

Acupuncture for Back Pain

A Meta-Analysis of Randomized Controlled Trials

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Background: Acupuncture is commonly used to treat back pain, but there is no published meta-analysis of trials of its effectiveness for this condition.

Objective: To perform a meta-analysis of trials of acupuncture for the treatment of back pain.

Methods: A systematic literature search was conducted to retrieve all randomized controlled trials of any form of acupuncture for any type of back pain in humans. The adequacy of the acupuncture treatment was assessed by consulting 6 experienced acupuncturists. The main outcome measure for the meta-analysis was numbers of patients whose symptoms were improved at the end of treatment.

Results: Twelve studies were included, of which 9 presented data suitable for meta-analysis. The odds ratio of improvement with acupuncture compared with control intervention was 2.30 (95% confidence interval, 1.28-4.13). For sham-controlled, evaluator-blinded studies, the odds ratio was 1.37 (95% confidence interval, 0.84-2.25).

Conclusion: Acupuncture was shown to be superior to various control interventions, although there is insufficient evidence to state whether it is superior to placebo.

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BACK PAIN is among the most prevalent health complaints of mankind.¹ It is, therefore, associated with much individual suffering and considerable socioeconomic consequences.² Back pain is also the most frequent indication for using unconventional therapies.³⁻⁵ Survey data suggest that back pain is one of the most common indications for referral to acupuncturists.⁶

Against this background, it is relevant to ask whether acupuncture can be shown to be effective. Even though several plausible mechanisms exist to explain its analgesic actions,⁷ reviews of acupuncture as a treatment for painful conditions invariably conclude that the published data are insufficient to judge it as effective or ineffective.⁸⁻¹² As different pain syndromes could respond differently to acupuncture, and as no systematic review or meta-analysis of acupuncture for back pain exists, the present study was aimed at filling this gap.

RESULTS

STUDIES IDENTIFIED

The search revealed 30 references for controlled trials.¹⁵⁻⁴⁴ Eighteen reports

were excluded for the reasons given in **Table 1**.

Table 2 summarizes the key data from the 12 studies that were included. In 2 studies, patients were recruited after admission to hospital, either for a course of rehabilitation³⁰ or for management of acute back pain.¹⁷ Patients were recruited via media advertisements in 1 study.¹⁶ In the remaining 9 trials, patients were recruited from hospital outpatient departments. In 4 studies,^{16,18,22,32} patients who were unresponsive to conventional therapy were included, and in the remaining 8 studies the included patients were described as having chronic back pain. Patients who had undergone back surgery were excluded in 2 studies^{17,42} and included in 1 study¹⁶; 9 reports did not specify history of back surgery as a study criterion. Treatment settings were conventional health service premises in 11 studies and a dedicated acupuncture clinic in 1.¹⁶

In 3 studies, conventional acupuncture points were not used: Garvey et al²² and Gunn et al²³ inserted needles into trigger points identified by tenderness, and Macdonald et al³⁵ placed needles superficially over trigger points. In the remaining 9 studies, recognized acupuncture points were used. In 9

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METHODS

DATA SOURCES

Searches were performed for clinical trials of any form of acupuncture for back pain in 3 computerized databases: MEDLINE (1969-1996); the Cochrane Controlled Trials Register (Issue 1, 1997); and CISCOP (November 1996), a database specializing in complementary medicine including much of the "gray literature," such as unpublished studies and conference reports. Searches were performed using keywords *acupuncture*, *electroacupuncture*, and *backache* and text-word searches for the above terms together with *low-back pain* and *lumbago*. In addition, our files of published articles selected over the years were screened and several experts in different countries were invited to contribute published studies on the topic. The bibliographies of all articles thus retrieved together with reviews of acupuncture treatment of pain were reviewed for further references. Authors of articles published in the past 5 years (1992-1997) were contacted and asked to inform us of any other articles they were aware of. Authors of abstracts were contacted and asked to provide the full reports.

STUDY SELECTION

All articles that reported a randomized controlled trial in which dry needles were inserted into the skin and for which the process was described by the author(s) as "acupuncture" for the treatment of any type of back pain in humans were included. The basis for selecting points for needle insertion was not restricted. Articles published in the English, French, German, Spanish, Italian, or Polish language were included. Trials in which one form of acupuncture was compared with another were excluded. When more than 1 publication described a single trial, only 1 report was included.

