

Acupuncture for the Management of Chronic Headache: A Systematic Review

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OBJECTIVE: The objective of this review was to evaluate the efficacy of acupuncture for treatment of chronic headache.

METHODS: We searched the databases of Medline (1966–2007), CINAHL, The Cochrane Central Register of Controlled Trials (2006), and Scopus for randomized controlled trials investigating the use of acupuncture for chronic headache. Studies were included in which adults with chronic headache, including migraine, tension-type headache or both, were randomized to receive needling acupuncture treatment or control consisting of sham acupuncture, medication therapy, and other nonpharmacological treatments. We extracted the data on headache intensity, headache frequency, and response rate assessed at early and late follow-up periods.

RESULTS: Thirty-one studies were included in this review. The majority of included trials comparing true acupuncture and sham acupuncture showed a trend in favor of acupuncture. The combined response rate in the acupuncture group was significantly higher compared with sham acupuncture either at the early follow-up period (risk ratio [RR]: 1.19, 95% confidence interval [CI]: 1.08, 1.30) or late follow-up period (RR: 1.22, 95% CI: 1.04, 1.43). Combined data also showed acupuncture was superior to medication therapy for headache intensity (weighted mean difference: -8.54 mm, 95% CI: -15.52 , -1.57), headache frequency (standard mean difference: -0.70 , 95% CI: -1.38 , -0.02), physical function (weighted mean difference: 4.16, 95% CI: 1.33, 6.98), and response rate (RR: 1.49, 95% CI: 1.02, 2.17).

CONCLUSION: Needling acupuncture is superior to sham acupuncture and medication therapy in improving headache intensity, frequency, and response rate.

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Headache is a major neurobiological disorder, affecting one third of the world's population. It is estimated that up to 10 million people visit the general practitioner for chronic headache in the United States.¹ Although pharmacological options remain the mainstay of management strategy, many patients continue to suffer distress and disruption of their normal daily activities. Moreover, side effects of medication may lead to limitations of drug therapy. Various nonpharmacological treatment strategies have been increasingly used to treat headache with various degrees of benefits.² In particular, acupuncture has been widely used to treat chronic headache. In a 1998 National Institute of Health consensus statement, acupuncture was accepted as a viable alternative for treating headache.³ However, the available evidence for the use of acupuncture for the management of headache remains

contradictory. A previous systematic review suggests that acupuncture has a role in the treatment of chronic headache.^{4,5} However, the conclusion was limited by the small number of well-conducted clinical trials. Since its publication in 2001, there have been a number of well-conducted larger scale clinical studies examining the use of acupuncture in headache. In this up-to-date systematic review, we evaluated the effectiveness and side effects profile of acupuncture for the management of chronic headache.

METHODS

Search Strategy

Published reports of clinical trials evaluating acupuncture for the management of chronic headache were sought. Medline (1966–2007), CINAHL, The Cochrane Central Register of Controlled Trials (2006), and Scopus were searched without language restriction. Free text and MeSH terms acupuncture, acupressure, acupoint, electro-acupuncture, headache, tension headache, and migraine were used for searching. The last electronic search was in November 2007. Abstracts of matching studies were screened by two independent reviewers. Relevant articles were obtained in full text for further review. The database of a Chinese medical journal was searched for relevant trials. The bibliographies of these articles and the older trials in

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previous systematic reviews were also screened for additional studies. We excluded data from letters, abstracts, meeting case reports, or basic science studies.

Selection Criteria

Only randomized controlled trials evaluating acupuncture for chronic headache in adult patients (age, >18 yrs) were included. We limited the inclusion of the studies to those in which the traditional needling acupuncture treatment was provided. Trials that reported at least one clinical outcome related to headache (e.g., headache intensity, headache frequency, global assessment of headache, health-related quality of life [QoL], etc.) were included. We excluded trials of only trigger-points therapy, trials using acupuncture techniques other than needling (e.g., laser acupuncture and electro-acupuncture without needles, etc.), trials evaluating acupuncture only for neck or facial pain, or trials where only different forms of acupuncture were compared. We also excluded trials with observation periods of less than 4 wks (i.e., from start of treatment to the end of observation) due to the short period of assessment.

Quality Assessment

The methodological quality of the trials was independently assessed based on the criteria of Juni et al.^{6,7} by two independent reviewers (YS and TJG). The modified Oxford Scale was used to assess the internal quality of included reports.^{8,9} Discrepancies in scores were resolved by discussion based on assessment of double-blinding. One point was assigned to the trials in which the patient and assessor blinding were stated and two points were given to the trial in which patients could not distinguish the group allocation by credibility or guessing test and the assessor blinding was described adequately. The maximum score was 7; trials with a score of 4 or more points were considered high quality.

