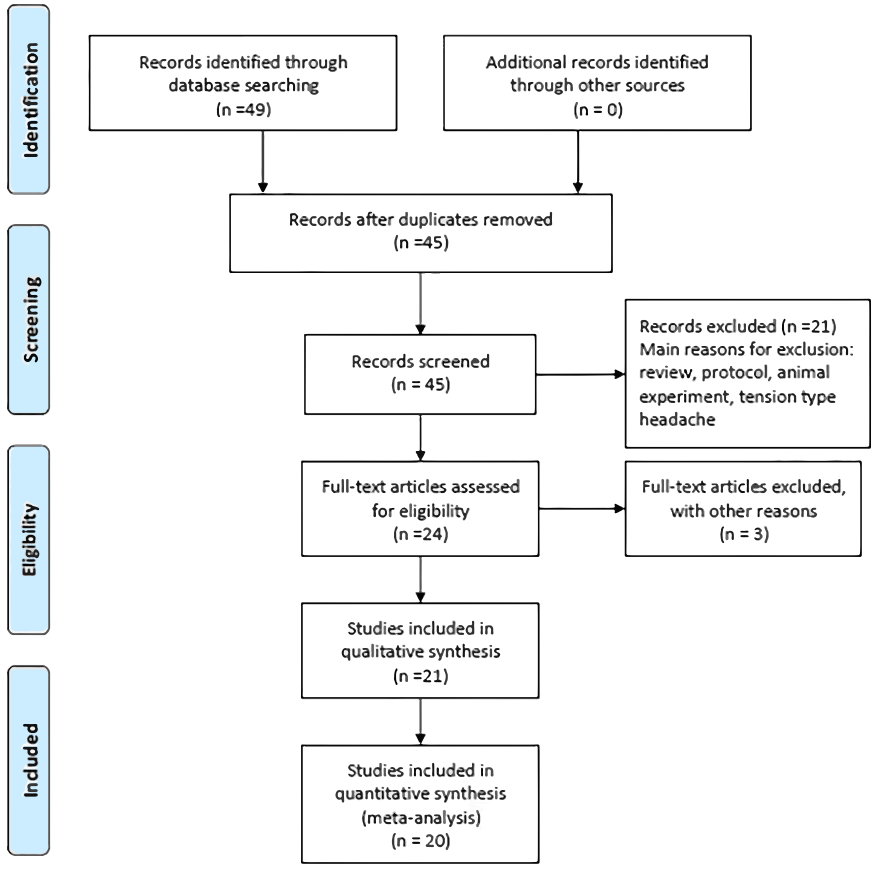

FIGURE 1. Flow chart of the literature search and study selection.

Study Characteristics

A total of 20 RCTs, including 2725 patients, fulfilled the inclusion criteria. All the studies were published between 1989 and 2020, and 7 of them came from multicenter investigations. The diagnostic criteria for the included studies followed the International Headache Society (IHS)[15–17] or the *International Classification of Diseases, 10th Revision* (ICD-10) guide for headaches[18] except for 2 unknown criteria.[19,20] Of the 20 studies, 10 were performed in China, 4 in Germany, 2 in Brazil, 1 in Italy, 1 in England, 1 in Sweden, and 1 in Iran. The mean age of the patients was between 30 and 43.8 years. Among the included studies, 18 trials were conducted with manual acupuncture, 1 with electrical stimulation, and 1 with balance acupuncture therapy. The main acupoints selected in the intervention groups were GB8 (*Shuaigu*), GB20 (*Fengchi*), EX-HN5 (*Taiyang*), LI4 (*Hegu*), GB40 (*Qiuxu*), GB34 (*Yanglingquan*), SJ5 (*Waiguan*). In most studies, the treatment time ranged from 4 to 20 weeks, and the follow-up time ranged from 4 weeks to 1 year, except for 2 studies on acute migraine. Also, the other 2 studies did not provide follow-up time. Characteristics of all the included studies are given in Table 1.

