

Acupuncture and Dry-Needling for Low Back Pain: An Updated Systematic Review Within the Framework of the Cochrane Collaboration

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Objectives. To assess the effects of acupuncture and dry-needling for the treatment of nonspecific low back pain.

Background. Low back pain is usually a self-limiting condition that tends to improve spontaneously over time. However, for many people, back pain becomes a chronic or recurrent problem for which a large variety of therapeutic interventions are employed.

Search strategy. We updated the searches from 1996 to February 2003 in CENTRAL, MEDLINE, and EMBASE. We also searched the Chinese Cochrane Centre database of clinical trials and Japanese databases to February 2003.

Selection Criteria. Randomized controlled trials of acupuncture (that involved needling) or dry-needling for adults with nonspecific acute/subacute or chronic low back pain.

Data Collection and Analysis. Two reviewers independently assessed methodologic quality (using the criteria recommended by the Cochrane Back Review Group) and extracted data. The trials were combined using meta-analysis methods or levels of evidence when the data reported did not allow statistical pooling.

Results. Thirty-five randomized clinical trials were included: 20 were published in English, 7 in Japanese, 5 in Chinese, and 1 each in Norwegian, Polish, and German. There were only 3 trials of acupuncture for acute low back pain. These studies did not justify firm conclusions because of their small sample sizes and low methodologic quality. For chronic low back pain, there is evidence of pain relief and functional improvement for acupuncture compared to no treatment or sham therapy. These effects were only observed immediately after the end of the sessions and in short-term follow-up. There is also evidence that acupuncture, added to other conventional therapies,

relieves pain and improves function better than the conventional therapies alone. However, the effects are only small. Dry-needling appears to be a useful adjunct to other therapies for chronic low back pain. No clear recommendations could be made about the most effective acupuncture technique.

Conclusions. The data do not allow firm conclusions regarding the effectiveness of acupuncture for acute low back pain. For chronic low back pain, acupuncture is more effective for pain relief and functional improvement than no treatment or sham treatment immediately after treatment and in the short-term only. Acupuncture is not more effective than other conventional and “alternative” treatments. The data suggest that acupuncture and dry-needling may be useful adjuncts to other therapies for chronic low back pain. Because most of the studies were of lower methodologic quality, there is a clear need for higher quality trials in this area.

Key words: systematic review, meta-analysis, Cochrane Collaboration, acupuncture, low back pain. **Spine 2005;30:944–963**

Low back pain is a major health problem among Western industrialized countries and a major cause of medical expenses, absenteeism, and disablement.¹ People with acute low back pain usually experience improvements in pain, disability, and return to work within 1 month, further but smaller improvements occur up to 3 months, after which pain and disability levels remain almost constant, and most people will have at least 1 recurrence within 12 months.² Although low back pain is usually a self-limiting and benign disease,³ a large variety of therapeutic interventions are available to treat it.⁴ However, the effectiveness of most of these interventions has not been convincingly demonstrated, and consequently, the therapeutic management of low back pain varies widely.

Acupuncture is one of the oldest forms of therapy and has its roots in ancient Chinese philosophy. Traditional acupuncture is based on a number of philosophical concepts, one of which postulates that any manifestation of disease is considered a sign of imbalance between the Yin and Yang forces within the body. In classic acupuncture theory, it is believed that all disorders are reflected at specific points, either on the skin surface or just below it. Vital energy circulates throughout the body along the so-called meridians, which have either Yin or Yang characteristics. An appropriate choice of the 361 classic acupuncture points located on these meridians for needling is believed to restore the balance in the body. When the

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needles have been placed successfully, the patient is supposed to experience a sensation known as Teh Chi (in some schools of traditional acupuncture). Teh Chi has been defined as a subjective feeling of fullness, numbness, tingling, and warmth, with some local soreness and a feeling of distension around the acupuncture point. There is no consensus among acupuncturists about the necessity of reaching Teh Chi for acupuncture to be effective.

