

Meta-Analysis: Acupuncture for Low Back Pain

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Background: Low back pain limits activity and is the second most frequent reason for physician visits. Previous research shows widespread use of acupuncture for low back pain.

Purpose: To assess acupuncture's effectiveness for treating low back pain.

Data Sources: Randomized, controlled trials were identified through searches of MEDLINE, Cochrane Central, EMBASE, AMED, CINAHL, CISCOP, and GERA databases through August 2004. Additional data sources included previous reviews and personal contacts with colleagues.

Study Selection: Randomized, controlled trials comparing needle acupuncture with sham acupuncture, other sham treatments, no additional treatment, or another active treatment for patients with low back pain.

Data Extraction: Data were dually extracted for the outcomes of pain, functional status, overall improvement, return to work, and analgesic consumption. In addition, study quality was assessed.

Data Synthesis: The 33 randomized, controlled trials that met inclusion criteria were subgrouped according to acute or chronic

pain, style of acupuncture, and type of control group used. The principal measure of effect size was the standardized mean difference, since the trials assessed the same outcome but measured it in various ways. For the primary outcome of short-term relief of chronic pain, the meta-analyses showed that acupuncture is significantly more effective than sham treatment (standardized mean difference, 0.54 [95% CI, 0.35 to 0.73]; 7 trials) and no additional treatment (standardized mean difference, 0.69 [CI, 0.40 to 0.98]; 8 trials). For patients with acute low back pain, data are sparse and inconclusive. Data are also insufficient for drawing conclusions about acupuncture's short-term effectiveness compared with most other therapies.

Limitations: The quantity and quality of the included trials varied.

Conclusions: Acupuncture effectively relieves chronic low back pain. No evidence suggests that acupuncture is more effective than other active therapies.

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Low back pain is the most common cause of activity limitation in people younger than 45 years of age in the United States and is the second most frequent reason for visits to the physician (1). A 1997 U.S. survey showed that 54% of patients reporting back or neck pain had used a complementary therapy within the past year (2), while a 2002 study showed back pain to be the most common reason for visits to acupuncturists in the United States (3). Given this high degree of public interest, the question of whether acupuncture alleviates low back pain is relevant.

Before our study, at least 3 publications systematically reviewed the primary research up to 1996 (4–6). Their conclusions, limited by the paucity, heterogeneity, and poor quality of the studies, were somewhat discordant. Several new studies have since been published. Some of these studies have been reviewed (7), but the review did not take full account of study quality and did not attempt a meta-analysis of the data.

We decided to undertake a new systematic review and meta-analysis to test the hypotheses that, for treating low back pain, acupuncture is more effective than penetrating and non-penetrating sham acupuncture, other sham treatments, active treatments, and no treatment. In addition, we address the hypothesis that treatment effect size is correlated with study quality, treatment factors, and patient factors.

METHODS

Search

We searched the following computerized databases from their inception until August 2004: MEDLINE; Coch-

rane Central; EMBASE; AMED; CINAHL; and 2 specialized European databases (CISCOP in London, United Kingdom [to February 2003], and GERA in La Garde, France) that include “gray literature,” such as unpublished studies and conference reports. We performed text word searches of titles and abstracts for *acupuncture*, *electroacupuncture*, *percutaneous electrical nerve stimulation*, and *backache*, *back pain*, *low back pain*, *dorsalgia*, and *lumbago*. We contacted experts in Japan who updated their earlier search of Igaku Chuo Zasshi (1987–2003) (8) and also hand-searched the *Journal of the Japan Society of Acupuncture and Moxibustion* (2000–2004). We reconsidered all studies that were included in previous reviews (4–7) for inclusion in our review.

In addition, we screened our own files, and we contacted experts in the United Kingdom, United States, Germany, Italy, Sweden, and Norway and asked them to con-

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Context

Many people with back pain seek treatment with acupuncture, but the effectiveness of acupuncture for low back pain is controversial.

Contribution

This meta-analysis of 33 randomized, controlled trials that compared acupuncture with sham, other active, or no treatment found evidence that acupuncture is more effective than sham or no treatment for patients with chronic low back pain. Evidence about acupuncture's effectiveness compared with other active treatments or for patients with acute back pain is inconclusive.

Cautions

Quality of included trials varied.

—The Editors

tribute any studies of which they were aware (see Acknowledgments). We obtained copies of all papers that could be reports of randomized, controlled trials (RCTs) or reviews of RCTs (9). We scanned the bibliographies of all papers retrieved for further references. We excluded unpublished reports.

Study Selection

Two authors independently considered articles reporting random assignment of human participants to acupuncture or a control group for the treatment of any type of low back pain for inclusion. We excluded studies that included both patients with neck and low back pain, unless the data for patients with low back pain were available separately. We defined “acupuncture” in an inclusive manner to reflect its use in various traditions and theoretical approaches: The intervention had to involve the insertion of needles into the skin, but not for the purpose of injection. This definition includes any intervention that the study author or authors described as “acupuncture” or that the reviewers clearly identified as acupuncture. We excluded therapies that are similar to acupuncture but do not involve needle insertion (for example, laser acupuncture and electroacupuncture without needles) because most authorities believe acupuncture entails needle insertion (10). We excluded trials that compared 1 form of acupuncture only with another form. We included studies that provided usable data for any of the following outcome measures: pain, measures of functional status (for example, Oswestry and Roland Disability Questionnaire), overall improvement, return to work, and analgesic consumption. We excluded studies that reported only relief of pain immediately after a single treatment with acupuncture.