DATA EXTRACTION

Data were extracted independently by both of us in a predefined, standardized manner. Differences were settled by discussion. For each trial, numbers of patients in experimental and control groups who were objectively rated as improved or who had returned to work were obtained. Where objective measures were not available, subjective ratings were used. Where more than 1 outcome measure was reported in this way, the least and most favorable results were extracted for separate evaluations. Where necessary, letters were sent to authors requesting these data.

ASSESSMENT OF METHODOLOGICAL QUALITY

The quality of the studies was assessed by a modification of the method described by Jadad et al.¹³ First, points were

awarded by the investigators (E.E. and A.R.W.) in 3 categories: randomization (2 points), blinding (2 points), and description of dropouts and withdrawals (1 point). Studies were rated as "blind" if the control group received an intervention that appears likely to be indistinguishable from acupuncture (ie, sham acupuncture) and if the outcome was assessed in a blind manner, whether by a blinded observer or by the blinded subject's self-report. Second, points up to a maximum of 2 were awarded for each study according to the adequacy of the acupuncture treatment used, as assessed by blinded experts. For this purpose, an extract was prepared for each study containing only details of patients and interventions, translated into English if necessary. All means of identification were removed. Six experienced medical acupuncturists involved both in clinical practice and in teaching studied these extracts and rated the adequacy of acupuncture in each trial on a visual analog scale (VAS) that consisted of a 100-mm line. The left end of the line was labeled "complete absence of evidence that the acupuncture was adequate" and the right end was labeled "total certainty that the acupuncture was adequate." Two points were awarded for mean VAS scores of more than 66, one point for scores between 33 and 66, and zero points for scores less than 33 mm.

DATA SYNTHESIS

Meta-analyses of the data were performed using custom-written software (RevMan 3.0, Cochrane Collaboration, Oxford, England). For each trial, the total numbers of patients included in each group and the numbers whose symptoms had improved were entered into tables for comparison. Subsequently, the odds ratio (OR) for each trial was calculated, ie, the ratio of successes to failures in the genuine treatment group, divided by the same ratio in the control group. Weighting studies according to their inverse variance, the program computed a combined OR for all trials in the comparison, using the random effects model of DerSimonian and Laird.¹⁴ Confidence intervals (CIs) were calculated from the sums of the individual variances, and were set at 95%. The primary meta-analysis combined all studies that contained data in the appropriate form. Further meta-analyses were performed to compare subsets of trials that were combined according to particular features: blinding, length of follow-up, adequacy of acupuncture, use of formula acupuncture or electrical stimulation, and number of treatment sessions.

SENSITIVITY ANALYSIS

The primary meta-analysis was performed using the data that were least favorable to acupuncture. A sensitivity analysis was performed by repeating this meta-analysis using the most favorable data.

studies, outcomes were measured only at the end of treatment and in 3 studies there was a follow-up period: Mendelson et al³⁹ and Gunn et al²³ used minimum follow-up periods of 8 and 12 weeks, respectively, and Thomas and Lundeborg⁴³ followed up all patients for 6 months.

Table 3 summarizes the quality ratings of all included studies. The range is wide yet the majority of studies scored 3 or more points. The expert acupuncturists held divergent opinions about the adequacy of the treatment in all studies except 1,³² which they agreed was almost totally inadequate.

Table 1. Meta-analysis of Acupuncture for Back Pain: Trials Excluded and the Reasons for Exclusion

Source, y	Reason for Exclusion
Boas and Hatangdi, ¹⁵ 1976	Not randomized
Fox and Melzack, ¹⁹ 1976	Not randomized
Kitsenko, ²⁷ 1976	Russian language
Laitinen, ²⁹ 1976	Not randomized
Mendelson et al, ^{37,38} 1977, 1978	Dual publication
Mazières et al, ³⁶ 1981	Incorrect citation (no response to inquiry)
Sodipo, ⁴² 1981	Not randomized
Gallacchi et al, ²¹ 1981	Dual publication
Lehmann et al, ³⁰ 1983	Dual publication
Lovacky et al, ³³ 1987	Not randomized
Hackett et al, ²⁴ 1988	Not needle acupuncture
Mencke et al, ^{40,41} 1988	Acupuncture compared with acupuncture
Li et al, ³⁴ 1989	Not randomized
Kitade et al, ²⁶ 1990	Acupuncture compared with acupuncture plus D-phenylalanine
Ishimaru et al, ²⁵ 1993	Acupuncture compared with heated-needle acupuncture
Kovacs et al, ²⁸ 1993	Author specified "not acupuncture"

META-ANALYSES

Nine studies presented data in a form suitable for inclusion in the meta-analyses. The results of the primary meta-analysis are presented in **Figure 1**. A total of 377 patients was included in the trials, and the overall OR was 2.30 (95% CI, 1.28-4.13). There was no significant heterogeneity between studies ($\chi^2_8 = 12.58$, $P > .1$).