Data Extraction and Study Summary

Two independent reviewers extracted information on patients, methods, interventions, outcomes, and results using a predefined form. Data of four outcomes were extracted from original trials: headache intensity, headache frequency, response rate, and health-related QoL. Response rate is an overall assessment of improvement after treatment. Response was defined as at least 33% improvement by assessing headache index or headache frequency or by overall evaluation. Pain intensity scores reported with visual analog score scale, 0–10 the verbal rating score scale, 0–10 or headache score 1–3 were converted to 0–100 mm. When various scales and questionnaires were provided to assess health-related QoL, only data of the two summary measures of physical and mental health from Short form (SF-36) Health Survey were extracted because the SF-36 health survey is most commonly used and is a reliable instrument for health status

assessment. Data from SF-12, the shorter alternative to SF-36, were also extracted.

To facilitate pooling of data, only data in early follow-up and late follow-up were analyzed. Early follow-up was defined as the measurement point closest to 8 wks but no longer than 3 mos after randomization, and late follow-up was defined as the measurement point closest to 6 mos but longer than 3 mos after randomization. Corresponding authors were contacted via e-mail or phone for additional data, if needed. For crossover trials, only data from first arm of the study were abstracted because of the potential risk of a carryover effect.

Data Synthesis and Meta-Analysis

Estimates of the mean difference with 95% confidence interval (CI) were reported for headache intensity and headache frequency. Only data expressed as mean with standard deviation or where these values could be calculated were pooled. The analysis prioritized the arms comparing acupuncture with sham acupuncture for those studies with multiple arms trials. For trials using two different scales to measure headache frequency (days with headache per month and attacks per month), standardized mean difference was used as the principal measure of effect size so that results could be combined. Weighted mean difference (WMD) with 95% CI was calculated for other continuous data, in which the results from changed scores and final values could be legitimately pooled. Dichotomous data were analyzed using risk ratio (RR) with 95% CI. A random effects model was used by default. The I^2 test was used to assess heterogeneity. A value more than 50% is considered as substantial heterogeneity.

Subgroup analysis was conducted based on the type of headache (migraine, tension-type headache). Sensitivity analyses were also conducted where appropriate, restricting the analyses to randomized controlled trials with validity score more than 3. Additional sensitivity analysis was performed for adequate trial blinding, in which two points were assigned to a blinding item of the validity scale. Analyses were performed using ReviewManager software (version 4.2, Cochrane collaboration).

RESULTS

Study Characteristic

Searches of computerized database, bibliography and two previous reviews generated 102 potentially relevant trials evaluating acupuncture for chronic headache. Thirty-one trials consisting of 3916 patients meeting inclusion criteria were included in this review (Fig. 1). The characteristics of included trials are summarized in Table 1. Of the 31 clinical trials, 17 were migraine, 10 were tension-type headache, and 4 trials were mixed chronic headache. Five trials were published in German,^{10–14} one in French,¹⁵ one in Danish,¹⁶ two in Chinese,^{17,18} and the rest in English.

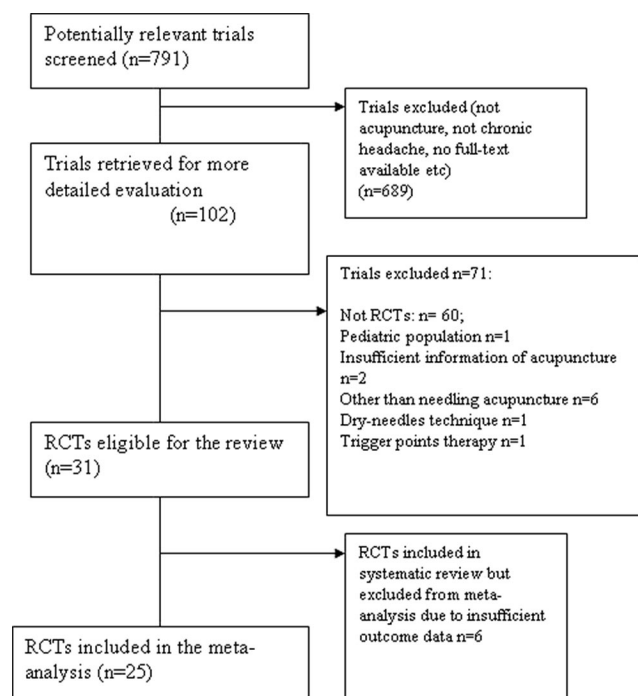


Figure 1. Selection process of trials for inclusion in the systematic review.

Twelve trials including in previous reviews were excluded from this meta-analysis due to various reasons, including incomplete data available,^{19–23} no needling acupuncture involved,^{24–27} trigger-points therapy,²⁸ pediatric population,²⁹ or no information provided for acupuncture points.³⁰ Seventeen new trials^{17,18,31–44,45} published since the last systematic review were included.

Twenty-one of included trials established the diagnosis of chronic headache using published criteria. Information on the qualification and/or experience of the acupuncturist was provided in 17 trials. Achieving DeQi (feeling of energy) sensation was described in 21 trials (Table 2).

