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REVIEW

Clinical Efficacy and Safety of Auricular Acupuncture for Migraine: A Systematic Review and Meta-Analysis of Randomized Controlled Trials

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Background: Migraine is a prevalent and debilitating neurological disorder that results in significant disability and imposes a substantial socioeconomic burden. Auricular Acupuncture (AA) has emerged as a potential therapeutic intervention for alleviating migraine symptoms. Although AA is extensively utilized clinically to treat migraines, a reanalysis investigating its benefits and risks, whose studies were conducted exclusively in China, indicated that notable enhancements in four outcomes relative to controls were achieved by AA.

Methods: We conducted a systematic review and meta-analysis of Randomized Controlled Trials (RCTs) to evaluate the efficacy and safety of AA for migraine. Eight databases were searched from inception to April 18, 2025. Sensitivity and subgroup analyses were performed to evaluate the robustness of the findings and to identify potential sources of heterogeneity. All results were assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) framework. Data analyses were conducted using Review Manager 5.4.

Results: Specifically, the visual analog scale (VAS) showed a mean difference (MD) of −0.65 (95% Confidence Intervals (CI): −0.86, −0.43; p<0.001) in ten RCTs involving 766 participants were included. Additionally, migraine attack frequency demonstrated an MD of −0.49 (95% CI: −0.59, −0.40; p<0.001) and attack duration had an MD of −0.58 (95% CI: −0.64, −0.52; p<0.001). The clinical effectiveness rate (CER) was reflected in a relative risk of 1.17 (95% CI: 1.10, 1.25; p<0.001).

Conclusion: Research evidence indicates that AA offers both efficacy and safety in the treatment of migraines. However, inferences resulting from this investigation face constraints arising from the methodological robustness of trials incorporated herein. To better define the role of AA in clinical guidelines, additional high-quality RCTs with expanded scope of population, standardized protocols and extended follow-up periods are required.

Systematic Review Registration: https://www.crd.york.ac.uk/PROSPERO/view/CRD420251028201.

Keywords: auricular acupuncture, migraine, meta-analysis, systematic review, randomized controlled trials

Introduction

Migraine is a neurological condition that significantly impacts individuals, marked by recurring, moderate-to-severe, one-sided pulsating headaches, frequently associated with symptoms such as nausea, sensitivity to light, and cognitive dysfunction.[1] Its pathogenesis involves complex interactions among genetic predispositions, environmental triggers, and endogenous regulatory mechanisms.[2–4] Migraine affects about 1.04 billion people worldwide, accounting for 14% of the global population. Studies spanning 1990 to 2019 document that South Asia exhibits the greatest migraine prevalence, reporting 154,490,169.8 cases. Additionally, for individuals globally between 15 and 49 years old, migraine constitutes the primary cause of disability burden.[5–7] As the second most significant contributor to global disability, migraine significantly affects socioeconomic factors, including reduced work productivity and higher healthcare costs.[8–12]

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Current pharmacological management relies primarily on acute and preventive therapies. According to the guidelines,[13] acute treatments include nonsteroidal anti-inflammatory drugs (NSAIDs; eg, ibuprofen, naproxen, diclofenac), acetaminophen, and triptans (eg, sumatriptan), which remain first-line for mild-to-severe attacks depending on response. Ergot derivatives (eg, dihydroergotamine), antiemetics (eg, metoclopramide, chlorpromazine), and combination regimens (eg, triptan plus NSAID) are also utilized in selected cases. Preventive therapies encompass beta-blockers (eg, propranolol, metoprolol), calcium channel blockers (eg, flunarizine, verapamil), antiepileptic drugs (eg, topiramate, valproate), and tricyclic antidepressants (eg, amitriptyline), as well as newer agents targeting the calcitonin gene-related peptide (CGRP) pathway. Despite the availability of these diverse classes, chronic use may lead to medication-overuse headaches, dependence, or adverse effects (eg, gastrointestinal disturbances), while substantial proportion of patients report inadequate symptom control.[14–18] These challenges underscore the need for safer, more tolerable therapeutic alternatives.