In 3 studies^{16,17,23} the outcome was markedly more positive than in the remainder. These studies have no uniformity of inclusion criteria, acupuncture approach, setting, or end points that could account for the divergence. Alternative (more favorable) outcome data were available in 1 study,¹⁷ yielding a new OR for all studies combined (Figure 1) of 2.54 (95% CI, 1.32-4.88).

META-ANALYSES OF SUBGROUPS

The results of the meta-analyses of studies grouped according to design features are given in **Figure 2**. The OR of the 4 sham-controlled, evaluator-blinded studies^{17,18,22,39} was 1.37 (95% CI, 0.84-2.25). The results were not meaningfully affected by length of follow-up, quality of acupuncture, type of acupuncture, or number of sessions. There are trends worthy of discussion but CIs of comparisons overlap, indicating that no firm conclusions can be drawn from these data.

STUDIES EXCLUDED FROM THE META-ANALYSIS

Three studies presented results in a form that was unsuitable for inclusion in this meta-analysis: Macdonald et al³⁵ concluded that acupuncture was significantly superior to control intervention, Yue⁴⁴ found a positive trend favoring acupuncture, and Gallacchi et al²¹ showed no superiority of acupuncture over sham acupuncture. The total sample size of these 3 studies was 95. It seems un-

likely that the omission of these studies seriously undermines the accuracy of the meta-analyses.

The funnel plot is presented in **Figure 3**. The studies are not evenly distributed around the combined OR, but there are too few studies to conclude whether publication bias has influenced the result of the meta-analysis.

COMMENT

Collectively, these data suggest that acupuncture is an effective treatment for back pain. The assessment of acupuncture for back pain is notoriously difficult for several reasons: there are many variations of acupuncture (eg, points used, method of stimulation) that are not necessarily comparable; back pain is not a distinct entity but an ill-defined category of complaints with diverse causes; acute back pain frequently disappears within days with or without treatment; concomitant treatments abound; and there is no objective, universally accepted outcome measure. The trials included in this analysis are heterogeneous in terms of study population, type of acupuncture used, outcome measure used, and length of follow-up. Thus, it is problematic to form a firm judgment.

Our search strategy was as comprehensive as possible. Yet, it is possible that some trials were not located. In particular, negative trials may not be published.⁴⁵ We also suspect that complementary medicine journals are heavily biased toward positive results.⁴⁶ Thus, systematic reviews could easily become distorted. Unfortunately, the present material gives no firm indication for or against the existence of a publication bias and we are unable confidently to exclude this source of error in our analysis.

One inclusion criterion for this analysis was randomization. We, therefore, dealt with trials of relatively high standard. The quality ratings (Table 3) show that the methodological quality was good in the majority of the studies. Only 2 trials, both published in the 1970s, were of low quality. Thus, the present meta-analysis is based largely on rigorous research, which lends weight to its findings.

All the studies recruited patients with chronic pain or who had failed to respond to conventional therapy. Only 2 studies^{17,43} specifically excluded patients with previous back surgery. Thus, the majority of study participants were associated with a poor prognosis and belonged to a category that is notoriously difficult to treat. The fact that nonetheless the overall result is positive suggests that acupuncture can be helpful even for difficult cases of back pain.

In most studies, the follow-up period was inadequate. Two studies^{28,43} suggest that the result measured immediately after treatment may be sustained if not improved (Figure 2). Unfortunately, this sample is too small to draw any conclusions, and the long-term effects of acupuncture on back pain remain uncertain. This, it seems, could be a fruitful area of future research.