The majority were conventional two-arm comparison trials: true acupuncture versus sham acupuncture (16 trials), acupuncture versus medication treatment (8 trials), and acupuncture versus physiotherapy (2 trials). Five trials have three arms, acupuncture, sham, and waiting list (one trial), acupuncture, sham, and usual medication (one trial), acupuncture, behavioral program, and waiting list (one trial), acupuncture, physiotherapy, and relaxation training (one trial), acupuncture, and transcutaneous electrical nerve stimulation (TENS) at acupuncture points and medication (one trial).

A set formula of acupuncture was performed in 11 trials^{10–12,15,16,31,35,40,42,46,47} and individual acupuncture treatment was used in 16 trials^{13,14,17,18,34,37–39,41,43,44,48–52} depending on the type and distribution of pain based on diagnosis of traditional Chinese medicine. Semi-standardized acupuncture was used in four trials,^{32,33,36,45} in which

basic points were applied for each session and additional points were selected individually based on the pain topography. Three trials used electrical needling acupuncture.^{18,40,48} The treatment session was, on average, 10 sessions (range, 6–16) during a mean of 8 wks (range, 4–24 wks).

Various sham designs were used to attempt to blind the study subject in the included trials. Two designs were commonly used: superficial needling at nonacupuncture points as sham, and needles touched without penetration at acupuncture points or nonacupuncture points. The former method was used in most of the trials (eight migraine and five tension-type headache trials) and the latter was used in three trials in tension-type headache^{37–39} and one trial in migraine.³⁵ Mock TENS by electro-pad as sham was used in one trial.⁴⁸ In nine trials, a credibility questionnaire or guess treatment test was used assessing the reliability of blinding. Results from eight trials^{32,33,36–39,41,45} showed that patients were unable to distinguish their treatment; one trial found that correct rate of guess treatment differed significantly between acupuncture and sham acupuncture groups.³⁵

Fourteen trials^{18,31–35,39–44,45,48} scored more than 4 points on the quality score, 12 of which were published since 2000. Randomization was sufficiently addressed and concealment of allocation was appropriately performed in nine trials. A maximum quality score of 7 was found in five studies^{32,33,35,41,45} (Table 1). The longest follow-up period was 1 yr in five trials.^{13,14,49,51,52}

Efficacy of Acupuncture

Acupuncture Versus Sham

Fourteen trials reported data on the proportions of patients responding to treatment at an early follow-up period.^{10,13,14,16,32,33,36,37,39,41,45,48,49,52} Combined data demonstrated a statistically significant higher response rate in the acupuncture group compared with sham acupuncture. Five-hundred ten of 961 (53%) acupuncture patients were classified as responders compared to 373 of 829 (45%) patients receiving sham acupuncture, resulting in a pooled random effects responders RR of 1.19 (95% CI: 1.08, 1.30) without heterogeneity ($I^2 = 0$) (Fig. 2). A significant difference was also found in subgroup analysis for tension-type headache.^{16,39,41,46,51} RR was 1.26 (95% CI: 1.10, 1.44) without heterogeneity ($I^2 = 0$). However, there was no significant difference between treatment groups for migraine. Only two studies reported the response rate at late follow-up in which combined data show that RR was 1.22 (95% CI: 1.04, 1.43), again without heterogeneity ($I^2 = 0$).^{15,45} (Fig. 2).

For headache intensity, pooled data showed there was no significant difference between acupuncture and sham groups at either early follow-up period. Combined data from three trials^{32,35,36} in migraine headache also did not show any difference. However, combined data from seven trials^{32,35–37,39,41,45} at the