Traditional Chinese Medicine (TCM) employs auricular acupuncture (AA) as an extensively utilized non-pharmacologic clinical intervention. When specific auricular points like Shenmen and Subcortical receive stimulation, AA induces modulation in serotonergic pathways along with endogenous opioid systems, thereby interrupting transmission of pain signals.[19,20] Its simplicity, cost-effectiveness, and favorable safety profile have driven increasing clinical adoption for migraine management.

Previous medical guidelines have examined the potential benefits of AA for migraine, with reported positive outcomes.[21] Despite this, the effectiveness of AA in migraine treatment remains debated. Meta-analysis, regarded as the highest form of evidence, offers a stronger basis for drawing conclusions. Thus, this study employed meta-analysis to assess both the efficacy and safety of AA in treating migraine, with the aim of providing robust evidence for this promising therapeutic approach.

Methods

The guidelines presented in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA)[22] were followed in this study. The detailed information were referred to Supplement 1. Additionally, the protocol was registered earlier on PROSEPERO (ID: CRD420251028201).

Search Strategy

We conducted a search across eight databases from their inception up to 18 April 2025 for RCTs assessing AA in the treatment of migraine. The databases searched included China National Knowledge Infrastructure, VIP Chinese Science and Technique Journals, Cochrane Library, Web of Science, PubMed, Embase, and Wanfang. A mix of Medical Subject Headings (MeSH) terms and free-text keywords was used, covering concepts such as "auriculotherapy", "auricular acupuncture", "acupuncture therapy", "migraine", "hemicrania", "migraine disorder", "randomized controlled trial", and "randomized clinical trial". The search strategy prioritized comprehensive retrieval of clinical evidence while maintaining specificity to the intervention and condition of interest. Full details of the search parameters, including database-specific syntax and filtering criteria, were provided in Supplement 2.

Inclusion and Exclusion Criteria

The studies eligible for inclusion had to meet the following criteria: (I) Study Type: Only RCTs that assessed the effectiveness of AA in treating migraine were considered. These studies must be clinical in nature. (II) Participant Criteria: No restrictions were applied regarding gender, age, ethnicity, or source of cases. Furthermore, a clear and consistent migraine diagnosis was required. (III) Interventions: Participants in the treatment group were required to receive AA either as the sole therapy or combined with other treatments. In contrast, the control group was restricted to alternative therapies, with AA being the only variable evaluated in the study. (IV) Outcomes: At least one of the following measures must be included: visual analog scale (VAS), frequency and duration of migraine attacks, or clinical effectiveness rate (CER).

Studies were excluded based on the following criteria: duplicate publications, unavailable full-text literature, conference abstracts, review articles, and studies involving animals.

Outcomes

Regarding primary outcomes, CER functions as a continuous variable reflecting significant alteration and constitutes treatment response. Based on amelioration extent in clinical symptoms along with functional activities, clinical efficacy is classified into curative, markedly effective, effective, and ineffective categories as follows: (I) Curative: Complete resolution of headache symptoms. (II) Markedly Effective: Headache intensity reduced by ≥50%, or headache attacks reduced to ≤2 episodes per month. (III) Effective: Headache intensity reduced by <50% but ≥20%, or headache frequency reduced. (IV) Ineffective: Improvement below the thresholds for "Effective".

Concerning secondary outcomes, principal quantification contained critical indices including frequency of migraine attacks (the number of migraine days per month), duration per occurrence (the typical untreated headache lasting 4 to 72 hours), VAS (a frequently utilized instrument assessing pain intensity across a 0–10 scale), alongside incidence of adverse events, among additional parameters.[1]

Data Extraction

Upon importing the collected literature into EndNote, two investigators independently performed initial screening of titles and abstracts according to predefined inclusion and exclusion criteria. Subsequently, a secondary screening was conducted through full-text evaluation. In cases of discordance, rulings were finalized by an additional arbiter. From the included RCTs, data extraction was independently executed by two assessors, covering core aspects: authorship and publication year (constituting study characteristics), subject age and sex, sample magnitude, therapy duration, implemented interventions, outcome indicators, as well as follow-up data combined with adverse incidents. To ensure transparent and comprehensible reporting, a PRISMA flow diagram was employed for complete procedural documentation.