Because acupuncture disseminated to the West several hundred years ago, many different styles of acupuncture have developed, including Japanese Meridian Therapy, French Energetic Acupuncture, Korean Constitutional Acupuncture, and Lemington 5 Element Acupuncture. Although these are similar to traditional acupuncture, they each have distinct characteristics. In recent decades, new forms of acupuncture have developed, such as ear (auricular) acupuncture, head (scalp) acupuncture, hand acupuncture, and foot acupuncture.⁵ Modern acupuncturists use not only traditional meridian acupuncture points, but also nonmeridian or extrameridian acupuncture points, which are fixed points not necessarily associated with meridians. Acupuncture commonly includes manual stimulation of the needles, but various adjuncts are often used, including electrical acupuncture (in which an electrical stimulator is connected to the acupuncture needle), injection acupuncture (herbal extracts injected into acupuncture points), heat lamps, and acupuncture with moxibustion (the moxa herb, *Artemisia vulgaris*, is burned at the end of the needle).⁵

Dry-needling is a technique that uses needles to treat myofascial pain in any body part, including the low back region. Myofascial pain syndrome is a disease of muscle that produces local and referred pain. It is characterized by a motor abnormality (a hard band within the muscle) and by sensory abnormalities (tenderness and referred pain). It is classified as a musculoskeletal pain syndrome that can be acute or chronic, regional or generalized. It can be a primary disorder causing local or regional pain syndromes, or a secondary disorder that occurs as a consequence of some other condition.⁶ In 1983, Travell and Simons published the book *Myofascial Pain and Dysfunction: The Trigger Point Manual*,⁷ which shows the pain pattern of trigger points in every muscle of the body. Myofascial trigger points, once carefully identified, can be inactivated by various methods including systemic muscle relaxants, botulinum toxin, antidepressants, deep muscle massage (for example: shiatsu), local injection of substances such as steroids or lidocaine, and dry-needling. Dry-needling involves the insertion of a needle (it can be an acupuncture needle or any other injection needle without injecting any liquid) at these trigger points. The needles are not left *in situ*; they are removed once the trigger point is inactivated. The inactivation of the trigger point should be followed by exercises (usually stretching) or ergonomic adjustments with the purpose to re-establish a painless, full range of motion and avoid recurrences.

It is still unclear what exact mechanisms underlying the action of acupuncture or dry-needling. Western scientific research has proposed mechanisms for the effect of acupuncture on pain relief. It has been suggested that acupuncture might act by principles of the gate control theory of pain. One type of sensory input (low back pain) could be inhibited in the central nervous system by another type of input (needling). Another theory, the diffuse noxious inhibitory control (DNIC), implies that noxious stimulation of heterotopic body areas modulates the pain sensation originating in areas where a patient feels pain. There is also some evidence that acupuncture may stimulate the production of endorphins, serotonin, and acetylcholine within the central nervous system, enhancing analgesia.^{8,9}

The effectiveness of acupuncture in the treatment of low back pain has been systematically reviewed before^{10,11} with inconclusive results due to the low methodologic quality of the included studies. This is an updated review of all available scientific evidence, including evidence from Chinese and Japanese trials, on the effectiveness of acupuncture for both acute and chronic low back pain, and dry-needling for myofascial pain syndrome in the low back region.

■ Objectives

The objectives of this systematic review were to determine the effects of acupuncture for (sub)acute and chronic nonspecific low back pain and dry-needling for myofascial pain syndrome in the low back region compared to no treatment, sham therapies, other therapies, and the addition of acupuncture to other therapies.

■ Criteria for Considering Studies for This Review

Types of Studies

Only randomized controlled trials (RCTs), with no language restriction, were included in this systematic review.

Types of Participants

Adults (>18 years of age) with nonspecific low back pain and myofascial pain syndrome in the low back region were included. Randomized controlled trials that included patients with low back pain caused by specific pathologic entities such as infection, metastatic diseases, neoplasm, osteoarthritis, rheumatoid arthritis, or fractures were excluded. Low back pain associated with sciatica as the major symptom, pregnancy, and postpartum were also excluded. Although some studies did not exclusively limit the study population to patients with nonspecific symptoms, studies were included if the majority of the patients had nonspecific low back pain according to the predefined criteria. Patients with (sub)acute (12 weeks or less) or chronic low back pain (more than 12 weeks) were included.

Types of Interventions

Articles evaluating acupuncture or dry-needling treatments that involve needling were included in this review.

Acupuncture was defined as “the diagnosis was made using traditional acupuncture theory and the needles were inserted in classic meridian points, extra points or ah-shi points (painful points).” Dry-needling was defined as “the cause of pain was diagnosed as ‘Myofascial Pain Syndrome,’ the points were chosen by palpation in the muscle, and the needles were inserted into these myofascial trigger points.” Studies were included regardless of the source of stimulation (*e.g.*, hand or electrical stimulation). Studies in which the acupuncture treatment did not involve needling, such as acupressure or laser acupuncture, were excluded. The control interventions were no treatment, placebo/sham acupuncture or other sham procedure, and other therapeutic interventions. Trials comparing 2 techniques of acupuncture or dry-needling were included, but analyzed separately.