The subgroup analyses revealed interesting trends. The OR of unblinded studies is larger than that of studies in which blinding had been introduced. This trend might indicate the importance of patient and therapist

Table 2. Details of Randomized Sham-Controlled Trials of Acupuncture for Back Pain*

Source, y	Design	No. (Treatment, Controls)	Patients
Edelist et al, ¹⁸ 1976	RCT, pt + evaluator blind, 2 parallel arms	15, 15	LBP, no response to conventional treatment
Yue, ⁴⁴ 1978	RCT, evaluator blind, 3 parallel arms	23, ?, ?	23 pts with chronic back or neck pain in experimental group
Lopacz and Gralewski, ³² 1979	RCT, nonblind, 2 parallel arms	18, 16	LBP >1 mo without root irritation
Coan et al, ¹⁶ 1980	RCT, nonblind, 2 parallel arms	25, 23	Chronic LBP
Gunn et al, ²³ 1980	RCT, nonblind, 2 parallel arms	29, 27	Chronic LBP, no response to conventional treatment
Gallacchi et al, ²¹ 1981	RCT, nonblind, 8 parallel arms	13 to 15 in each group	Chronic "tendomyotic cervical and lumbar syndrome"
Duplan et al, ¹⁷ 1983	RCT, pt + evaluator blind, 2 parallel arms	15, 15	Acute LBP, admitted to hospital for no response to conventional treatment
Macdonald et al, ³⁵ 1983	RCT, pt + evaluator blind, 2 parallel arms	8, 9	Chronic LBP, no response to conventional treatment
Mendelson et al, ³⁹ 1983	RCT, pt + evaluator blind, crossover	77	Chronic LBP
Lehmann et al, ³⁰ 1983	RCT, nonblind, 3 parallel arms	17, 18, 18	Chronic, disabling LBP
Garvey et al, ²² 1989	RCT, pt + evaluator blind, 4 parallel arms	20, 13, 14, 16	Nonradiating LBP (>4 wk), no response to conventional treatment
Thomas and Lundeborg, ⁴³ 1994	RCT, nonblind, voluntary crossover, with untreated controls	40	Chronic "nociceptive" LBP

*Acup indicates acupuncture; RCT, randomized controlled trial; pt, patient; LBP, low back pain; EA, electroacupuncture; question mark, no sample size given for control groups; NA, not applicable; VAS, visual analog scale; SLR, straight-leg raising; and TENS, transcutaneous electrical nerve stimulation.

†End point used in the meta-analysis (not a primary end point if in parentheses).

expectations in terms of clinical outcome and suggests that acupuncture (like most hands-on interventions) is associated with a powerful placebo effect.⁴⁷ In 2 studies^{16,32} acupuncture was rated as inadequate, yet tended to be more effective than that judged as adequate. This seems counterintuitive at first glance but might be explained quite easily. In both cases, the descriptions of the acupuncture were minimal. Difficulty in judging the trials was reflected in the large SDs of the experts' scores (Table 3). Thus, the acupuncture technique was poorly described in these reports, but may still have been of good quality. Furthermore, it is relevant to note that both individualizing the selection of points for treatment and repeating the acupuncture more than 4 times were associated with larger effect sizes. The latter trend would be compatible with the dose-response curve of an effective therapy.

In a review of 7 acupuncture trials of acupuncture for pain, including back pain, Deyo⁴⁸ concluded that "acupuncture is little more effective than placebo therapy which mimics active treatment." Our subgroup analysis of 4 sham-controlled, evaluator-blinded studies yielded a combined OR of 1.37 (95% CI, 0.84-2.25) in favor of genuine acupuncture. Although this finding is not conclusive, it does suggest that further trials are justified to determine whether acupuncture works through specific or nonspecific effects.

It has been suggested that sham acupuncture is an unfair comparison since needling the skin can relieve pain through the process of diffuse noxious inhibitory control.⁴⁹ This effect can be minimized by needling non-meridian, nontender points. Future studies should include both sham-control groups and other comparison groups in parallel. The optimal study in acupuncture for back pain should be randomized and fully blinded, with an adequate acupuncture technique and follow-up. It should include a sample size based on power calculation, should evaluate success with a widely accepted outcome measure, and should test acupuncture on a homogeneous subtype of back pain that has previously been suggested to respond favorably. In light of the poor reporting quality of some acupuncture trials (see above), the optimal study should, of course, detail all aspects of the method accurately.

If one accepts that acupuncture is an effective form of treatment for back pain, one might ask about its value compared with other forms of treatment. So far, only exercise treatments,⁵⁰ transcutaneous electrical nerve stimulation (TENS),⁵¹ and spinal manipulation⁵² have been evaluated in a systematic way. Koes et al⁵⁰ concluded that it is "uncertain whether exercise is better than other conservative treatments for back pain or whether a specific type of back pain is more effective." The review by Gadsby