Quality Assessment

Utilizing the Cochrane Collaboration's designated instrument RoB2[23,24] encompassing five domains, bias risk evaluation for RCTs was independently performed by two assessors. Divergent judgments occurring during appraisal were adjudicated through consultation with an additional investigator. Application of the Grading of Recommendations Assessment, Development and Evaluation framework (GRADE)[25] facilitated quality assessment of evidence within this investigation via its recommended hierarchical approach.

Statistical Analysis

Meta-analysis procedures were executed employing Review Manager software version 5.4. At the preliminary stage, heterogeneity assessments were conducted for all investigations. Should I^2 values reach ≤50% concurrently with $P > 0.1$, this denotes non-significant statistical heterogeneity across included studies, permitting fixed effects model implementation; conversely, instances where $I^2 > 50\%$ alongside $P < 0.1$ suggest marked heterogeneity within the investigations, mandating random effects model adoption. Under these circumstances, either sequential elimination of individual articles enabled sensitivity analysis, or subgroup examination was undertaken to determine heterogeneity origins. Continuous variable analysis applied MD. Computation of RRs occurred for dichotomous outcomes, including derivation of corresponding 95% CIs. Results exhibiting P-values inferior to 0.05 were regarded as statistically significant. Furthermore, assessment of publication bias via funnel plots was initiated when subgroup investigation counts surpassed ten.

All forest plots and funnel plots were generated using RevMan 5.4 and no manual alterations were made to data representations. Original RevMan output files will be provided if necessary.

Results

Study Selection

Initial literature retrieval yielded 928 studies of potential relevance. Subsequent elimination of duplicated records retained 427 publications. Proceeding with scrutiny of titles and abstracts, exclusion of investigations failing to meet preset inclusion/exclusion criteria permitted selection of[26] 7 articles for deeper assessment. This screening cascade

culminated in the ultimate inclusion of 10 studies. Both procedural methodology and screening outcomes are comprehensively delineated within Supplement 3.

Characteristics of the Included Studies

Within the 10 incorporated investigations, temporal coverage exhibited publication dates, ranging from 2009 through 2021, highlighting a pronounced maximum of four published reports during 2021. Each study was conducted exclusively in China, collectively enrolling 766 research subjects. Accessible demographic records indicated an age spectrum extending from 31 to 56 years among recruited patients, with mean values computed as 43.97 years for interventional arms and 40.99 years among comparator cohorts. The interventions evaluated in these studies centered on AA, including auricular bean pressing (a method applying seeds or magnetic beads to ear acupoints for sustained stimulation,[27] otopoint needle embedding (the insertion of intradermal needles into ear points, retained for days to provide continuous stimulation),[28] auricular needle implantation in the fronto-temporal-occipital region (a specialized penetrating needling technique across specific ear zones),[29] and auricular tip bleeding (pricking the ear apex to release a small amount of blood for therapeutic purposes).[30] Among the included studies, four studies[31–34] employed auricular bean pressing as the primary treatment modality. Outcomes varied across the included trials: six articles[32,35–39] reported VAS, six studies[29,31,34,36–38] documented the frequency of migraine attacks, five studies[29,31,33,34,36] assessed the duration of migraine episodes, and nine studies[29,31–37,39] provided data on CER (with one study omitting this metric). The main characteristics of the included studies are summarized in Table 1.

Risk of Bias Assessment

The quality assessment of the 64 studies was performed using RoB2. Seven trials[31–33,35–37,39] were categorized under "some concern" based on the "Randomization process" domain, while three trials[29,34,38] were classified as "low risk". (I) Randomization process: Among the 10 studies, 7 trials[29,32,34–36,38,39] used the random number table method, 1 trail[37] employed the odd-even number method, and the remaining 2 trials[31,33] did not specify the exact randomization method. As for the allocation concealment methods, 2 trials[31,35] mentioned that they were used opaque envelopes, and 1 trail[29] employed random envelopes and random numbers. The remaining studies did not describe the allocation concealment methods. (II) Deviations from intended interventions: 1 trail[38] adopted triple-blind measures, meaning that neither the participants, the researchers, nor the data analysts knew the groupings. The remaining trials did not mention the specific procedures for blinding. (III) Missing outcome data: The data integrity of the results from all 10 trials was complete, 3 of which trials[29,34,38] clearly reported the data on participant withdrawals and the reasons for them. (IV) Measurement of the outcome: None of these trials mentioned whether the measurement of the outcome was affected. (V) Selection of the reported result: 10 trials did not have selective reporting bias. The results of bias for all included studies are shown in Figure 1A and B.