Table 1. Characteristics of Included Trials

Study (reference)	Patients			Location/ published language	Quality score (0–7) [R/C/D/F]	Intervention	
	n	% female	Mean age (yrs)			Treatment (no. sessions/ no. weeks)	Control
Migraine							
Baust and Sturtzbecher ¹⁰	44	75	NA	Germany/German	2 [1/01/0]	Formula MA (6/6)	Sham: needles inserted away from acupoints
Dowson et al. ⁴⁸	48	83	39	UK/English	4 [2/1/1/0]	Individualized EA (6/6)	Sham: patch electrodes attached off acupoints with mock EA
Henry et al. ¹⁵	30	73	34	France/French	3 [1/0/1/1]	Formula MA (8/ 15) + EA	Sham: dry-needling 1 cm away from acupoints
Doer-Proske and Wittchen ¹¹	30	77	39	Germany/German	1 [1/0/0/0]	Formula MA (10/10?)	1-behavioral program; 2-waiting list
Heydrenreich and Thiessen ¹²	150	84	39	Germany/German	1 [1/0/0/0]	Formula MA (8/8)	1 TENS at the same acupuncture points 2 medication (iprazochrom and dihydroergo tocinmesylate)
Vincent ⁵²	32	84	37	UK/English	3 [1/0/1/1]	Individual MA (6/6)	Sham: needles insert superficially away from acupoints
Weinschutz ¹³	40	90	41	Germany/German	1 [1/0/0/0]	Individual MA (8/8)	Sham: needle inserted superficially away from acupoints
Weinschutz et al. ¹⁴	41	90	38	Germany/German	1 [1/0/0/0]	Individual MA (8/8)	Sham: needles inserted superficially away from acupoints
Gao et al. ⁴⁹	64	72	15–58	China/English	1 [1/0/0/0]	Individual MA (10/2–6?)	Medication: ergot plus caffeine for acute attack, Chinese medicine other time
Allais et al. ³¹	160	100	38	Italy/English	5 [2/1/0/2]	Formula MA (12*/6 months)	Flunarizine
Diener et al. ³²	794	84	37	Germany/English	7 [2/1/2/2]	Individual MA (10/6)	1 Sham needles inserted at non-acupoints area 2 standard treatment with medication
Alecrim-Andrade et al. ³³	28	79	36	Brazil/English	7 [2/1/2/2]	Semi-standardized MA (16/12)	Sham: needles inserted superficially at others acupoints
Huang et al. ¹⁷	50	84	36	China/Chinese	1 [1/0/0/0]	Individual MA (10)	Nimodipine
Streng et al. ³⁴	114	88	40	Germany/English	5 [2/1/0/2]	Individual MA (8–15/12)	Metoprolol
Linde et al. ³⁵	28	100	>20	Germany/English	3 [1/0/1/1]	Formula MA (9/12?)	Sham: needles touched without penetrated at acupoints
Linde et al. ³⁶	302	88	43	Germany/English	7 [2/1/2/2]	Semi-standardized MA (12/8)	1 Sham: needles inserted superficially at nonacupoints 2 waiting list
Zhou et al. ¹⁸	286	66	43	China/Chinese	4 [2/1/0/1]	Individual MA (20/4) + EA	Standard medication
Tension-type headache							

(Continued)

Table 1. Continued

Study (reference)	Patients				Quality Score (0–7) [R/C/D/F]	Intervention	
	n	% female	Mean age (yrs)	Location/published language		Treatment (no. sessions/ no. weeks)	Control
Hansen and Hansen ¹⁶	25	67	36	Danmark/Dannish	3 [1/0/1/1]	Formula MA (6/3 weeks†)	Sham: needles superficially inserted at nonacupoints
Tavola et al. ⁵¹	30	87	33	Italy/English	3 [1/0/1/1]	Individual MA (8/8)	Sham: needles inserted at nonacupoints
Carlsson et al. ⁴⁶	62	100	34	Sweden/English	2 [1/0/0/1]	Formula MA (5–10/2–8)	Physiotherapy
Karst et al. ³⁸	39	49	47	Germany/English	3 [1/0/1/1]	Individual MA (10/5)	Sham: needles touched without penetrated at acupoints
Karst et al. ³⁷	69	55	48	Germany/English	3 [1/0/1/1]	Individual MA (10/5)	Sham: needles touched without penetrated at acupoints
White et al. ³⁹	50	76	48	UK/English	6 [2/1/1/2]	Individual MA (8/6†)	Sham: needles touched without penetrated at non acupoints
Xue et al. ⁴⁰	40	65	42	Australia/English	6 [2/1/1/2]	Formula EA (8/4‡)	Sham: needles superficially inserted at non-acupoints
Melchart et al. ⁴¹	270	75	43	Germany/English	7 [2/1/2/2]	Individual acup. (12/8)	Sham: needles inserted superficially at non-acupoints
Soderberg et al. ⁴²	90	81	38	Sweden/English	5 [2/1/1/1]	Formula MA (10–12/10–12)	1 Physiotherapy 2 relaxing training
Enders et al. ⁴⁵	403	78	39	German/English	7 [2/1/2/2]	Semi-standardized acup. (10–15/5–8) + medication	Sham: superficially inserted at non-acupoints + medication
Mixed or others							
Loh et al. ⁴⁷	55	69	42	UK/English	1 [1/0/0/0]	Formula MA (NA/NA)	Medication (mainly Propranolol)
Vickers et al. ⁴³	401	84	46	UK/English	5 [2/1/0/2]	Individual MA (12/3 months)	no acupuncture treatment (usual medication)
Wylie ⁵⁰	67	67	38	UK/English	1 [1/0/0/0]	Individual MA (6/?)	Massage and relaxation
Coeytaux et al. ⁴⁴	74	80	46	USA/English	5 [2/1/0/2]	Individual MA (10/6 weeks) + medication	Usual medication

MA = manual acupuncture; EA = electro acupuncture; NA = not available.

Quality Score: R = randomization; C = concealment of allocation; D = double blinding; F = flow of patients.

* Weekly sessions for first 2 mos and then once a month for the next 4 mos.

† Weekly sessions for 6 weeks with two follow-up treatments after 1 and 2 mos.