Risk of Bias Among Included Studies

Of the 20 included studies, researchers discovered 16 studies had a low risk of bias on randomization because they used appropriate randomization procedures (eg, computer-based number sequence, random number table, etc.); the remaining 4 only mentioned randomization, but they did not explain the specific methods.[19,33,34,36] Thirteen studies provided adequate details to enable a judgment of a low risk of bias for the concealment of allocation; the remaining 7 contained insufficient or no information, and they were decided to have an unclear risk of bias.[19,23,28,33–36] Seventeen studies described adequate blinding of participants and personnel; therefore, we considered these trials to have a low risk of bias. Of the remaining 3, 2 did not report details about their blinding methods, and so they were considered to have an unclear risk of bias.[28,34] One did not use blinding of participants and personnel, so it was considered to have a high risk of bias.[33] Seventeen studies described adequate blinding of outcome assessment; therefore, we considered these trials to have a low risk of bias. Two did not report on blinding outcome assessment, and so they were considered to have an unclear risk of bias.[28,34] One did not use blinding of outcome assessment. It was judged to have a high risk of bias.[33] Twenty studies reported attrition, but 3 studies data were incomplete and considered to have a high risk of bias.[33,35,36] The other one had an unclear risk of bias,[34] so 16 studies were judged as having a low risk of bias. Sixteen studies reported primary and secondary or important outcomes. They were deemed to have a low risk of bias of selective reporting. The remaining 4 did not report important outcomes.[19,21,28,33] Two studies were found to have other sources of bias because they had significant baseline imbalances,[32,24] and another 2 studies may also have other sources of bias. So, researchers considered them to have an unclear risk of bias.[34,35] The overall risk of bias for all the 20 included trials is presented graphically in Figure 2. Summary details for each trial are illustrated in Figure 3.

TABLE 1. Characteristics of Included Studies

References	Country	Patients (A/SA)	Mean Age (y) (A/SA)	Diagnostic Criteria	Duration of Treatment	Follow-up	Primary Outcome	Conclusion
Vincent[19]	England	16/16	36/38	NR	6 wk	54 wk	Pain score, medication intake	A > SA
Foroughipour et al[21]	Iran	50/50	35.8/37.2	IHS	4 wk	12 wk	Migraine frequency	A > SA
Li et al[22]	China	358/118	36.7/37.5	IHS	4 wk	12 wk	Migraine days	A > SA
Linde et al[23]	Germany	145/81	43.3/41.3	IHS	8 wk	16 wk	Migraine days	A = SA
Alecrim-Andrade et al[24]	Brazil	19/17	36.7/33.2	IHS	12 wk	24 wk	Response rate	A = SA
Diener et al[20]	Germany	290/317	37.1/38.3	NR	6 wk	20 wk	Migraine days	A = SA
Wang et al[25]	China	75/75	37.8/38.6	IHS	30 min	72 h	VAS	A > SA
Xu et al[26]	China	60/60	36.6/36.0	IHS	8 wk	12 wk	Migraine days, migraine frequency	A > SA
Linde et al[27]	Sweden	15/13	35.2/37.4	IHS	12 wk	24 wk	Attack frequency	A = SA
Zhao et al[10]	China	83/80	36.4/39.1	IHS	4 wk	20 wk	Migraine frequency	A = SA
Facco et al[28]	Italy	40/80	35.2/37.4	ICD-10	6 wk	18 wk	MIDAS	A > SA
Wang et al[29]	China	19/19	30/31	IHS	4 wk	4 wk	Comprehensive score, VAS	A > SA
Wang et al[30]	China	26/24	41.6/43.8	IHS	20 wk	54 wk	Frequency duration, intensity	A > SA
Li et al[31]	China	58/117	33/36	IHS	1 session	24 h	VAS	A > SA
Alecrim-Andrade et al[32]	Brazil	14/14	32.5/39.1	IHS	12 wk	24 wk	Response rate	A = SA
Liu et al[33]	China	116/80	22.8	IHS	8 wk	4 wk	GM volume	A = SA
Li et al[34]	China	35/11	21.5/21.2	IHS	4 wk	0 wk	VAS, frequency	A > SA
Backer et al[35]	Germany	9/10	43.5	IHS	8 wk	4 wk	Response rate	A > SA
Wallasch et al[36]	Germany	18/17	37.2/39.3	IHS	8 wk	24 wk	TCD, migraine days	A > SA
Zhao et al[37]	China	40/40	33.3/33.2	IHS	8 wk	0 wk	VAS	A > SA

A indicates acupuncture; GM, gray matter; ICD-10, *International Classification of Diseases, 10th Revision* ; IHS, International Headache Society; MIDAS, Migraine Disability Assessment Scale; NR, not report; SA, sham acupuncture; TCD, transcranial Doppler sonography; VAS, Visual Analog Scale.