Meta-Analysis

VAS

A total of six investigations[32,35–39] involving 502 participants documented VAS outcomes. Heterogeneity assessments performed on all eligible studies indicated substantial homogeneity across this collection (P =0.24, I^2=26%). Subsequently, a fixed-effects framework was selected to conduct the meta-analysis. The results demonstrated significantly reduced VAS values in the treatment group versus the control cohort, evidenced by an MD of −0.65 (95% confidence interval: [−0.86, −0.43]; p<0.001; Figure 2).

Frequency of Migraine Attacks

Six clinical trials[29,31,34,36–38] comprising 502 participants documented frequency of migraine attacks measurements. Heterogeneity assessment across all eligible investigations confirmed substantial inter-study consistency (P =0.11, I^2=45%). Consequently, a fixed-effects analytical framework was implemented. Pooled data analysis established that migraine attack frequency was significantly diminished in the therapeutic cohort versus controls (mean difference=−0.49, 95% confidence interval: [−0.59, −0.40]; p<0.001; Figure 3).

Table 1 Basic Characteristics of the Included Studies

Study	Age (y)		Gender (M/F)		Sample Size		Interventions		Duration	Outcomes	Follow-Up	Side Effects	
	T	C	T	C	T	C	T	C				T	C
Yang, 2024[35]	31.61±6.35	30.78±8.85	14/27	16/24	42	42	A+H	H	4 weeks	①,④	No	NR	NR
Li, 2022[31]	33.54±5.46	33.67±5.29	18/12	16/14	30	30	B+H	H	4 weeks	②,③,④	No	NR	NR
Liu, 2021[36]	49.17±9.43	50.66±8.95	10/20	12/17	31	31	A+G	G	4 weeks	①,②,③,④	No	NR	NR
Tu, 2021[32]	55.58±10.88	55.64±10.92	6/24	9/21	30	30	B+H	H	10 days	①,④	No	NR	NR
Tang, 2021[37]	48.1±3.7	47.2±3.6	32/42	30/44	74	74	C	H	16 weeks	①,②,④	Yes	NR	NR
Li, 2012[33]	43.2±5.9	39.7±7.6	9/21	10/20	30	30	B+H	H	10 days	③,④	No	NR	NR
Yi, 2021[34]	44.97±14.14	43.67±14.25	7/23	8/22	30	30	B+H	H	4 weeks	②,③,④	Yes	NR	NR
Qi, 2019[38]	46.33±12.35	42.64±11.63	8/32	15/25	40	40	C	D	16 weeks	①,②	No	NR	NR
Wang, 2017[39]	36.0±10.5	34.0±9.25	8/22	11/19	30	30	F+G	G	6 days	①,④	Yes	NR	NR
Zheng, 2009[29]	32.5±20.5	36.0±20.25	14/32	9/37	46	46	E	H	4 weeks	②,③,④	Yes	0	7

Notes: T: Treatment group. C: Control group. A, auricular acupuncture; B, auricular bean pressing; C, otopoint needle embedding; D, shamotopoint needle embedding; E, auricular needle implantation in the fronto-temporal-occipital region; F, auricular tip bleeding; G, conventional acupuncture; H, medicine; ① Visual analog scale; ② frequency of migraine; ③ duration of migraine; ④ Clinical effectiveness rate.