Types of Outcome Measures

Randomized controlled trials were included that used at least 1 of the 4 outcome measures considered to be important in the field of low back pain: pain intensity (*e.g.*, visual analogue scale [VAS]), a global measure (*e.g.*, overall improvement, proportion of patients recovered, subjective improvement of symptoms), back specific functional status (*e.g.*, Roland Disability Scale, Oswestry Scale), and return to work (*e.g.*, return to work status, number of days off work). The primary outcomes for this review were pain and functional status. Physiologic outcomes of physical examination (*e.g.*, range of motion, spinal flexibility, degrees of straight leg raising or muscle strength), generic health status (*e.g.*, Short Form 36, Nottingham Health Profile, Sickness Impact Profile), and other symptoms, such as medication use and side effects, were considered secondary outcomes.

Search Strategy for Identification of Studies

The previous review had searched the literature from 1966 until 1996. The following search strategies were used for this updated review:

1. CENTRAL, The Cochrane Library 2003, Issue 1
2. MEDLINE (OVID) from 1996 to February 2003 (see Appendix 1, available for viewing on Article Plus only, for strategy)
3. EMBASE (OVID) from 1996 to February 2003 (see Appendix 2, available for viewing on Article Plus only, for strategy)
4. The Cochrane Back Review Group Trials Registry
5. The Chinese Cochrane Centre Trials Registry
6. A database search of controlled clinical trials published in Japan, using “Igaku Chuo Zasshi” (Japana Centra Revuo Medicina) web version (between 1987 and 2003)
7. Reference lists in review articles and trials retrieved
8. Personal communication with experts in the field

Methods

Study Selection. For this updated review, 1 reviewer (A.D.F.) generated the electronic search strategies in CENTRAL, MED-

LINE, and EMBASE and downloaded the citations into Reference Manager 9.0. Two reviewers (M.v.T, B.K.) then independently reviewed the information to identify trials that could potentially meet the inclusion criteria. Full articles describing these trials were obtained, and the same 2 reviewers independently applied the selection criteria to the studies. Consensus was used to solve disagreements concerning the final inclusion of RCTs, and a third reviewer was consulted if disagreements persisted. One reviewer (H.T.) searched and selected the studies from the Japanese databases. The Chinese Cochrane Centre generated the searches in their Trials Register, and 1 reviewer (L.X.L.) selected the studies. The authors of recent original studies were contacted to obtain more information when needed.

Methodologic Quality Assessment. The methodologic quality of each RCT was independently assessed by 2 reviewers (not always the same pair of reviewers). Reviewers were not blinded with respect to authors, institution, and journal because they were familiar with the literature. Consensus was used to resolve disagreements, and a third reviewer was consulted if disagreements persisted.

The methodologic quality of the RCTs was assessed by using the criteria list recommended in the Updated Method Guidelines for Systematic Reviews in the Cochrane Collaboration Back Review Group.¹² Each item was scored as “yes,” “no,” or “don’t know” according to the definitions of the criteria.

The methodologic quality assessment of the studies was used for 2 purposes: first, to exclude studies with fatal flaws (such as dropout rate higher than 50%, statistically significant and clinically important baseline differences that were not accounted in the analyses). Studies that passed the first screening for fatal flaws were classified into lower or higher quality: higher quality was defined as a trial fulfilling 6 or more of the 11 methodologic quality criteria and not having a fatal flaw. Lower quality trials were defined as fulfilling fewer than 6 criteria and not having a fatal flaw. The classification into higher/lower quality was used to grade the strength of the evidence.

Data Extraction. Two reviewers independently extracted the data on the study characteristics, funding, ethics, study population, interventions, analyses, and outcomes. The authors of recent studies (published in the past 5 years) were contacted to obtain more information when needed.