Effects of Interventions

Migraine Frequency

Of the 20 included studies, 9 studies (n = 1038) evaluated migraine frequency of acupuncture versus sham acupuncture after treatment,[10,21–23,26,27,29,34,37] and the meta-analysis showed that acupuncture was superior to sham acupuncture in reducing the migraine frequency (MD = −0.52, 95% CI: −0.71 to −0.34, $P < 0.00001$; Fig. 4). Meanwhile, 8 studies (n = 931) showed the outcomes of follow-up and indicated that acupuncture was significantly superior to sham acupuncture (MD = −0.51, 95% CI: −0.70 to −0.32, $P < 0.00001$; Fig. 4).[10,21–23,26,27,29,35]

Visual Analog Scale (VAS)

Nine studies (n = 907) reported VAS after treatment, which showed that acupuncture was superior to sham acupuncture in reducing VAS (MD = −0.72, 95% CI: − 1.17 to −0.27, $P = 0.002$; Fig. 5).[10,22,23,25,29–31,34,37] Six studies (n = 721) showed the outcomes of follow-up, and they indicated that acupuncture was more effective than sham acupuncture in reducing VAS (MD = −0.82, 95% CI: −1.31 to −0.33, $P = 0.001$; Fig. 5).[10,22,26,29–31]

Migraine Days

Eight studies, including 1320 participants, reported migraine days as an outcome in the comparison between acupuncture and

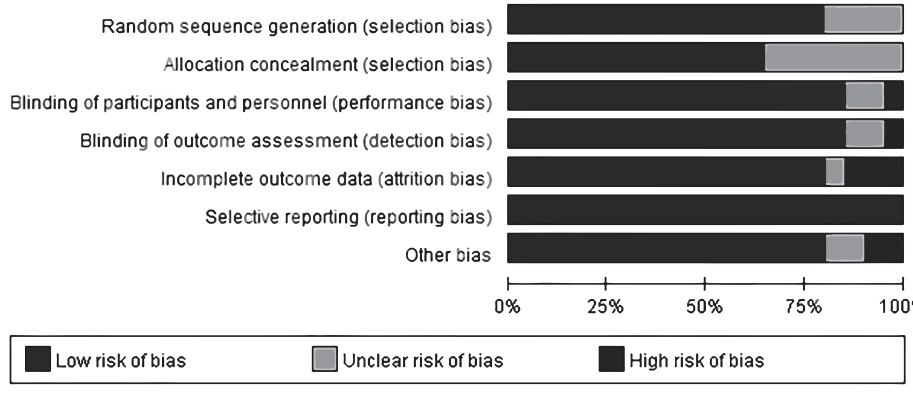

FIGURE 2. Quality assessment of the included trials—risk of bias graph.