Intervention (No. of Treatments)	Primary End Points	Follow-up	Result (Significance)	No. Improved in Each Group	
				Acup	Control
Formula EA vs sham acup (3)	Evaluator's rating of change† including pt report	None	No intergroup differences	7/15	6/15
Formula acup vs sham acup vs physiotherapy (not stated)	Pain, range of movement	None	Acup was superior to physiotherapy but not to sham	NA	NA
Formula acup + sodium chloride injection vs sham electrical stimulation (4)	Global assessment by 2 physicians†	None	Acup superior to controls ($P>.05$)	14/18	10/16
Individualized traditional acup vs waiting-list controls (11)	Pain score (combined pt and evaluator rating†)	10-15 wk	Pain reduction: acup, 51%; controls, 2%	19/23	5/16
Needling at muscle motor point (mean 7.9) + standard physiotherapy vs physiotherapy alone	Pain and work status†	12-42 wk	Needling superior to controls ($P<.01$)	18/29	4/27
Formula acup vs 2 forms of sham acup vs 5 forms of laser acup (8)	VAS for pain	None	All groups improved, no intergroup differences	NA	NA
Formula acup vs sham acup (5)	Pain VAS (1) on standing 10 min,† (2) on resting†	None	Acup superior to sham for severe pain, supported by SLR changes	(1) 11/15 (2) 13/15	(1) 6/15 (2) 5/15
Superficial needling (with or without EA) vs sham TENS (10)	VAS for pain	None	Pain reduction greater after needling ($P<.01$)	NA	NA
Formula acup vs lidocaine injections (8)	VAS for pain (>33% relief†)	4, 12, and 16 wk	No significant difference between groups	44/77	41/77
Individualized EA (6) vs TENS (15) vs sham TENS (15); + education and exercise program	VAS for pain and disability + physician's assessment (return to work†)	Immediate and 6 mo	EA superior to TENS ($P<.11$); no difference between TENS and sham TENS	10/17	10/18
Trigger point needling vs vapocoolant spray + acupressure vs lidocaine injection vs lidocaine + corticosteroid injection (1)	Pt assessment of improvement†	None	Needling and acupressure yielded the best results ($P>.05$)	11/20	8/16
Flexible formula acup vs low-frequency EA vs high-frequency EA by pt choice (average 6.8) vs waiting-list controls	Activity related to pain, mobility, verbal descriptors of pain, pt assessment of improvement†	Immediate, 6 wk, 6 mo	After 6 wk all EA groups superior to untreated controls ($P<.05$); after 6 mo this was only the case for low-frequency EA	17/30	4/10

Table 3. Meta-analysis of Acupuncture for Back Pain: Quality Assessment Scores of Included Studies*

Source, y	Expert Assessment Score, Mean (SD)†	Adequacy of Acupuncture‡	Quality Assessment Score			
			Randomization	Blinding	Dropouts	Total
Duplan et al, ¹⁷ 1983	46.5 (30.6)	1	1	2	1	5
Edelist et al, ¹⁸ 1976	49.0 (31.9)	1	1	2	1	5
Garvey et al, ²² 1989	31.3 (34.9)	1	1	2	1	5
Mendelson et al, ³⁹ 1983	50.7 (33.1)	1	1	2	0	4
Thomas and Lundeberg, ⁴³ 1994	69.5 (23.5)	2	1	0	1	4
Coan et al, ¹⁶ 1980	26.5 (34.2)	0	2	0	1	3
Gunn et al, ²³ 1980	53.3 (33.0)	1	1	0	1	3
Gallacchi et al, ²¹ 1981	45.3 (37.0)	1	1	0	1	3
Lehmann et al, ³⁰ 1983	41.5 (26.8)	1	1	0	1	3
Macdonald et al, ³⁵ 1983	43.3 (24.1)	1	1	0	1	3
Lopacz and Gralowski, ³² 1979	9.3 (5.3)	0	1	0	0	1
Yue, ⁴⁴ 1978	18.8 (35.6)	0	1	0	0	1

* In descending order of quality.

† Adequacy of acupuncture was assessed by expert panel on visual analog scale (VAS) of 0 to 100.