We included reports written in English, Japanese, Korean, and Chinese, as well as in Germanic (including Scandinavian) and Romance languages. Where necessary, we obtained translations of essential details. When more than

1 publication described a single trial, we included only 1 report.

Data Abstraction

Two authors abstracted data independently onto a piloted spreadsheet, except in the case of non-English-language articles, from which an expert extracted data and checked them in-house (see Acknowledgments). Differences were settled by discussion with reference to the original article. In the few instances where disagreements persisted, we consulted an additional independent researcher who is an expert in review methods. For our purposes, we defined 3 styles of acupuncture and 3 methods (Table 1).

We extracted data for 5 outcome categories (pain, functional status, overall improvement, return to full work, and analgesic consumption) where available.

We extracted outcomes for all time intervals reported. We considered outcomes less than 6 weeks to be short-term, and we used the measurement closest to 3 weeks for the meta-analysis. We considered outcomes more than 6 weeks to be long-term, and we included the measurement closest to 6 months in the meta-analysis. For crossover studies, we considered the risk for carryover effects to be prohibitive, so we considered only the first group of the study.

Quality Assessment

We assessed the quality of the studies in 2 ways. First, by using a modification of a validated method (11), we awarded a maximum of 5 points in 3 categories: randomization (2 points for an appropriate method, 1 point if method not described, or 0 points for an inappropriate method); blinding (1 point for patient blinding and 1 point if blinding was tested after treatment); and withdrawals and dropouts (1 point if a statement gave full details of withdrawals and dropouts or confirmed that no patient withdrew or dropped out). As recommended (11), a score of 2 points or less indicates poor quality.

Second, we assessed quality by using 10 criteria taken from the Cochrane Back Review Group (Table 2) (12), used in a recent review (13), extracted by 1 author with random confirmation by another author. A score of 4 points or less indicates poor quality.

Quantitative Data Synthesis

We placed the studies into predefined subgroups defined according to the following criteria: 1) acute (≤ 3 months) or chronic (> 3 months) low back pain (where not described, a decision was made from the trial setting and recruitment information [for example, we considered primary care to include acute pain and secondary care to cover chronic pain]); 2) style of acupuncture (Table 1); and 3) control group (sham acupuncture involving needle penetration, nonpenetrating sham acupuncture, sham transcutaneous electrical nerve stimulation [TENS] [Table 1], no additional treatment, and other active treatments). The no-additional-treatment control grouping includes studies that administered adjunctive treatment, such as

Table 1. Acupuncture-Related Terms and Their Relevance*

Term	Definition and Relevance
Acupuncture	A healing technique that involves the insertion of needles into the body to promote health. It can be traced back at least 2500 years as part of the healing system in China.
Sham controls in acupuncture research	
Sham acupuncture	Any intervention designed to make patients believe that they are receiving acupuncture. Usually this involves inserting needles superficially and/or at inappropriate sites, and not stimulating them, known as "penetrating" sham. Blunt devices are occasionally used to apply pressure, without penetration.
Sham TENS	A procedure that involves attaching 1 end of a TENS electrode to the patient's skin and the other end to an inactivated apparatus. This intervention is designed to at least partially control for the placebo effects of acupuncture treatment.
Styles of acupuncture	
Chinese acupuncture	Needles inserted into traditional meridian points, usually with the intention of influencing energy flow in the meridian. Additional tender points may also be used.
Japanese acupuncture	Superficial needling in the area of the pain and traditional points, using traditional Chinese concepts.
Western acupuncture	The use of unnamed tender or trigger points only, to stimulate nerves or muscles, rejecting traditional concepts of energy and meridians. This treatment may not be accepted as "acupuncture" by traditional acupuncturists.
Methods of selecting acupuncture points	
Individual	The practitioner is free to choose any point.
Formula	The same fixed points are used for all patients.
Flexible formula	A fixed formula is used and some additional points are chosen according to a patient's tenderness or symptoms.
De qi	"Arrival of energy": A sensation of numbness or distention sometimes generated by stimulating acupuncture needles by hand or with an electrical current. According to acupuncture theory, activation of de qi may be one indication that acupuncture is exerting its beneficial effects.

* We hypothesized that the effects of acupuncture treatment may be correlated with methods of selecting acupuncture points, de qi, and many other treatment-related factors. TENS = transcutaneous electrical nerve stimulation.

physical therapy, to both the acupuncture and the control group and also includes those studies in which the control intervention consisted of providing patients with educational materials on low back pain.

The primary outcome of the review was quantitative synthesis of the short-term effectiveness of acupuncture on pain in each category. To test whether sham acupuncture and controlled trials of sham TENS were sufficiently ho-

mogeneous to combine for the secondary analyses, we used the I^2 method (14).

We used Comprehensive Meta-Analysis software (Biostat, Inc., Englewood, New Jersey) for data analysis. We used the inverse-variance computational model, and we used the more conservative random-effects model to account for the expected heterogeneity. We performed separate analyses for each main outcome measure by using standardized mean difference (the Hedge g effect size) or odds ratio, depending on the nature of the measure. For the standardized mean difference, 1 unit of effect size for pain and functioning corresponds with a 25-point difference on the visual analogue scale (VAS) and a 6-point difference on the Roland Disability score. Using standards established by the Cochrane Back Group Editorial Board, we considered a minimum 10-mm difference on the VAS and a 2-point difference on the Roland Disability score to be clinically important (13). We analyzed short-term end points and long-term end points, as defined earlier. When the studies in any predefined subgroup were clinically very heterogeneous or insufficient data were reported for pooling, we planned to use a narrative synthesis rather than a meta-analysis. We assessed for the likelihood of small study bias by using a funnel plot.