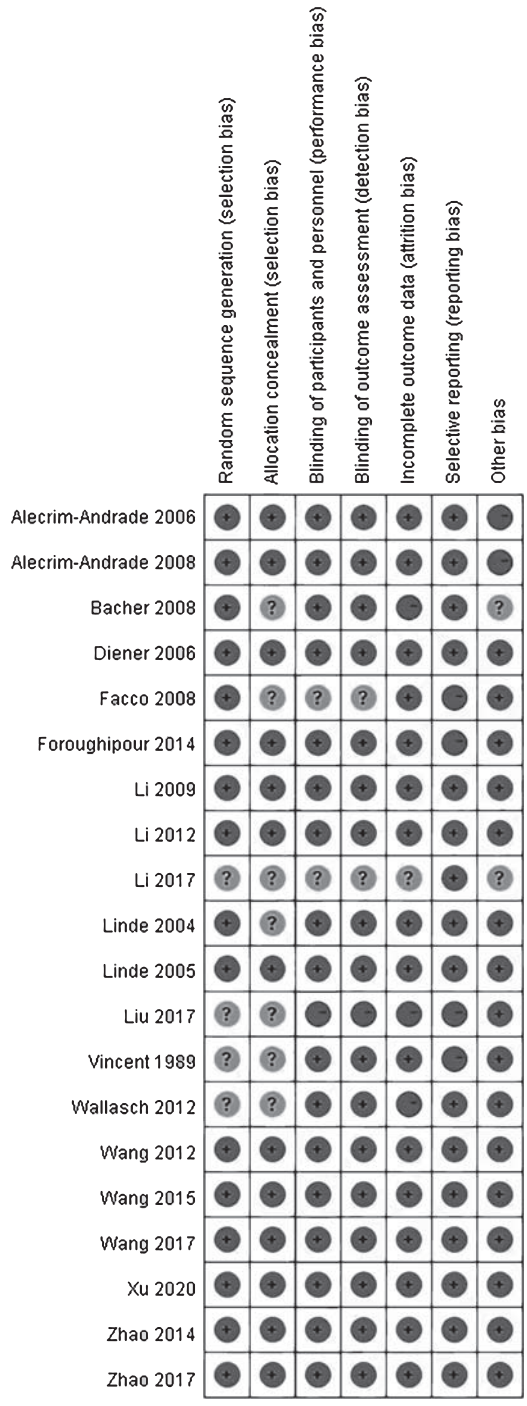

FIGURE 3. Quality assessment of included trials—risk of bias.

sham acupuncture after treatment.[10,20,22,23,26,30,36,37] Pooled analysis showed that the reduction of migraine days in the acupuncture group was not significantly different from that in the sham acupuncture group after treatment (MD = −0.62; 95% CI: −1.31 to 0.08; $P = 0.08$; Fig. 6). Seven studies, including 1227 participants, showed that there was no statistically significant difference for the number of migraine days between acupuncture and sham acupuncture groups on the follow-up (MD = −0.68; 95% CI: −1.52 to 0.17; $P = 0.12$; Fig. 6).[10,20,23,26,27,30,36]

Responder Rate

Data from 7 studies (n = 1084) were available for the analysis of responder rate.[20,24,26,27,30,32,35] They indicated that acupuncture was superior to sham acupuncture on responder rate (relative risk = 1.28, 95% CI: 1.00-1.64, $P = 0.05$; Fig. 7).

Medication Use

Nine studies with 1277 participants reported the medication usage for migraine during treatment and follow-up. Four studies[20,24,27,32] showed no differences between acupuncture and sham acupuncture, and 5 studies[19,23,25,28,30] showed that the dosage of medication in the acupuncture group was less than that in the sham acupuncture group. However, because different studies used different methods to evaluate medication use, forest plot analysis is not applicable.

Adverse Events

Thirteen studies including 2159 participants reported the occurrence of adverse events during the trial process in acupuncture and sham acupuncture groups. But none of the groups' adverse events were serious. The common adverse events ranged from mild to moderate in severity. These included: bruising, subcutaneous hematoma, tingling sensation and pain, fatigue, leg weakness, and vertigo. These symptoms dissipated quickly after treatment. The ratio of patients adverse events ranged from 4%[25] to 25%[27] among the acupuncture groups and 0%[26] to 24%[20] in the sham groups.

DISCUSSION

The results of this meta-analysis suggest that acupuncture had greater effects in reducing the frequency of migraine attacks, intensity, and responder rate when compared with sham acupuncture. However, there was no significant difference in the number of migraine days between acupuncture and sham acupuncture group. The adverse events in the 2 groups were not serious. Although these findings indicate that acupuncture treatment was superior to sham acupuncture, the interstudy heterogeneity was too great to draw a definitive conclusion. Previously, some meta-analyses have already mentioned the superiority of acupuncture therapy over nonacupuncture treatments,[38–40] but they did not confirm whether that same superiority existed over sham acupuncture. Maybe our study has some advantages in this regard. In this meta-analysis, we found evidence to support that the use of acupuncture may be of greater benefit to migraine patients than sham acupuncture.

We implemented a meticulous search strategy and a rigorous procedure to identify and analyze all relevant peer-reviewed articles from multiple medical databases, thereby improving the credibility of this study. We also contacted authors of potentially eligible studies to obtain either dichotomous or continuous data; moreover, the internationally recognized measurement tools for pain intensity, frequency of headache attack, migraine days, and responder rate were selected as the main outcome indicators. These indicators were more objective for evaluating the degree of pain and relief. Because significant heterogeneity was observed between studies, we pooled the data with a random-effect model to minimize the possibility of treatment effects being overestimated. We should have used subgroup analysis to evaluate the effect of acupuncture versus sham acupuncture. But because we did not identify enough data to create a subgroup, we failed to perform this analysis.