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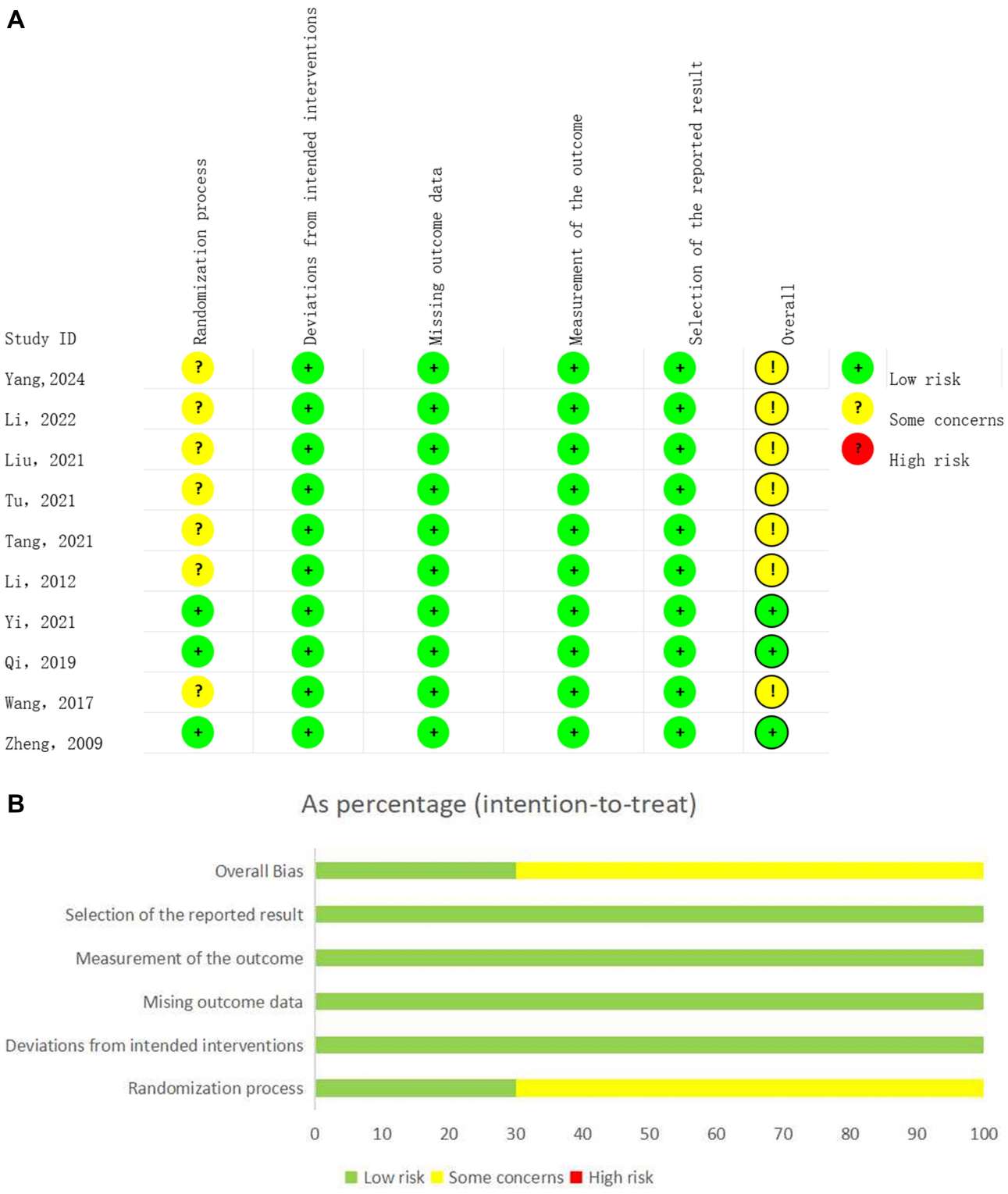

Figure 1 (**A**) The risks of bias in individual studies. (**B**) The risks of bias a summary.

Duration of Migraine Attacks

Five clinical investigations[29,31,33,34,36] comprising 334 subjects documented duration of migraine attacks data. Heterogeneity assessment across all eligible studies indicated sufficient inter-study consistency (P =0.37, I^2=7%). Consequently, a fixed-