In reports that did not provide these values, we used the method previously described (13), in which the median is the mean and the SD is 25% of the measure's range. To test the effect of these assumptions, we performed a sensitivity analysis on the short-term pain primary outcome measure, substituting imputed mean values both 1 SD higher and 1 SD lower than the imputed values and then substituting an SD equal to the maximum of any study (80% [15]).

Finally, we used the I^2 tests to evaluate whether the results of the effects of acupuncture at different levels of any of the quality criteria-, treatment-, or patient-related factors were heterogeneous. We conducted these heterogeneity analyses separately for the sham-controlled and no-additional-treatment-controlled sets of trials on the short-term pain outcome. We based the cut-points for

Table 2. Cochrane Back Review Group Criteria List for Methodologic Quality Assessment of Randomized, Controlled Trials*

Criteria
Was there a randomization method using an adequate procedure?
Was the treatment allocation concealed?
Was the care provider blinded to the intervention?
Was there control for co-interventions?
Were co-interventions reported for each group separately?
Was the patient blinded to the intervention?
Was the outcome assessor blinded to the intervention?
Was the withdrawal and drop-out rate <20% short-term and <30% long-term with no substantial bias?
Was the timing of the outcome assessment in both groups similar?
Was the analysis done according to intention-to-treat?

* Adapted from van Tulder et al. (12).

Table 3. Study Characteristics and Results of Studies Not Combined in Meta-Analysis*

Study, Year (Reference)	Quality†	Acupuncture Type; Number of Sessions; Times per Week	Patients Assigned to Acupuncture Group, n	Control Interventions	Patients Assigned to Control Group, n
Acute low back pain					
Duplan et al., 1983 (27)	2; 5	Chinese; 5; 5	15	Sham acupuncture	15
Kittang et al., 2001 (37)	3; 3	Chinese; 4; 2	30	NSAID	30
Kurosu, 1979 (38)	1; 0	Chinese; 3; NR	10	Moxibustion	10
Tsukayama et al., 2002 (49)	3; 4/5	Chinese; 4; 2	10	TENS	10
Antenatal low back pain					
Wedenberg et al., 2000 (51)	1; 2	Chinese; 10; 1 or 2	27	Usual care	34
Kvorning et al., 2004 (39)	3; 5	Chinese; 6; 2 then 1	34	Usual care	34
Guerriero da Silva et al., 2004 (33)	3; 2	Chinese; 6; 1	30	Physical therapy	30
Chronic low back pain, western acupuncture					
Garvey et al., 1989 (29)	3; 5	Western; 1; NA	20	a) TP injection; b) spray + acupressure	a) 27; b) 16
Gunn et al., 1980 (34)	1; 1	Western; 8; 2	29	No acupuncture	27
Macdonald et al., 1983 (42)	1; 3	Western; 10; 1	8	Sham TENS	9
Yokoyama et al., 2004 (53)	2; 2/3	Western; 16; 2	20	TENS	20

*JOA = Japanese Orthopaedic Association measure function; NA = not applicable; NR = not reported (or details not clear); NSAID = nonsteroidal anti-inflammatory drug; TENS = transcutaneous electrical nerve stimulation; TP = trigger point; VAS = visual analogue scale.

† Modified Jadad quality score (range, 0–5); Cochrane Back Review Group quality score (range, 0–10). Higher alternative score indicates that one outcome was assessed masked.

‡ Measurement points: follow-up time points are duration from end of treatment.

dichotomizing levels of the treatment- or patient-related factors on a literature review of earlier clinical trials and systematic reviews, practice patterns of acupuncturists, and Eastern texts. For example, we dichotomized the number of sessions at 6 or more versus fewer than 6 sessions because an earlier systematic review (16) showed that 6 or more treatments was associated with better effects of acupuncture. On the basis of our literature review, we set cut-points for treatment factors (individualized vs. formulaic [16], number of needles [16–18], obtaining de qi [16, 19], number of treatments [16, 17], length of each session [20], number of sessions per week, and manual vs. electrical stimulation) and patient factors (in primary or secondary–tertiary care, previous surgery or no previous surgery, and leg pain or no leg pain). The Appendix (available at www.annals.org) includes additional details on methods.

Role of the Funding Sources

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the British Medical Acupuncture Society. The funding sources had no role in the design, conduct, or reporting of the study or in the decision to submit the manuscript for publication.

RESULTS

We considered 561 possibly relevant references (see **Appendix Figure 1**, available at www.annals.org), of which we retrieved full copies for 82 papers and 5 new reviews. We excluded 3 studies that were included in previous reviews: 1 for insufficient data (21), 1 for not presenting separate results for patients with low back pain (22), and 1 for using saline injections rather than acupuncture (23). We included 33 studies in our review (15, 24–55). Ten studies were from previous reviews (26–29, 34, 40, 42, 43, 48, 50), 16 were new studies from our own files or were identified through MEDLINE (24, 25, 30–33, 36, 37, 39, 41, 44, 45, 49, 51–53), 3 were from the GERA database