Adequacy of Treatment. Three reviewers, who are experienced acupuncturists (A.D.F., L.X.L., H.T.), judged the adequacy of treatment. The data extraction included 4 questions about the adequacy of treatment, which were derived from the STRICTA¹³ recommendations: 1) choice of acupoints; 2) number of sessions; 3) needling technique; and 4) acupuncturist experience. The control groups were also judged as: 1) appropriateness of sham/placebo intervention; and 2) adequate number of sessions/dose. In addition, a panel of experts in acupuncture treatment for low back pain was consulted in a 3-hour session in which each study was presented for discussion (only the population and interventions were presented, so the panel was blinded to authors, journal, year, country, outcomes, and results). The panel consisted of 6 physicians trained in a variety of acupuncture methods (traditional Chinese medicine, Ryodoraku, dry-needling, trigger point injections, and scalp needling) who work at a multidisciplinary pain clinic in Sao Paulo, Brazil. The panel also classified each study as acupuncture or dry-needling.

Clinical Relevance. The 2 reviewers who extracted the data also judged the clinical relevance of each trial using the 5 questions recommended by Shekelle *et al*¹⁴ and the Updated Method Guidelines¹²:

1. Are the patients described in detail so that you can decide whether they are comparable to those that you see in your practice?
2. Are the interventions and treatment settings described well enough so that you can provide the same for your patients?
3. Were all clinically relevant outcomes measured and reported?
4. Is the size of the effect clinically important?
5. Are the likely treatment benefits worth the potential harms?

Analysis. The primary analyses, decided *a priori*, were:

- Acupuncture compared to no treatment, placebo, or sham therapy
- Acupuncture compared to another intervention
- Acupuncture added to an intervention compared to the intervention without acupuncture

Any other comparisons were considered secondary analysis.

The results of each RCT were plotted as point estimates, *i.e.*, relative risks (RR) with corresponding 95% confidence interval (95% CI) for dichotomous outcomes, mean and standard deviation (SD) for continuous outcomes, or other data types as reported by the authors of the studies. When the results could not be plotted, they were described in the table of included studies or the data were entered into “other data tables.” For continuous measures, preference was given to analyze the results with weighted mean differences (WMD) because these results are easier to interpret for clinicians and other readers. If this was not possible, then standardized mean differences (SMD) or effect sizes were used. The studies were first assessed for clinical homogeneity with respect to the duration of the disorder, types of acupuncture, control group, and the outcomes. Clinically heterogeneous studies were not combined in the analysis, but separately described. For studies judged as clinically homogeneous, statistical heterogeneity was tested by Q test (χ^2) and I^2 . Clinically and statistically homogeneous studies were pooled using the fixed effect model. Clinically homogeneous and statistically heterogeneous studies were pooled using the random effects model. Funnel plots were constructed when at least 10 studies were available for the meta-analysis.¹⁵

When the data could not be entered in the meta-analysis because of the way the authors of the trials reported the results (for example: no information about standard deviation of the means), we performed a qualitative analysis by attributing various levels of evidence to the effectiveness of acupuncture, taking into account the methodologic quality and the outcome of the original studies¹²:

- *Strong evidence**—consistent** findings among multiple higher quality RCTs
- *Moderate evidence*—consistent findings among multiple lower quality RCTs and/or 1 higher quality RCT
- *Limited evidence*—1 lower quality RCT
- *Conflicting evidence*—inconsistent findings among multiple trials (RCTs)
- *No evidence*—no RCTs

*There is consensus among the Editorial Board of the Back Review Group that strong evidence can only be provided by multiple higher quality trials that replicate findings of other researchers in other settings.

**When more than 75% of the trials report the same findings.

The results were grouped according to the following study characteristics:

1. Type of acupuncture: 2 subgroups were analyzed separately:
 - a. Acupuncture in which the points were chosen by the meridian theory
 - b. Dry-needling in which needles were inserted in trigger points
2. Duration of pain: 3 subgroups were analyzed separately:
 - a. Acute and subacute pain (duration 12 weeks or less)
 - b. Chronic (duration more than 12 weeks)
 - c. Unknown or mixed duration
3. Control group:
 - a. No treatment
 - b. Placebo or sham acupuncture
 - c. Other interventions or acupuncture in addition to other interventions
 - d. Two different techniques of acupuncture
4. Outcome measures:
 - a. Pain
 - b. Global measure
 - c. Functional status
 - d. Physical examination
 - e. Return to work
 - f. Complications
5. Timing of follow-up:
 - a. Immediately after the end of the sessions—up to 1 week after the end of the sessions
 - b. Short-term follow-up—between 1 week and 3 months after the end of the sessions
 - c. Intermediate-term follow-up—between 3 months and 1 year after the end of the sessions
 - d. Long-term follow-up—1 year or longer after the end of the sessions