‡ Before crossover period.

late follow-up period showed a WMD of -2.62 mm was in favor of acupuncture (95% CI: $-5.07, -0.17$), whereas data from trials in tension-type headache showed that acupuncture significantly reduced the headache score at either the early follow-up^{37–41,45} or late follow-up period,^{33,35,37,41} where WMD was -3.77 mm (95% CI: $-7.00, -0.55$) and -3.66 mm (95% CI: $-6.54, -0.79$), respectively (Fig. 3).

For headache frequency, pooled data from nine trials^{32,35–41,45} did not show any difference between acupuncture and sham acupuncture in either the early or late follow-up period as well as in subgroup analyses.

For health-related QoL, four studies^{32,36,41,45} reported suitable data of physical and mental health in either the early follow-up or late follow-up period.

Table 2. Characteristics of Included Trials

Study (reference)	Qualification of acupuncturist	Dechi sensation achieved	Diagnosis of headache	Credibility test
Migraine				
Baust and Sturtzbecher ¹⁰	No information	No information	Therapy -resistant	NA
Dowson et al. ⁴⁸	No information	Y	No information	NA
Henry et al. ¹⁵	No information	No information	Ad Hoc	NA
Doer-Proske and Wittchen ¹¹	Y	No information	Therapy -resistant	NA
Heydrenreich and Thiessen ¹²	No information	No information	No information	NA
Vincent ⁵²	No information	No information	No information	NA
Weinschutz ¹³	Y	Y	IHS	NA
Weinschutz et al. ¹⁴	Y	Y	IHS	NA
Gao et al. ⁴⁹	No information	N	No information	NA
Allais et al. ³¹	Y	Y	IHS	NA
Diener et al. ³²	Y	Y	IHS	Y
Alecrim-Andrade et al. ³³	Y	Y	IHS	Y
Huang et al. ¹⁷	No information	Y	No information	NA
Streng et al. ³⁴	Y	Y	IHS	NA
Linde et al. ³⁵	Y	Y	IHS	Y
Linde et al. ³⁶	Y	Y	IHS	Y
Zhou et al. ¹⁸	Y	Y	IHS	NA
Tension type headache				
Hansen and Hansen ¹⁶	No information	Y	No information	NA
Carlsson et al. ⁴⁶	No information	Y	Ad Hoc	NA
Tavola et al. ⁵¹	No information	Y	Ad Hoc	NA
Karst et al. ³⁸	No information	No information	IHS	Y
Karst et al. ³⁷	No information	No information	IHS	Y
White et al. ³⁹	Y	Y	IHS	Y
Xue et al. ⁴⁰	Y	Y	IHS	NA
Melchart et al. ⁴¹	Y	Y	IHS	Y
Soderberg et al. ⁴²	Y	Y	IHS	NA
Enders et al. ⁴⁵	Y	Y	IHS	Y
Mixed or others				
Loh et al. ⁴⁷	Y	Y	No information	NA
Wylie ⁵⁰	No information	No information	IHS	NA
Vickers et al. ⁴³	Y	Y	IHS	NA
Coeytaux et al. ⁴⁴	Y	Y	IHS	NA

IHS: the criteria of International Headache Society (1988) Ad Hoc: the Ad Hoc Committee's criteria (1962).

NA = not available.

Combined data showed no significant difference between acupuncture and sham acupuncture in both physical and mental health.

Both sensitivity analyses for high validity trials (validity score ≥ 4) and adequate blinding trials (the scale of blinding assessment was 2) did not affect the overall results. However, the value of I^2 was reduced for each analysis.

Acupuncture Versus Medication

Data from all types of headache were combined for meta-analysis. Patients receiving acupuncture reported significant improvement at the early follow-up period in headache intensity (WMD: -8.54 mm, 95% CI: $-15.52, -1.57$),^{34,43} but the result was heterogeneous. The standardized mean difference in headache frequency was also in favor of the acupuncture group. Days with headache per month and attacks per months was -0.22 (95% CI: $-0.41, -0.03$)^{34,43} and -1.22 (95% CI: $-2.34, -0.10$),^{17,31} respectively. Pooled data from seven trials^{12,17,18,31,43,44,47} showed 62% of patients receiving acupuncture have a significantly

higher response rate to treatment, compared with 45% of patients receiving medication at the early follow-up period. RR was 1.80 (95% CI: 1.16, 2.81) (Fig. 4). This significant difference was also found at 1 year follow-up in one study.⁴⁹ Three trial reported suitable data for health-related QoL in the early-period. Pooled data from three trials^{34,43,44} showed that acupuncture produced significantly better physical function in the early follow-up period (WMD: 4.16, 95% CI: 1.33, 6.98). However, no significant difference was found in mental health.