Table 3—Continued

Any Co-Intervention (Except Drugs) in All Groups	Pain Measure	Function Measure	Global Score; Work; or Drug Intake	Measurement Points (Not All Outcomes at All Points)†	Result (Main Comparison)
–	VAS on standing	–	Analgesic use	End of treatment	Acupuncture significantly superior for both outcomes
–	VAS	–	Analgesic use	End of treatment, 3 mo, 6 mo	VAS, no significant difference; acupuncture, significantly fewer drugs
–	Change rating (from –1 to +2)	–	–	End of treatment	No significant difference
–	VAS pain relief	JOA	–	End of treatment	Acupuncture significantly superior for pain only
–	Numeric rating scale (average pain)	Numeric rating scale	Global, 10 points (patient); analgesic use; work capacity, 10 points	End of treatment	Acupuncture significantly superior for all outcomes
–	Numbers with decrease in pain	Effect of pain on 8 activities (3 points)	Analgesic use	End of treatment	Acupuncture significantly superior for all outcomes
–	VAS, evening	Disability rating index	Global (“good or excellent help”)	End of treatment	Acupuncture significantly superior for pain and disability
Showers, activity restriction	–	–	Global, 2 points (patient)	2 wk	No significant difference between groups
Physical therapy	–	–	Fit for work	End of treatment	Acupuncture significantly superior
–	VAS pain, and VAS pain on activities	–	–	End of treatment	Acupuncture significantly superior for most outcomes
–	VAS peak pain	Physician assessment (4 points)	Anti-inflammatory drug use	End of treatment, 1 mo, 2 mo	Acupuncture significantly superior for all outcomes at end of treatment; no difference at 2 mo

(15, 54, 55), 1 was sent by an acupuncture researcher in Italy (46), and 3 were located by the Japanese searches (35, 38, 47). We obtained additional details on methods from another paper (56) and unpublished data from 5 authors (outcome data [24, 33, 48] and methodologic information [15, 46]).

Description of Studies

Table 3 describes the main study characteristics and summarizes the findings of the 11 RCTs that could not be combined because of their fundamental heterogeneity. Four RCTs were in patients with acute low back pain and used different control interventions, 3 were in patients with pregnancy-associated low back pain, and 4 evaluated western-style acupuncture for patients with chronic low back pain and used various control interventions.

Table 4 gives the characteristics of the 22 RCTs of Chinese acupuncture for chronic low back pain that we included in the meta-analyses. (Appendix Tables 1 to 6, available at www.annals.org, contain further study details.)

Eight trials include patients with more severe status, either because they were located in an inpatient care (40, 45), tertiary care (24, 46), or rehabilitation unit (15) setting or because they included a large number of patients with leg pain (26, 52) or patients who had previously had back surgery (26, 40, 41, 46). In 9 studies, all patients were offered co-interventions: physical therapy in 3 studies (15, 41, 45), back exercises in 3 studies (25, 36, 52), education in 1 study (40), and Chinese massage in 2 studies (54, 55). Three studies (29–31) also included some patients with higher spinal (but not neck) pain, but we included them in our review. Most studies used well-validated instruments to measure pain (15, 24, 25, 30–32, 35, 36, 40, 41, 43–47, 52) and functional status (25, 30, 31, 35, 41, 44, 47, 52).

Data Synthesis

Figure 1 shows the short-term effectiveness of acupuncture on pain compared with each of the controls. Acupuncture is statistically significantly more effective than sham acupuncture, sham TENS, and no-additional-treat-

Table 4. Characteristics of Chinese Acupuncture Studies Included in Meta-Analysis*

Study, Year (Reference)	Quality†	Acupuncture Style‡; Number of Sessions; Times per Week	Patients Assigned to the Acupuncture Group, n	Control Intervention	Patients Assigned to the Control Group, n
Carlsson and Sjölund, 2001 (24)	4; 5	Formula EA; 10; 1	34	Sham TENS	16
Cherkin et al., 2001 (25)	3; 7 3; 7	Individual EA; 8; 1	94	a) Massage b) Self-care education	78 90
Coan et al., 1980 (26)	3; 2	Individual EA; 11; NR	25	No treatment	25
Edelist et al., 1976 (28)	2; 3	Formula EA; 3; 3	15	Sham acupuncture	15
Giles and Müller, 1999 (30)	3; 2 3; 2	Flexible formula EA; 6; 2	18	a) Manipulation b) Analgesic medication	32 20
Giles and Müller, 2003 (31)	3; 4 3; 4	Individual; 18; 2	36	a) Analgesic medication b) Manipulation	43 36
Grant et al., 1999 (32)	3; 5	Individual; 8; 2	32	TENS	28
Ito, 2000 (35)	2; 3	Individual EA; 4; 2	14	Medication: drugs and herbs	12
Kerr et al., 2003 (36)	2; 2	Formula; 6; 1	30	Sham TENS	30
Lehmann et al., 1986 (40)	2; 2 2; 2	Individual EA; 6; 2	17	Sham TENS TENS	18 18
Leibing et al., 2002 (41)	4; 6 3; 5	Formula; 20; 5	50	a) Sham acupuncture b) No treatment	50 50
Mazières et al., 1985 (15)	1; 3	NR; 6; 3	17	No treatment	17
Mendelson et al., 1983 (43)	3; 3	Flexible formula; 8; 2	36	Sham acupuncture	41
Meng et al., 2003 (44)	3; 5	Flexible formula EA; 10; 2	31	No treatment	24
Molsberger et al., 2002 (45)	4; 6 3; 4	Flexible formula; 12; 3	65	a) Sham acupuncture b) no treatment	61 60
Nobili et al., 1985 (46)	2; 3	Formula EA; 7; 3	24	TENS	24
Sakai et al., 2001 (47)	3; 4	Flexible formula EA; 5; 3	31	TENS	33
Thomas and Lundberg, 1994 (48)	2; 3	Flexible formula EA; 7; 2	33	No treatment	10
von Mencke et al., 1988 (50)	3; 6	Flexible formula; 6; 2	35	Sham acupuncture	30
Yeung et al., 2003 (52)	2; 7	Formula EA; 12; 3	26	No treatment	26
Zhang et al., 2002 (54)	1; 1	Individual EA; 10 to 60; 5	96	No treatment	98
Zhang, 2002 (55)	1; 1	Individual EA; 20; 2	30	No treatment	31

* EA = electroacupuncture; JOA = Japanese Orthopaedic Association measure function; NR = not reported (or details not clear); TENS = transcutaneous electrical nerve stimulation; VAS = visual analogue scale.