Description of Studies. The review published in 1999 included 11 studies.^{10,11} This updated review includes 35 studies and 2861 patients. Twenty were published in English, 7 in Japanese,^{16–22} 5 in Chinese,^{23–27} 1 in Norwegian,²⁸ 1 in Polish,²⁹ and 1 in German.^{30,31} The majority of the population included in these trials had chronic low back pain (24 studies, 1718 patients). The control groups were the following: no treatment, sham acupuncture, sham transcutaneous electrical nerve stimulation (TENS), Chinese herbal medicine, education, exercise, massage, moxibustion, nonsteroidal anti-inflammatory drugs (NSAIDs), physiotherapy, spinal manipulation, TENS, trigger point injections, and usual treatment by a general practitioner. Six studies compared the effectiveness of 2 different acupuncture techniques. The characteristics of study design, population, interventions, outcomes, and results are detailed in Table 1.

Methodologic Quality of Included Studies. The results of the methodologic quality assessment are shown in Table 2. There were 2 studies with fatal flaws: the trial by Giles and Muller³² had a 52% dropout during treatment period in the

Table 1. Characteristics of Included Studies

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Araki <i>et al</i> , 2001 ¹⁶	40 patients with acute LBP (less than 3 days) and no sciatica. Mean age: 44 yrs; 28 males and 7 females. Setting: private clinic in Osaka (Japan)	1) Needling at SI3 bilaterally, depth 2.5 cm, 1 session 2) Sham needling was performed at SI3 (bilaterally) point, 1 session	1) Pain intensity 2) Function: JOA 3) Flexion: finger floor distance	There is no difference between the effect of acupuncture and that of sham acupuncture
Carlsson and Sjolund, 2001 ³⁴	51 patients with LBP for 6 mos or longer (mean 9.5 yrs) without radiation below the knee and normal neurological examination. Mean age: 50 yrs; 17 males and 33 females. Setting: pain clinic in Malmo General Hospital, Sweden	1) Manual acupuncture: local and distal points 2) Manual acupuncture plus electrical stimulation of 4 needles 3) Sham TENS All 3 groups received treatment once per wk for 8 wks	1) Pain intensity 2) Global assessment by physician 3) Present work status 4) Intake of analgesics 5) Sleep quality 6) Complications	The authors demonstrated a long-term pain-relieving effect of needle acupuncture compared with true placebo in some patients with low back pain
Ceccherelli <i>et al</i> , 2002 ³⁵	42 patients with continuous pain for more than 3 mos with no signs of radicular compression. Mean age 42 yrs; 30 males and 12 females. Setting: pain clinic, University of Padova, Italy	1) Deep acupuncture (1.5 cm) total of 8 sessions in 6 wks 2) Depth of insertion was only 2 mm in the skin	Pain: McGill Pain Questionnaire	Clinical results show that deep stimulation has a better analgesic effect when compared with superficial stimulation
Cherkin <i>et al</i> , 2001 ³⁶	262 patients who visited a primary care physician for LBP who had persistent pain for at least 6 wks and bothersomeness of back pain less than 4 (on a 0–10 scale). Mean age: 44.9 yrs; 42% males and 58% females. Setting: Health Maintenance Organization in Washington State	1) Traditional Chinese medical acupuncture. Mean of 12 needles (range 5–16) were inserted in each visit, up to 10 visits over 10 wks for each patient 2) Massage up to 10 visits over 10 wks per patient. 3) Self-care education: a book and 2 professionally produced videotapes	1) Pain 2) Function 3) Disability 4) Health care utilization 5) Costs 6) Satisfaction 7) Mental and physical health	Massage is an effective short-term treatment for chronic LBP, with benefits that persist for at least 1 yr. Self-care educational materials had little early effect, but by 1 yr were almost as effective as massage. If acupuncture has a positive effect, it seems to be concentrated during the first 4 wks because there was little improvement thereafter
Coan <i>et al</i> , 1980 ⁴³	50 patients with LBP for at least 6 mos. Mean age: 47 yrs (range 18–67); 23 males and 27 females. Setting: acupuncture center in Maryland	1) Classical Oriental meridian theory. Electrical acupuncture in some patients. Selection of acupuncture loci varied, 10 or more sessions, approximately 10 wks 2) Waiting list, no treatment for 15 wks	1) Pain intensity 2) Function: verbal scale from 0–3 3) Mean pain pills per wk 4) Global improvement	This study demonstrated that acupuncture was superior for these people with LBP, even though they had the condition for an average of 9 yrs
Ding, 1998 ²³	54 patients with chronic LBP, frequent recurrence, worse during work and relief with rest. Mean age: 44 yrs (range 19–68); 40 males and 14 females. Setting: university in Guangzhou, China	1) Ancient needling technique 'the turtle exploring the holes,' daily up to 10 treatments 2) Regular needling technique, daily for up to 10 days	Pain on a 4-point scale: 'cure,' 'marked effective,' 'improved,' and 'no change'	An ancient needling technique is better than the regular needling technique in treating chronic LBP
Edelist <i>et al</i> , 1976 ⁴⁴	30 patients with LBP with no improvement after conventional therapy. Setting: University Hospital in Toronto, Canada	1) Manual insertion of 4 needles into traditional acupuncture points, then electroacupuncture, 3 treatments in maximum 2 wks 2) Sham acupuncture, 4 needles placed in areas devoid of classic acupuncture points	1) Subjective improvement of back/leg pain 2) Objective improvement of spinal movement, in tests for nerve root tension and in neurological signs	There seemed to be no difference in either the subjective or objective changes between the 2 effects and suggest that much of the improvement in pain syndromes associated with acupuncture may be on the basis of placebo effect (Table continues)