Acupuncture Versus Other Nonpharmacological Controls

Four trials compared acupuncture with other non-pharmacological interventions. The heterogeneity in the control groups made data analysis impossible. Three studies^{11,46,50} found that nonpharmacological therapies, including physiotherapy and massage were significantly better than acupuncture for chronic headache. A recently published study found similar effects

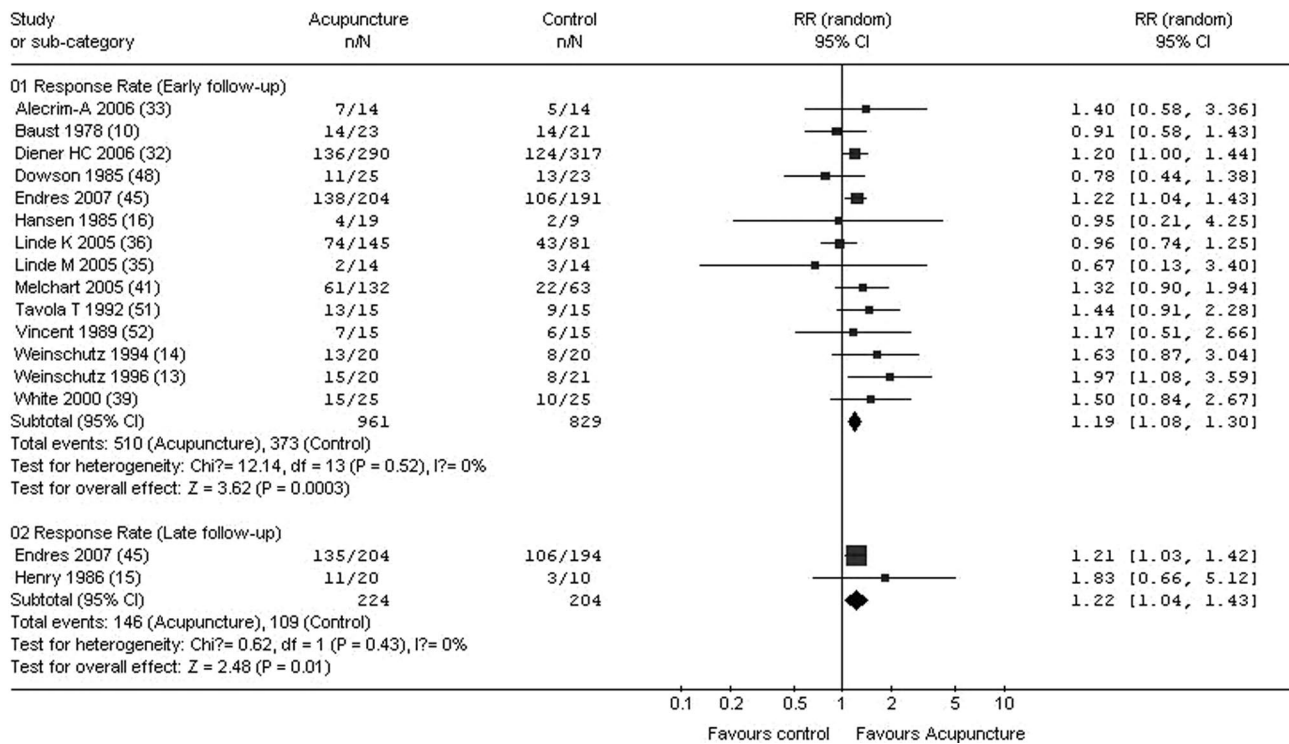


Figure 2. Response rate in acupuncture versus sham-controlled trials for chronic headache. RR = relative risk; CI = confidence interval.

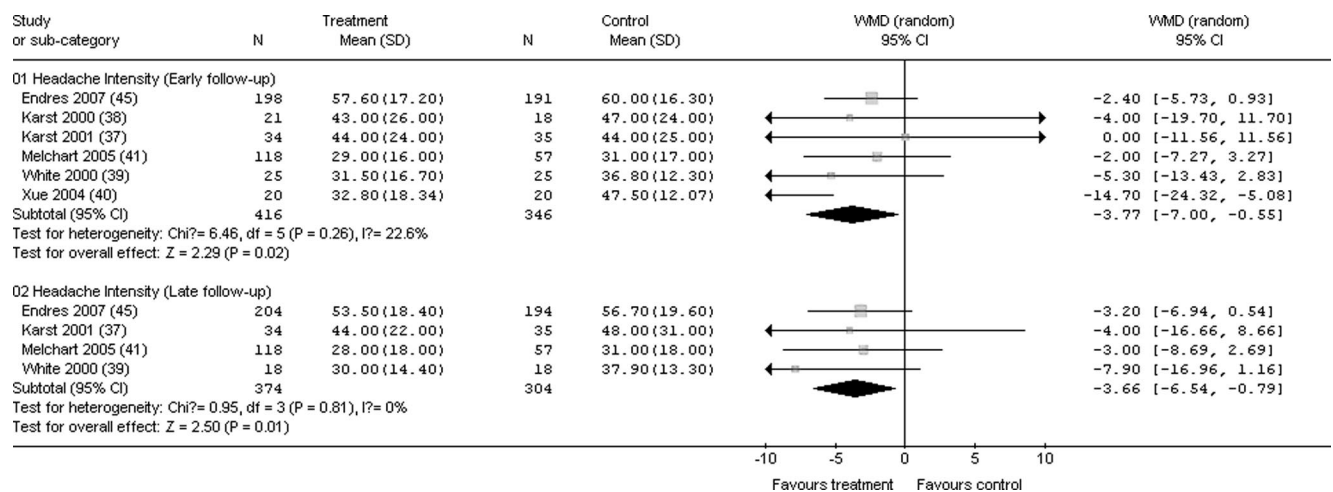


Figure 3. Headache intensity in acupuncture versus sham-controlled trials for tension-type headache. WMD = weighted mean difference; CI = confidence interval.