† Modified Jadad quality score (range, 0–5) (≥ 3 indicates good quality); Cochrane Back Review Group quality score (range, 0–10) (≥ 5 indicates good quality).

‡ EA indicates that the report states that needles were stimulated electrically in some or all patients.

§ Measurement points: Follow-up time-points are duration from end of treatment.

|| SD imputed from measure's range.

¶ Means imputed from medians.

** Outcomes or time-points in square brackets were not combined in meta-analysis.

†† Means imputed from percentage with pain relief.

ment controls for patients with chronic low back pain. The effect size of 0.58 for the comparison of acupuncture versus sham acupuncture corresponds with a clinically important improvement of 14.5 mm on the VAS. Acupuncture is not more effective than other active treatments and was statistically significantly less effective than spinal manipulation.

Figure 2 shows the long-term effects of acupuncture on pain. Acupuncture is statistically significantly more effective than the no-additional-treatment and sham TENS controls. Acupuncture is also more effective than the 4 sham-controlled trials combined (standardized mean difference, 0.61 [95% CI, .21 to 1.01]). Acupuncture is statistically significantly worse than massage (on the basis of the results of 1 trial).

Figure 3 shows the short- and long-term effects of acupuncture, compared separately with sham, no addi-

tional treatment, and the various active controls, on the outcomes of functional status and overall improvement. Since sham acupuncture and sham TENS trials were statistically homogeneous, we performed the analyses in Figure 3 after combining these studies.

For improving functioning, acupuncture was statistically significantly more effective than the no-additional-treatment control in the short-term effects (0.62 [CI, 0.30 to 0.95]) (Figure 3). For overall improvement, acupuncture was statistically significantly more effective than the sham controls and no-additional-treatment control in both the short- and long-term effects (Figure 4). Two trials assessed return to work and 3 trials assessed analgesic use, and no conclusions can be drawn from these data (Appendix Figures 2 and 3, available at www.annals.org).

Table 4—Continued

Any Co-Interventions (Except Drugs) in All Groups	Pain Measure	Function Measure	Global Score; Work; or Drug Intake	Measurement Points (Not All Outcomes at All Points)§
–	VAS morning	–	Global, 2 points (masked evaluator); fit for work; tablet intake	End of treatment, 1 mo, 3 mo, 6 mo
Exercise (some patients)	Bothersomeness rating	Roland Disability Score, modified	Analgesic use	End of treatment, 1 y
–	Numeric rating	Activity limitation (4 points)	Global, 2 points (patient)	1 mo
–	–	–	Global, 2 points (patient)	End of treatment
–	VAS ¶	Oswestry ¶	Global, 2 points (patient)	End of treatment
–	VAS ¶	Oswestry ¶	Global (“recovery”)	End of treatment End of treatment
–	VAS ¶	–	[Analgesic use]**	End of treatment, 3 mo
–	Numeric rating scale	JOA	–	End of treatment
Exercise booklet	VAS	–	Global, 2 points (patient)	End of treatment, 6 mo
Multidisciplinary education	VAS	–	Fit for work	End of treatment, 6 mo
Physical therapy	VAS	Pain Disability Index	–	End of treatment, 9 mo
Physical therapy	VAS	–	–	End of treatment
–	VAS	–	–	End of treatment, 10 wk
–	VAS	Roland Disability	Global, 2 points (patient)	[1 wk**], 4 wk
Conventional orthopedic treatment	VAS	–	Global, 4 points (patient); [analgesic use]**	End of treatment, 3 mo
–	50% reduction in VAS††	–	–	[End of treatment**], 1 mo, [3 mo**], 6 mo
Poultices	VAS	JOA	–	End of treatment
–	Number of descriptors checked	Listed activities with <50% pain	Global, 3 points (patient)	End of treatment, 6 mo
–	Pain scale (undefined)	–	–	End of treatment
Back exercises	Numeric rating scale	Aberdeen disability	Analgesic use	[End of treatment**], 1 mo, 3 mo
Tuina massage	–	–	Global, 3 points (patient)	End of treatment
Tuina massage, cupping	–	–	Global, 3 points (patient)	End of treatment

For the 7 sham-controlled trials, the results were clearly homogeneous (Figure 1), and no results on heterogeneity tests were positive for any criterion of the quality scales or patient- or treatment-related factor. For the no-additional-treatment-controlled trials, 3 heterogeneity test results were positive because of a heterogeneous factor in Cherkin and colleagues’ trial (25), which had different results from all the other no-additional-treatment-controlled trials. None of the following sensitivity analyses affected the statistical significance of the results: adjustment of the values of the imputed means and SDs, exclusion of the trials not reporting randomization procedures, or inclusion of only trials that included co-interventions or only trials that excluded co-interventions.