Acupuncture is not simply considered as a psychological or "placebo" mechanism. On the contrary, based on the meridian theory of traditional Chinese medicine, acupuncture has a

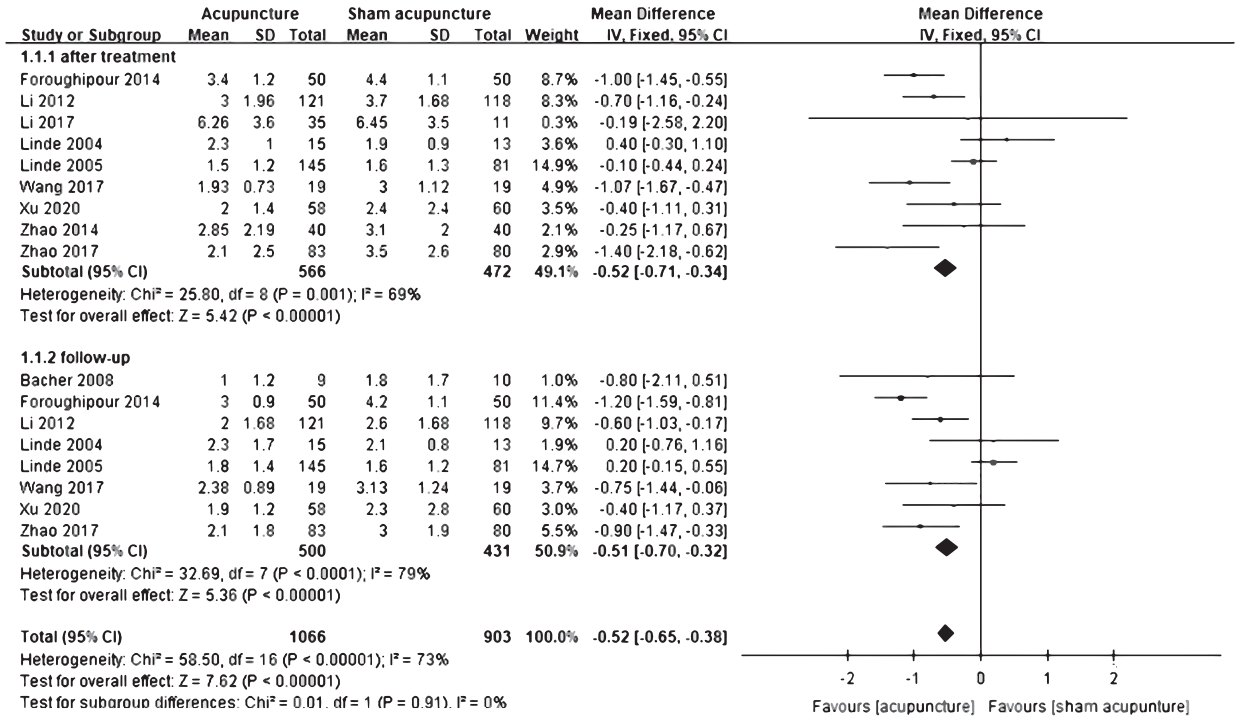

FIGURE 4. Forest plots of migraine frequency of acupuncture versus sham acupuncture after treatment and follow-up. CI indicates confidence interval; IV, interval variable.

definite degree of efficacy. The key to the curative effect of acupuncture is to select and act on meridians and acupoints, so as to produce a relatively definitive therapeutic effect, which is also called the specific effect of acupuncture. When a needle inserts into a meridian point, it can elicit a sensation called *de qi* and therefore has a therapeutic effect.[10] However, sham acupuncture cannot elicit the *de qi* sensation.[41] This could explain why acupuncture is better than sham acupuncture. In clinical practice, patients with migraine or headache account for a large proportion of populations treated with acupuncture for pain