acupuncture group and the trial by Grant *et al*³³ had clinically important differences in the main outcome measures at baseline. Therefore, these 2 trials are not included in the analyses or used to draw conclusions. Of the remaining 33 trials, 14 were

judged to be of higher^{16–18,21,28,34–42} and 19 to be of lower methodologic quality.^{20,22–27,29–31,43–51} In none of the 35 trials was the care provider blinded; in 28 trials, the timing of the outcome assessment was similar in all groups. The biggest

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Garvey <i>et al</i> , 1989 ³⁷	63 patients with acute nonradiating LBP, normal neurological examination, persistent pain despite initial treatment of 4 wks. Mean age 38 yrs; 41 men and 22 women. Setting: Outpatient clinic in a U.S. hospital	<ol style="list-style-type: none"> 1) Dry-needling with a 21-gauge needle, 1 session 2) Injection of 1.5 mL of 1% lidocaine, 1 session 3) Injection with 0.75 mL of 1% lidocaine and 0.75 mL of Triamcinolone Hexacetonide, 1 session 4) Ethyl chloride spray from 6 inches away, followed by acupressure using the plastic needle guard, 1 session 	<ol style="list-style-type: none"> 1) Global improvement: percentage of not improved or improved 2) Complications 	The injected substance apparently is not the critical factor, because direct mechanical stimulus to the trigger-point seems to give symptomatic relief equal to that of treatment with various types of injected medication
Giles and Muller, 1999 ³²	77 patients with spinal pain for at least 13 wks (median 6 yrs). Median age: 42 yrs; 30 males and 47 females. Setting: Outpatient pain clinic in a hospital setting, Townsville, Australia	<ol style="list-style-type: none"> 1) Acupuncture according to the 'near and far' technique; 6 treatments in a 3- to 4-wk period 2) High-velocity, low-amplitude spinal manipulation; 6 treatments in a 3- to 4-wk period 3) Tenoxicam (20 mg/day) and ranitidine (50 mg × 2/day) for the defined 3- to 4-wk treatment period 	<ol style="list-style-type: none"> 1) Pain intensity 2) Pain frequency 3) Function: Oswestry Disability Index 4) Crossover to another intervention after the study period 5) Complications 	The manipulation group displayed the most substantial improvements that were uniformly found to be significant. In the other intervention groups, not a single significant improvement could be found in any of the outcome measures
Giles and Muller, 2003 ⁴⁵	109 patients with uncomplicated spinal pain for a minimum of 13 wks (average duration was 6.4 yrs). Median age: 39 yrs; 60 males and 49 females. Setting: outpatient pain clinic in a hospital setting, Townsville, Australia	<ol style="list-style-type: none"> 1) Acupuncture according to the 'near and far' technique; 2 treatments per week up to 9 wks 2) High-velocity, low-amplitude spinal manipulation; 2 treatments per wk up to 9 wks 3) A medication could be selected that had not already been tried. The patients normally were given Celecoxib (200–400 mg/day), Rofecoxib (12.5 to 25 mg/day), or paracetamol (up to 4 g/day) 	<ol style="list-style-type: none"> 1) Pain intensity 2) Pain frequency 3) Function: Oswestry Disability Index 4) Crossover to another intervention after the study period 5) SF-36 Health Survey Questionnaire 	In patients with chronic spinal pain, manipulation, if not contraindicated, results in greater short-term improvement than acupuncture or medication