The interpretation of our funnel plots was hindered by the small number of large trials and the small number of

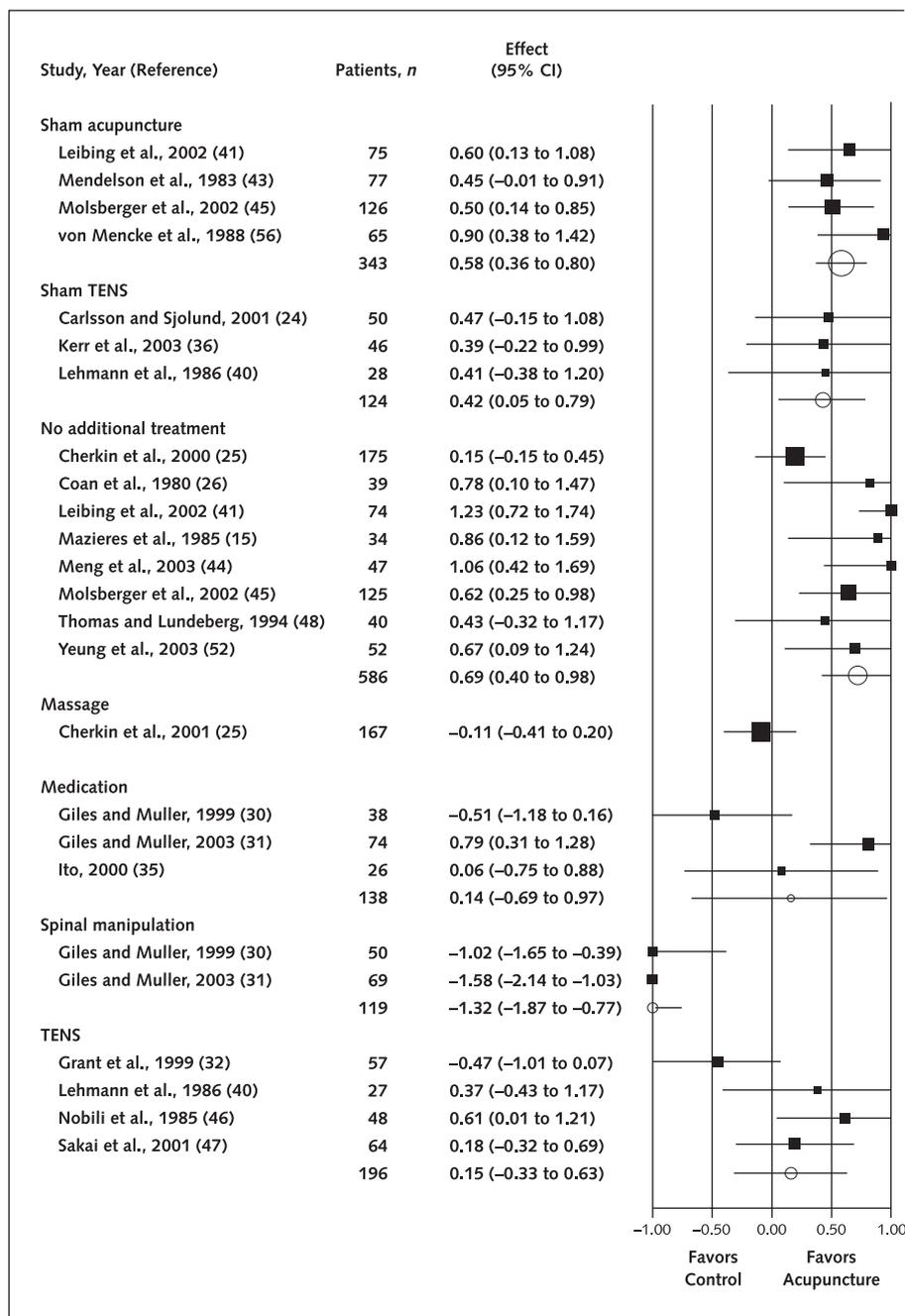
trials overall (Appendix Figures 4 to 6, available at www.annals.org).

DISCUSSION

Overall, data from the 22 randomized trials included in our meta-analyses suggest that acupuncture is an effective treatment for chronic low back pain. For patients with acute low back pain, data are sparse and inconclusive. Currently, no evidence suggests that acupuncture is more effective than other active therapies for chronic low back pain, and acupuncture seems less effective than spinal manipulation on the strength of 2 studies.

Drawing generalized conclusions is complicated by the fact that different RCTs used different controls, included

Figure 1. Short-term effects of acupuncture on pain.