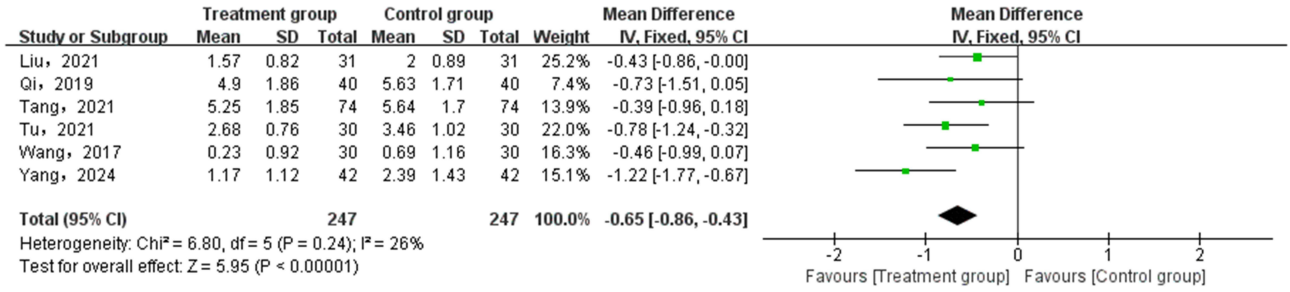

Figure 2 Forest plot for Visual Analogue Scale (VAS).

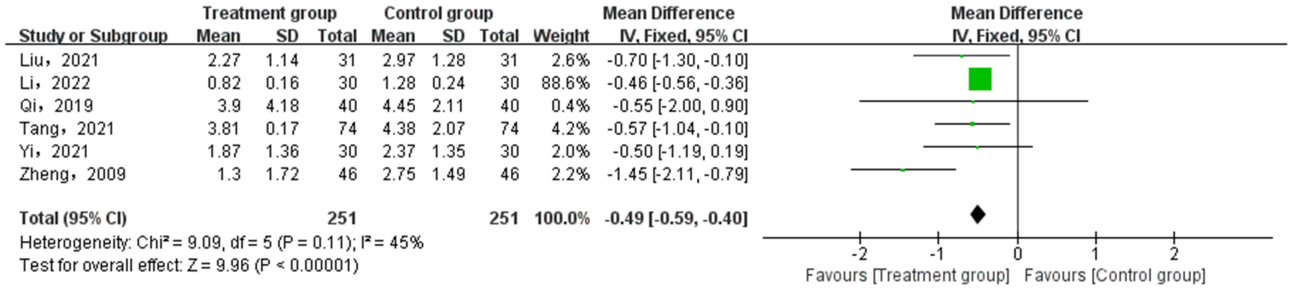

Figure 3 Forest plot for frequency of migraine attacks.

effects analytical framework was implemented. Pooled results demonstrated significantly reduced migraine attack duration in the therapeutic cohort versus controls (mean difference=−0.58; 95% CI: [−0.64, −0.52]; p<0.001; Figure 4).

CER

A set of nine investigations[29,31–37,39] comprising 686 participants documented CER outcomes. Heterogeneity evaluations across eligible trials revealed substantial inter-study consistency (P =0.64, I^2=0%). Consequently, a fixed-effects analytical approach was adopted. Collective findings demonstrated the therapeutic cohort's significantly elevated overall clinical response rate versus controls (RR=1.17; 95% confidence interval: 1.10 to 1.25; p<0.001; Figure 5).

Certainty of Evidence

The GRADE methodology was employed to evaluate evidence quality levels for all outcome measures. Outcomes encompassing VAS, migraine attack frequency/duration, and CER each received moderate ratings. Evidence downgrading resulted from identified biases in randomization, allocation concealment, and blinding affecting included investigations. Comprehensive details of this assessment process are provided in Supplement 4.

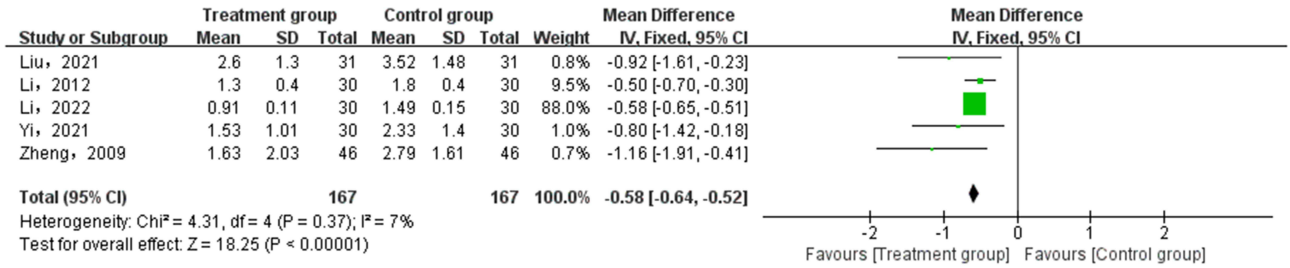

Figure 4 Forest plot for duration of migraine attacks.