Grant <i>et al</i> , 1999 ³³	60 patients aged 60 yrs or older with a complaint of LBP of at least 6 mos duration. Mean age: 73.6 yrs; 6 males and 54 females. Setting: outpatient clinic in the United Kingdom	<ol style="list-style-type: none"> 1) Two sessions of manual acupuncture weekly for 4 wks, <i>i.e.</i>, 8 sessions in total 2) TENS; the patient was given her/his own machine to use at home and instructed to use it during the day as required for up to 30 mins per session to a maximum of 6 hrs per day 	<ol style="list-style-type: none"> 1) Pain intensity 2) Pain subscale of the 38-item Nottingham Health Profile part 1 3) Analgesics consumption 4) Spinal flexion 5) Complications 	A 4-wk course of either acupuncture or TENS had demonstrable benefits on subjective measures of pain and allowed them to reduce their consumption of analgesic tablets. The benefits of both treatments remained significant 3 mos after completion, with a trend towards further improvement in the acupuncture patients
Gunn <i>et al</i> , 1980 ⁴⁶	56 males with chronic LBP of at least 12 wks. Mean age: 40.6 yrs (range 20–62). Setting: pain clinic in Richmond, British Columbia, Canada	<ol style="list-style-type: none"> 1) Standard therapy (physiotherapy, remedial exercises, occupational therapy, industrial assessment) plus dry-needling on muscle motor points plus low voltage electrical stimulation. Maximum of 15 treatments (average 8) once or twice a wk 2) Standard therapy only 	Global improvement: 'no improvement,' 'some improvement,' 'good improvement,' or 'total improvement'	The group that had been treated with needling was found to be clearly and significantly better than the control group with regard to status at discharge at 12 wks and at final follow-up
He, 1997 ²⁴	100 patients with LBP (5 days to 6 mos duration), limited range of motion and worse in cold and raining weather. Age: 22 to 79 yrs; 44 males and 56 females. Setting: outpatient clinic in a hospital, University Centre in Sichuan Province, China	<ol style="list-style-type: none"> 1) Manual acupuncture with moxibustion plus Chinese herbal medicine. Treatments were given daily up to 10 treatments 2) Chinese herbal treatment alone 	Overall assessment that includes pain, physical function, sensitivity to weather change and return to work: 'cured,' 'marked effective,' 'improved,' or 'no changes'	Manual acupuncture with moxibustion plus Chinese herbal medicine is better than Chinese herbal medicine alone for treating LBP with cold and dampness based on TCM diagnosis

(Table Continues)