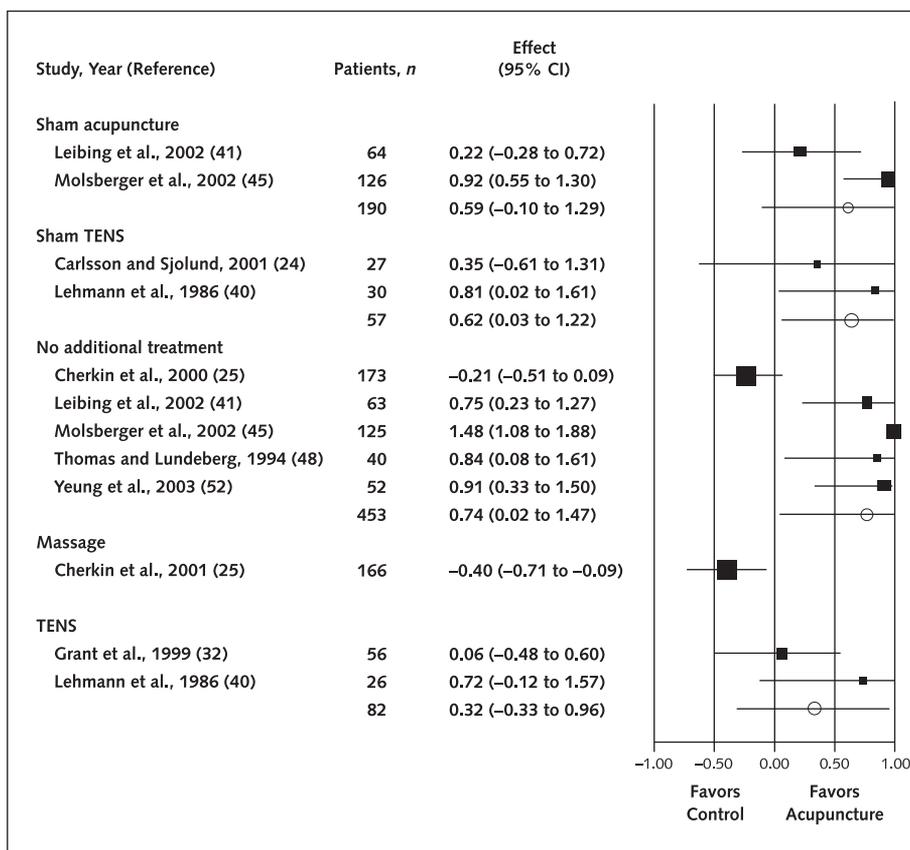
TENS = transcutaneous electrical nerve stimulation.

patients with different categories of pain, and evaluated different types of outcomes. To address the heterogeneity among studies, our protocol stipulated that short-term pain relief would be the primary outcome and that several meta-analyses would be conducted, stratifying by type of acupuncture, control, pain, and outcome. For the primary outcome of short-term pain relief among patients with chronic low back pain, acupuncture demonstrated statistically significant and clinically important benefits when compared with a sham treatment or no-additional-treat-

ment control but not when compared with other active therapies.

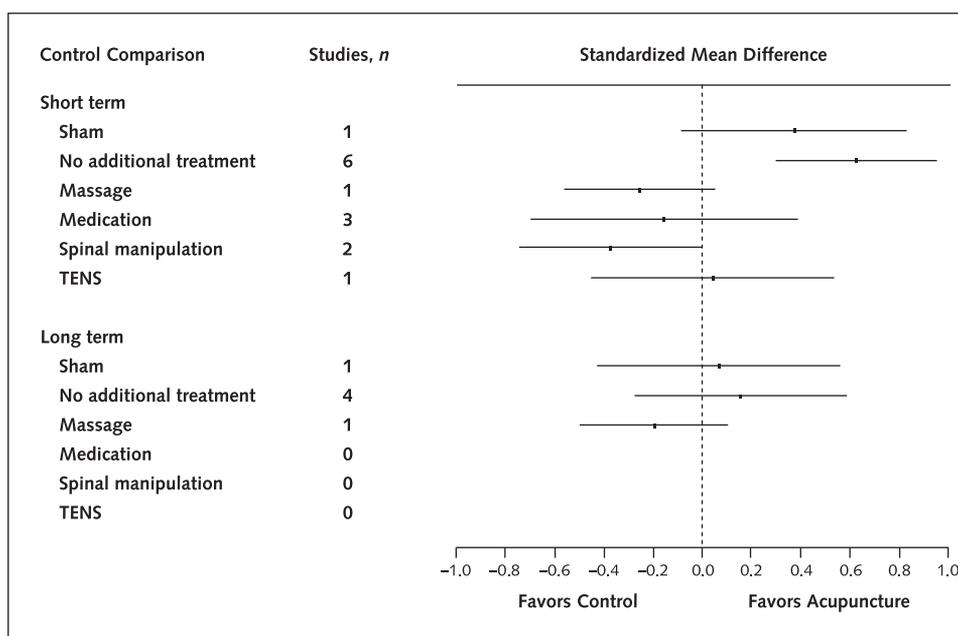
We analyzed studies comparing acupuncture with various different control types separately because different control comparators address different questions. In addition, each control has advantages and limitations that must be considered in interpreting the analysis results. A sham acupuncture control is intended to control for the nonspecific effects of acupuncture and addresses the following question: Are acupuncture's effects due to the specific ef-

Figure 2. Long-term effects of acupuncture on pain.



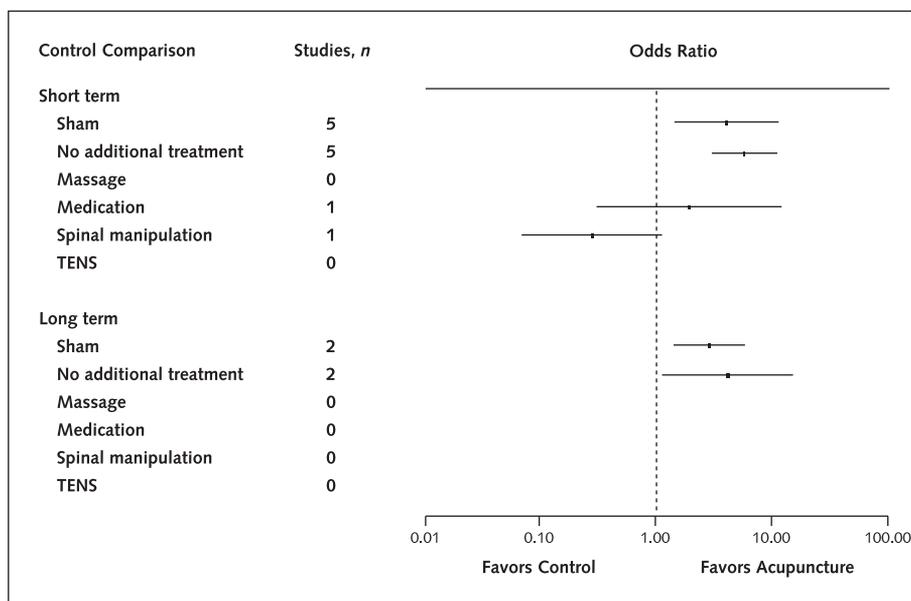
TENS = transcutaneous electrical nerve stimulation.