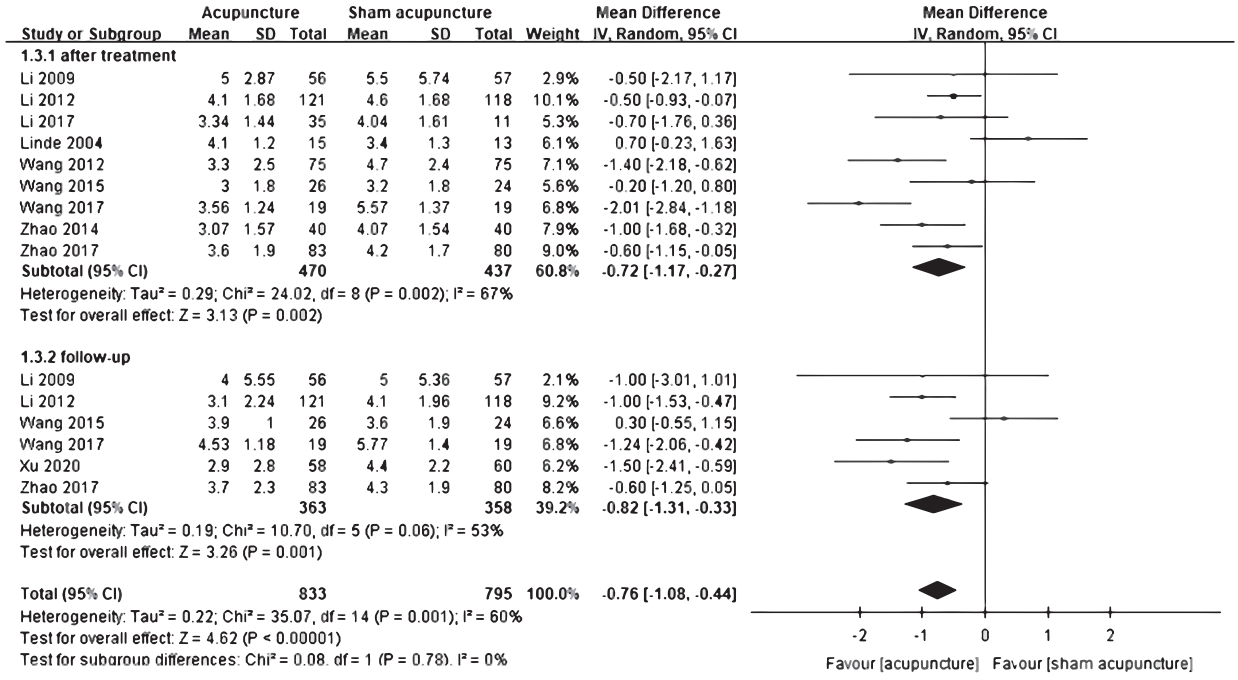

FIGURE 5. Forest plots of migraine Visual Analog Scale score of acupuncture versus sham acupuncture after treatment and follow-up. CI indicates confidence interval; IV, interval variable.