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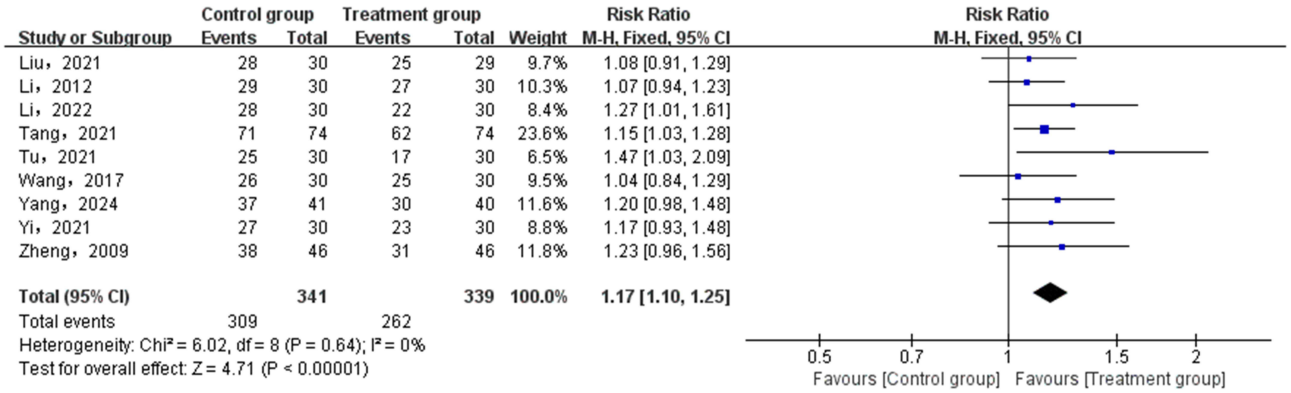

Figure 5 Forest plot for clinical effectiveness rate (CER).

Publication Bias

Due to the inclusion of only a small number of RCTs (specifically fewer than 10) for all outcomes in this analysis, the assessment of publication bias was not feasible.

Adverse Events

Within the ten incorporated investigational trials, solely one research[29] documented adverse events confined to the control cohort. Predominant reactions comprised dizziness and nausea, recognized as typical manifestations. Crucially, investigations universally failed to report AA-related severe adverse outcomes, exemplified by organ impairment, major infections demanding intravenous antibiotics or inpatient care, and irreversible functional loss. However, the granularity of adverse event documentation proved uniformly inadequate. Most investigations exhibited deficiencies in systematic collection and recording protocols, coupled with characteristically abbreviated follow-up durations.

Discussion

Summary of Findings

The results of this meta-analysis, which synthesized data from 10 RCTs involving 766 participants with migraine, suggest that AA is associated with a higher therapeutic efficiency and was evaluated as an adjunct to standard pharmacotherapy. Compared to control interventions, AA demonstrated statistically significant improvements in key clinical outcomes: the lower VAS, lower attack frequency and attack duration, and higher overall clinical response. No serious adverse events related to AA were reported in the included trials. However, only one study[29] systematically monitored and documented adverse events, precluding a definitive conclusion on its safety profile.

In the bias risk assessment assessed RoB2, the conclusions of 64 included studies of showed no “high risk” results, which demonstrate the authenticity of the result. According to the GRADE framework, the quality of evidence for all outcomes (VAS, frequency and duration of migraine attacks, and CER) was assessed as moderate, underscoring the dependability of the study results.

In accordance with the “moderate” certainty rating from the GRADE assessment, the pooled results support a Grade B recommendation for the use of AA as an effective and safe adjunctive therapy. This suggests that AA is a reasonable option for most patients and should be considered within a comprehensive migraine management plan.