Figure 3. Functional status.



TENS = transcutaneous electrical nerve stimulation.

Figure 4. Overall improvement.



TENS = transcutaneous electrical nerve stimulation.

ffects of stimulating the points into which needles are inserted or to the nonspecific effects of the needles or treatment milieu in which acupuncture is administered? Sham acupuncture, while considered the most rigorous control because it enables the blinding of patients, evaluators, or both to treatment received, may also have the undesirable effect of underestimating the specific effects of acupuncture. Because the sham needles may unintentionally stimulate a physiologic response, sham acupuncture could have some specific analgesic effects (57, 58), especially when needles that penetrate the skin are used (as was the case for all sham acupuncture RCTs included in our meta-analysis). The sham-controlled RCTs generally showed less benefit of acupuncture compared with the no-additional-treatment-controlled RCTs (Figures 1 and 2). This was expected, assuming that inserting needles at nonspecific points has some therapeutic benefits or that acupuncture is associated with a placebo response. The no-additional-treatment control, while not blinded and therefore considered less methodologically rigorous, may be better than the sham control for estimating the total specific plus nonspecific effects of acupuncture under real-life conditions, as opposed to the decontextualized effects of inserting needles at specific points, which are best measured by using the sham control. Meta-analytic results from the no-additional-treatment control RCTs address the question of whether a policy of administering acupuncture is preferable to not treating patients with low back pain. The active control studies address the question of whether acupuncture is better than other active treatments for patients with low back pain. No evidence suggested that acupuncture was better than any other active treatment.

Our positive results concur with those from a meta-

analysis published by 2 authors in 1998 (4), in which the primary analysis showed an overall odds ratio of improvement of 2.30 (CI, 1.28 to 4.13) in favor of acupuncture. In that review (4), Ernst and White grouped all the identified studies together—regardless of type of control, pain, outcome, or acupuncture—for the same primary meta-analysis, thus allowing them to draw only general conclusions about acupuncture, as compared with an unspecified control for overall short-term improvement. Because our meta-analysis includes more than twice as many RCTs as in Ernst and White's study (4), (we included RCTs published since 1998, as well as earlier RCTs that Ernst and White [4] did not identify), our power to compare acupuncture versus distinct control categories is improved. While Ernst and White's review (4) could only suggest that acupuncture may be superior to a sham control, our update provides stronger evidence for acupuncture's superiority to sham control. We also can now quantitatively examine the longer-term effects of acupuncture. Our results suggest that acupuncture not only provides short-term amelioration but may also provide longer-term relief from chronic low back pain; however, additional sham-controlled RCTs are necessary to verify that these longer-term benefits are a specific effect of acupuncture.

Our results differ from those of van Tulder and colleagues' 1999 Cochrane Review (5) of acupuncture for low back pain, which did not conclude that acupuncture was effective. One suspected reason for this difference is that 5 high-quality, relatively large, sham or no-treatment control RCTs (24, 41, 44, 45, 52) have been published since 1999, of which 4 favored acupuncture. The next revision of the Cochrane Review will probably consider these new RCTs. Another possible explanation for the difference in the find-

ings is that we used a different data analysis approach than van Tulder and colleagues (5). While we used meta-analysis, the Cochrane reviewers declined to combine the trials because of trial heterogeneity. Any strictly qualitative approach may be problematic since it can be more subjective than meta-analysis: Reviewer bias can potentially influence the reviewers' classification of studies as positive or negative, as well as how individual studies affect the review's overall conclusions (59). The homogeneity of results of the no-additional-treatment–controlled RCTs (with the exception of Cherkin and colleagues' study [25]) and the sham-controlled RCTs strengthens our confidence in the appropriateness of using meta-analysis in our systematic review and in our results.

Our search for eligible reports was nearly comprehensive, resulting in the identification of 33 RCTs—more than twice as many as included in any previous review on this topic. Because of resource limitations, we did not search Chinese databases. This may have deflated our estimates of effects because acupuncture RCTs published in China have been shown to be positive in 100% of all cases (60). The comprehensiveness of our searches (with the exception of Chinese databases) might be expected to limit the effects of publication bias.

Current data show that acupuncture is more effective than sham acupuncture and no additional treatment for providing short-term relief of chronic low back pain. This short-term relief seems to be sustained over the longer term; however, we are uncertain about a sustained effect because longer-term follow-up data are limited in quantity and quality. The main results of 2 large RCTs in the United Kingdom (61) and Germany (62), which are unpublished but have been presented at conferences, concur with our results. More research is needed to evaluate acupuncture's effects on acute low back pain, and the evidence comparing acupuncture to other active treatments is inconclusive. Although current estimates of acupuncture's effects on chronic low back pain are statistically significant and clinically important, they are still somewhat preliminary, and the publication of several large ongoing trials will have a major effect on the evidence.

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