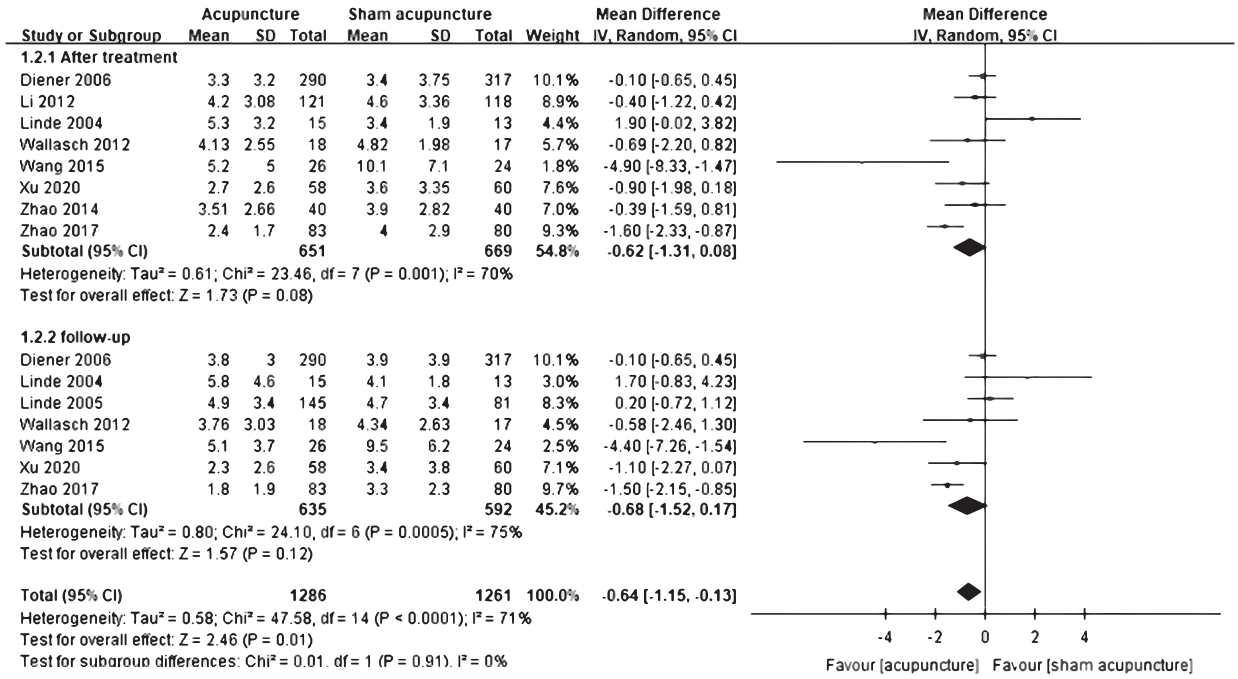

FIGURE 6. Forest plots of migraine days of acupuncture versus sham acupuncture after treatment and follow-up. CI indicates confidence interval; IV, interval variable.

management, and many patients are willing to receive acupuncture treatment.[42,43] In recent years, a series of scientific evaluations have been conducted on the efficacy and safety of acupuncture in treating migraine.[10,26] Currently, increasingly more evidence supports the use of acupuncture in migraine patients.[44,45] Although a number of previous systematic reviews have confirmed the clinical efficacy and safety of acupuncture for migraine, evaluations focusing only on acupuncture versus sham acupuncture are rare. In this review, the findings indicated that acupuncture was superior to sham acupuncture for migraine treatment. Therefore, when discussing an alternative treatment strategy with patients, maybe clinicians can provide them with information about acupuncture as a viable option.

There are several limitations to this systematic review and meta-analysis. First, although the quality of most of the included studies was relatively high, due to the objective limitations of the included sample size, potential biases might influence the reliability of the overall conclusions. Second, due to the particularity of acupuncture, it is difficult to implement methods of blinding in the comparison of acupuncture and sham acupuncture, so it might cause a potential risk of bias that reduce the quality of evidence. Third, acupuncture treatment varied widely in duration and in the selected acupuncture points, which may also have caused a risk of bias. In addition, all of the included studies were published in English, and some studies published in other languages were excluded, therefore publication bias might be inevitable.

CONCLUSIONS

Acupuncture appears to be an effective treatment modality for migraine. Compared with sham acupuncture, acupuncture had led to greater improvements in the frequency of migraine attacks, VAS, and responder rate. However, there was no statistically significant difference in migraine days between acupuncture and sham acupuncture. The adverse events in the 2 groups were not serious. Based on the current findings, future studies should aim to further evaluate the effect of acupuncture in large-scale, multicenter, and well-designed RCTs with a longer intervention period.

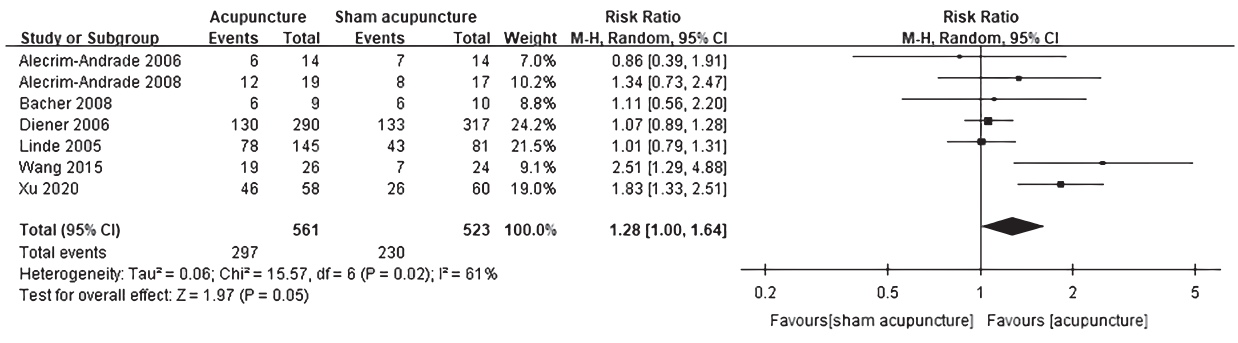

FIGURE 7. Forest plots of migraine responder rate of acupuncture versus sham acupuncture after treatment and follow-up. CI indicates confidence interval; M-H, Mantel-Haenszel.

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