‡ Points awarded for VAS score less than 33, zero points; VAS score of 33 to 66, 1 point; and VAS score greater than 66, 2 points.

and Flowerdew⁵¹ “provides some evidence to support the use of TENS.” Finally, a meta-analysis of spinal manipulation found that it was of short-term benefit.⁵² The last findings are so convincing that several national guidelines now recommend spinal manipulation as a first-

line treatment.^{53,54} It is interesting, therefore, to see that the overall OR calculated by Shekelle et al⁵² for all 7 randomized control trials meta-analyzed is similar to the one emerging from this article (OR, 2.0 [95% CI, 1.48-2.77] for spinal manipulation compared with 2.30 [95% CI,

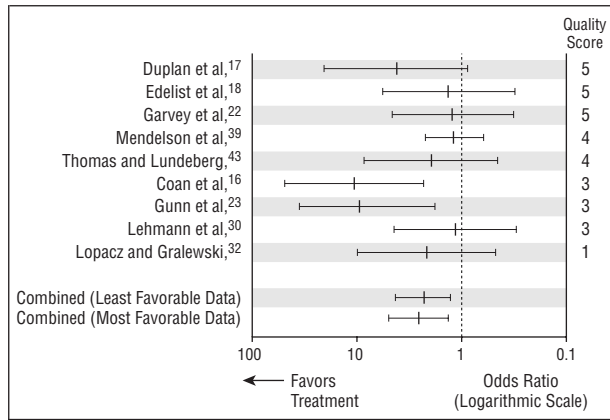


Figure 1. Meta-analysis of randomized controlled trials of acupuncture for back pain, in descending order of quality.

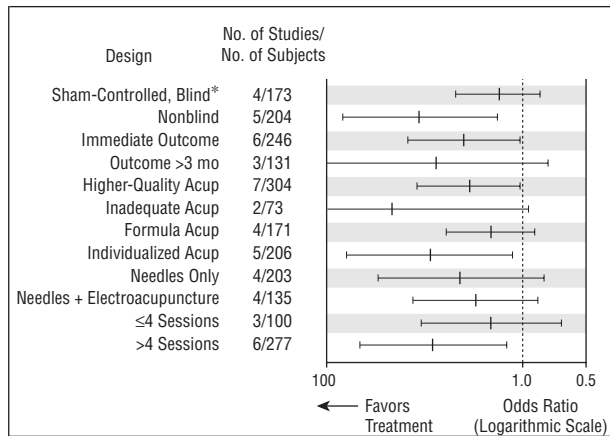


Figure 2. Meta-analyses of randomized controlled trials of acupuncture (Acup) for back pain grouped according to common design features. Asterisk indicates patient- and evaluator-blinded design.

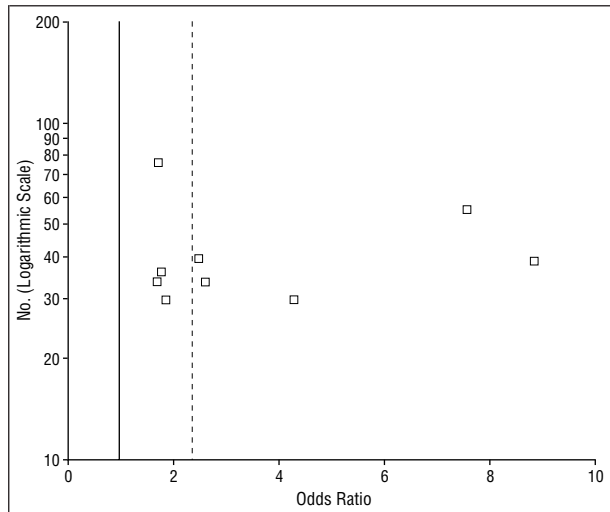


Figure 3. Funnel plot showing individual odds ratios of randomized controlled trials of acupuncture for back pain against sample size. Continuous line indicates an odds ratio of 1 (no effect); dashed line, combined odds ratios of trials.

1.28-4.13] for acupuncture). This suggests equal effectiveness for both treatments. However, the usefulness of a therapy is not only determined by effectiveness—safety and costs are other factors. In 2 recent surveys, we

found adverse reactions of acupuncture to be considerably less frequent than those of spinal manipulation.⁵⁵ Unfortunately, no fully conclusive data about the true prevalence of adverse effects for either method exist. This, it seems, is another area of important research for the future. The costs of acupuncture may well be lower than for spinal manipulation: treatment sessions are usually shorter and often less frequent. When 1020 episodes of back pain were investigated, chiropractors had a greater mean number of visits per episode than any other profession,⁵⁶ which is supported by other data.⁵⁷ Considering the socioeconomic importance of back pain,² it would be relevant to establish the relative cost-effectiveness of all major treatments for this condition.

In conclusion, the combined result of all studies shows acupuncture to be superior to various control interventions. The combined results of 4 sham-controlled, evaluator-blinded studies did not show acupuncture to be superior to placebo; further studies are required to conclude with certainty whether acupuncture has specific effects in addition to its nonspecific effects.

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