between acupuncture and physiotherapy for tension-type headache. However, patient well-being improved only in the physiotherapy treatment group in this study.⁴²

Acupuncture Versus Waiting List

No study compared only acupuncture with waiting list control. The findings from two trials^{11,36} comparing acupuncture with waiting list and other controls showed acupuncture was better than waiting list control in both headache frequency and intensity in either the early or late follow-up period.

Safety of Acupuncture

Twelve trials reported the side effects related to acupuncture, with 11 providing detailed information.^{18,31-36,39,41,44,45} Pooling of those data across the trials was deemed to be impossible due to the heterogeneous reporting outcomes and methods. The common side effects associated with acupuncture were minor bleeding and bruising or local paraesthesia at the needle insertion sites.^{33,34,36,39,41,44} Triggering of a migraine attack or headache were reported by needle insertion from five trials.^{36,39,41,44,45} A similar overall pattern of side effects was found in most

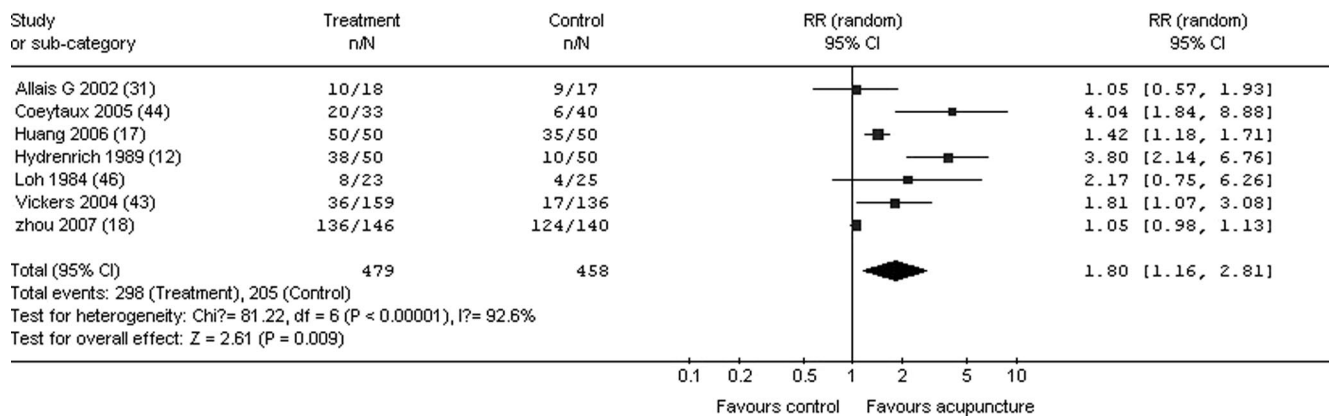


Figure 4. Response rate in acupuncture versus medication-controlled trials for chronic headache. RR = relative risk; CI = confidence interval.

studies comparing acupuncture with sham acupuncture. However, the total number of side effects was significantly lower in the acupuncture group compared with medication treatment in three trials.^{18,31,34}

DISCUSSION

This systematic review demonstrates that acupuncture is an effective treatment for chronic headache. Specifically, acupuncture is superior to sham with a significantly higher response rate in patients with migraine and tension-type headache, and it significantly reduced headache intensity at the late follow-up period. Interestingly, subgroup analysis found that acupuncture is more effective in reducing headache intensity than sham in tension-type headache, but it did not provide the same positive result for migraine. When compared with pharmacological and waiting list options, acupuncture was also more effective for reducing headache intensity and frequency. In addition to reducing headache symptoms, acupuncture might provide higher patient's health-related QoL than pharmacological treatment as demonstrated by a significant improvement of physical functioning of SF-36.

Headache is a complex condition involving both physical and psychological factors, therefore, the placebo effect is an important consideration in the management of headache. Results from the trials comparing acupuncture with medication demonstrated superior efficacy in reducing headache intensity and headache frequency, increasing response rate and improving general physical health. The drop-out rate in the medication group was higher than the acupuncture group, which may have been related to side effects of the pharmacotherapy. This finding agrees with previously published data in chronic knee pain.^{53,54} However, the findings from three of four included trials comparing acupuncture with other nonpharmacological treatment showed that other nonpharmacological treatments, especially physiotherapy, were better than acupuncture.^{11,46,50} Nevertheless, these trials were either small or insufficiently reported or had methodological weakness. Therefore, this meta-analysis

performed an important comparison between acupuncture and sham acupuncture groups to observe the added effects of acupuncture beyond the effects seen in the control group. The evidence comparing acupuncture with sham indicates that acupuncture may have specific effect, i.e., beyond the placebo effects, for headache treatment.