Comparison with Previous Studies

Previous studies have shown that AA is effective in treating migraines. A randomized controlled trial evaluating auricular semi-permanent (ASP) needles, which demonstrated that the ASP group exhibited significantly lower pain intensity and attack frequency compared to the control group.[40] A separate investigation indicated that the combination of acupuncture and auricular bean embedding was effective in improving dysfunction of the autonomic nervous system. This therapeutic approach enhanced the activity of both sympathetic and parasympathetic nerves, leading to a restoration of autonomic

balance. Consequently, a reduction in clinical symptoms was also observed among individuals suffering from migraines.[41] The mechanism through which AA alleviates migraines is suggested to involve the activation of the descending pain modulation pathways in both the locus coeruleus and dorsal raphe nuclei. By stimulating special auricular acupoints, the auricular vagus nerve is triggered, and the excitation is spread to the central nervous system.[20] Ultimately, the pain relief effect is achieved. Besides, some studies have shown that AA for migraines is related to the increase in E2 and 5-HT levels in the serum, thereby improving the hormone levels in the body.[30]

Regarding systematic reviews, no Meta-analysis or network Meta-analysis on AA for migraine has been formally published to date, with only a protocol for such a study reported[26] and other studies focused on "acupuncture for migraines". Therefore, this analysis summarizes the previously published research on AA for migraines, aiming to filling in the research gaps and providing clinical robust support for AA's role as a standalone or adjunctive intervention.

Clinical and Research Implications

The analysis further confirmed the effectiveness and safety of AA on migraines, providing a relatively sufficient clinical basis for AA to be used as an alternative therapy for migraines. This can reduce the expenses of people for treating migraines and lower the social healthcare costs economically. In terms of quality of life, the symptoms of migraines can be simply and effectively alleviated by AA instead of drugs, which not only significantly reduces people's reliance on medication and the side effects of long-term drug treatment on the body but also improves work efficiency and enables people to better engage in their daily lives and work. Apart from filling the research gap in the field of AA for migraines, the study highlights the advantages of traditional Chinese medicine in treating pain, such as low cost, quick efficacy, and fewer adverse reactions. It provides certain research directions for future studies in the field of pain, and encourages researchers to pay more attention to the research and application of traditional Chinese medicine's unique therapeutic methods and external treatment techniques.

Strength and Limitations

The analysis expands the scope of the research subjects, without setting any age restrictions, and included all patients diagnosed with migraines,[1] which ensures the universality of AA for migraines. In terms of intervention measures, most previous trials focused on "acupuncture for migraines" or "AA combined with other therapies for migraines", and trials solely studying AA were very few. Either "acupuncture" or "AA combined with other therapies" as variables failed to highlight the clinical effect of AA alone. Furthermore, variables such as "auricular bean pressing" or "otopoint needle embedding" lacked sufficient data support. This study starts from the perspective of "AA", including treatment measures such as "auricular tip bleeding", "auricular needle implantation in the fronto-temporal-occipital region", etc., in addition to the aforementioned "auricular bean pressing" and "otopoint needle embedding". We collected and sorted out relevant previous literature to ensure the completeness and high quality of the research.

While our results suggest that AA might be more effective in the treatment of migraine, it is important to take into account that there was some limitations between the studies analyzed: (I) The sample size of the analysis is too small, incorporating only 10 trials (mean 85 participants per trial). Small-study effects results in high data homogeneity, restricting subgroup analyses and compromising the generalizability of findings. (II) No specific classification of migraines was conducted, so the efficacy of AA for different types of migraines remains to be investigated. (III) The mechanism of AA for migraines was not clearly defined.

Conclusion

This investigation revealed that AA, both as a standalone treatment and in conjunction with other therapeutic approaches, led to a significant reduction in pain, as well as in the frequency and duration of migraine attacks. The intervention demonstrated considerable clinical benefits. Available data from the included trials indicate no major safety concerns though more rigorous safety reporting is needed in future studies. Nonetheless, the overall validity of these findings is constrained by the methodological limitations observed in the included studies. Future investigations should primarily focus on large-scale, multicenter trials with standardized protocols to validate the efficacy of AA across more diverse

populations. Additionally, further exploration into AA's underlying mechanisms, including its influence on serotonergic systems and the trigeminovascular pathway, is warranted to consolidate the evidence base.

Generative AI Statement

The authors declare that no Gen AI was used in the creation of this manuscript.

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Data Sharing Statement

The datasets used and analyzed during the current study are available from the corresponding author (Shenmei Zheng, E-mail Address: 1084360295@qq.com) on reasonable request.

Author Contributions

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

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Disclosure

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

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