Complete blinding of the control group has always been a challenging issue in acupuncture clinical trials. Different strategies have been adopted to provide the best blinding possible. Sham control, often regarded as approaching the ideal strategy, provides the control subjects with the impression closest to true acupuncture but without any real analgesic effects. The most often used sham is superficial needling in which needles are inserted superficially at nonacupuncture points. Ten of 14 studies^{10,13,14,15,32,33,36,41,45,51} in this analysis using this method found positive results in response rate, but no significant difference between acupuncture and sham in headache frequency and intensity. However, it has been argued that needling at nonacupuncture points may produce similar physiological effects. Biochemical evidence suggests that stimulation of nonacupuncture points may also result in the release of endorphins and hence produce analgesia. As such, the treatment effects of acupuncture might be under-estimated.^{55,56} Alternative methods without penetration included a blunt needle against the skin or tapping a cocktail stick against a bony surface to create the pricking sensation but without producing analgesic effects. One of the included trials used Mock TENS design as sham control and the observed acupuncture effect was significantly better than sham in improving the response rate.⁴⁸

Safety is an important consideration in the management of chronic conditions such as headache. The common pharmacological therapies, such as metoprolol and flunarizine have associated side effects, including drowsiness, ataxia, and blushing.^{18,31,34} In this analysis, we found a lower incidence of side effects in the acupuncture group when compared with medications.

Acupuncture is known to be relatively safe when performed by qualified acupuncturists. The minor side effects reported were related to the local insertion of needles, such as redness, spot bleeding, and local discomfort.

In this systematic review, trials were included based on the quality as assessed using the criteria of Juni et al. In addition, an objective scoring system was used to further validate the quality of the included trials. We have included 16 acupuncture trials for the management of headache not considered in the previous analysis.^{7,8} We believe the results of the present review have a greater degree of reliability with the inclusion of better designed clinical trials with larger sample size, which were not included in the previous review. The quality of the more recent trials is higher than the older trials, with more emphasis on proper randomization, allocation concealment, and description of patient dropout. We excluded 12 studies included in the previous review¹⁹⁻³⁰ as the quality of the data did not meet our criteria for inclusion. Additionally, where possible, we conducted subgroup and sensitivity analyses to provide further robustness to the data and identified the type of headaches for which acupuncture may be a better treatment option. Moreover, the analysis for health-related QoL was performed in this meta-analysis, which was not reported by previous reviews.

There are several limitations to this review. Heterogeneity of study results is often considered a limitation in a systematic review. The heterogeneity of this present review is variable due to a wide variability of acupuncture treatment, the type of headache, and sham control designs. Subgroup analysis and sensitivity analyses did lower heterogeneity, but we limited them to only sham-controlled trials. The heterogeneous outcomes reported were another limitation of this review. Outcomes measures were not consistent and only 12 of the included studies reporting consistent data in headache frequency and intensity which could be considered for meta-analysis.^{17,31,32,34-40,43,45} In addition, psychosocial function is a clinically meaningful measurement for chronic headache as it affects patient's daily activity; however, only 7 of 31 included trials had available data for analysis due to various scores or scales reporting. We have added an analysis for health-related QoL by the SF-36. Although the combined data showed no significant difference between acupuncture and sham acupuncture, there was a significant difference in favor of acupuncture when compared with medication treatment. The varied nonpharmacological controls of some studies also made pooling of data inappropriate. As with any meta-analysis, publication bias cannot be excluded. Finally, we restricted this analysis to trials in adults as data in children are lacking.

This systematic review identified a number of areas where future research on acupuncture for chronic headache is warranted. The majority of the included studies compared true acupuncture with sham acupuncture. Only 8 of 30 included trials compared

acupuncture with medication therapy. Many studies lack adequate blinding strategies. Outcomes and duration of observation are not well defined. Future studies investigating the role of acupuncture should be adequately powered to examine a well-defined outcome, e.g., headache intensity, frequency, and time to meaningful response. Health-related QoL, which was regarded as a clinically significant measurement for headache, should be assessed in the future by using a well-validated instrument, such as the SF-36. Long-term outcome should be an important consideration and if the headache returns after the cessation of therapy. Further studies need to establish the optimal timing of the administration of acupuncture, the points used, as well as the ideal frequency of treatment. Studies incorporating acupuncture techniques as part of a multimodal regimen are likely to be more clinically relevant than those using a single modality.

In conclusion, acupuncture is more effective for the treatment of chronic headache when compared with sham acupuncture, medication treatment, and waiting list option. No serious acupuncture-related adverse effects were observed in all included studies. Prospective, well-controlled, and adequately powered clinically relevant studies using multimodal strategies are needed to define the role of acupuncture for the management of chronic headache.

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