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Inoue <i>et al</i> , 2000 ¹⁷	27 patients with LBP of unknown duration Mean age: 59.6 yrs Gender: no information Setting: university hospital in Kyoto, Japan	1) Two acupoints chosen bilaterally from lumbar area (<i>i.e.</i> , 4 points in total): BL52 and extra point (yao-yan: EX-B7). Needles were inserted 20 mm in depth, manipulated by sparrow pecking method for 20 s, and then removed; 1 treatment session was performed 2) Sham acupuncture: The same 2 points were chosen. Acupuncturist mimicked needle insertions: tapped head of needle guide tube, then gesture of needling was performed for 20 s; 1 session.	Pain intensity	There was no difference between real needling and sham needling Pain significantly reduced after the treatment session in both groups. However, there was not a significant difference between the acupuncture group and sham needling group
Inoue <i>et al</i> , 2001 ¹⁸	21 patients with LBP of unknown duration Mean age: 55.1 yrs Gender: no information Setting: university hospital in Kyoto, Japan	1) One needling point was chosen from lumbar area: most painful locus was detected. Needles were inserted and sparrow-picking technique was performed for 20 s; 1 session 2) Sham acupuncture: most painful locus was detected, acupuncturist mimicked needle insertion: tapped head of needle guide tube, then gesture of needling was performed for 20 s; 1 session	Pain intensity	Real needling is superior to sham needling There was a significant difference between acupuncture group and sham needling group. Pain in the acupuncture group improved more
Kerr <i>et al</i> , 2003 ⁴⁷	60 patients with chronic LBP (>6 mo) with or without leg pain and with no neurologic deficits. Mean age: 41 yr old; 28 males and 32 females Setting: outpatient clinic in a hospital in Northern Ireland	1) Same set of acupoints for everyone, regardless of the distribution of their symptoms: 6 sessions, over a 6-wk period. 2) Placebo-TENS: a nonfunctioning TENS machine was attached to 4 electrodes placed over the lumbar spine and the unit was placed so as to make it difficult to interfere with the apparatus; 6 sessions over a 6-wk period	1) Pain intensity 2) SF-36 3) Physical examination: finger-floor distance 4) Global improvement measured at 6 mos 5) Complications	Although acupuncture showed highly significant differences in all the outcome measures between pre- and posttreatment, the differences between the 2 groups were not statistically significant
Kittang <i>et al</i> , 2001 ²⁸	60 patients with acute LBP (lasting less than 10 days). Between 18 and 67 yrs of age, both genders Setting: Private clinic in Flora and Kinn, Norway	1) Needling in 'lumbago 1 and 3' with medial lumbago and in 'upper lip' with more lateral pain. Later treatments were with 5 needles across at level L2, at 'Ashi points' (local pain points) and in both ankles; 4 treatments within 2 wks 2) Naproxen 500 mg twice daily for 10 days	1) Pain intensity 2) Use of rescue analgesics 3) No. of back pain episodes 4) Side effects 5) Stiffness 6) Lateral flexion	No difference in reduction of pain or stiffness over 6 mos evaluation
Kurosu, 1979 ¹⁹	20 patients with lumbar or sacral region pain. Most of patients were between 40 and 50 yrs old, 10 males and 10 females Setting: Private clinic in Tokyo, Japan	1) Acupuncture: the needles were inserted, and left <i>in situ</i> for 10 mins, and then removed. Insertion depth was 2 to 4 cm. Six to 8 points in lumbar area. Minimum 4 sessions 2) Garlic moxibustion in lumbar region: Moxa is placed on top of a slice of garlic. Point selection was the same as the acupuncture group	Pain: 10-item questionnaire about the specific actions which caused pain	There is no difference between needle retention technique and garlic moxibustion for LBP

(Table continues)

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Kurosu 1979 ¹⁹	20 patients with lumbar or sacral region pain. Most of the patients were between 40 and 50 yrs old, 11 males and 9 females Setting: Private clinic in Tokyo, Japan	1) Acupuncture: the needles were left in situ for 10 mins, and then removed. Depth was 2 to 4 cm. Six to 8 points in lumbar part were chosen and 3 extra channel points by palpation. Abdominal needling was added; 1 to 1.5 cm in depth, minimum 4 sessions 2) Other acupuncture technique: needles were removed immediately after insertion	Pain: 10-item questionnaire about the specific actions that caused pain	Results of needle retention technique is superior to that of simple insertion technique for LBP
Lehmann <i>et al</i> , 1986 ⁴⁸	54 patients with chronic (>3 mos) disabling LBP. Mean age: 39 yrs (ranged from 20–59) Gender: 33% females Setting: Multidisciplinary inpatient clinic in a University of Iowa Hospital	1) Electroacupuncture with needles, twice weekly for 3 wks 2) Real TENS, 15 treatments in 3 wks 3) Sham TENS, same as TENS but dead battery	1) Pain intensity 2) ADL 3) Physician's perception of improvement 4) Range of motion 5) Return to work 6) Complications	There were no significant differences between treatment groups with respect to their overall rehabilitation The electroacupuncture group demonstrated slightly better results than the other groups
Leibing <i>et al</i> , 2002 ³⁸	150 patients with chronic (>6 mos) nonradiating LBP. Mean age: 48.1 yrs, 58% female Setting: Outpatient clinic, Department of Orthopaedics, University Goettingen, Germany	1) 20 sessions of combined traditional body and ear acupuncture plus active physiotherapy over 12 wks 2) Only active physiotherapy over 12 wks 3) Sham acupuncture plus active physiotherapy over 12 wks. Sham acupuncture consisted of 20 sessions (each 30 mins) of minimal acupuncture by the same physician. Sham acupuncture was done following the standards of minimal acupuncture. Needles were inserted superficially, 10–20 mm distant to the verum-acupoints, outside the meridians, and were not stimulated	1) Pain intensity 2) Pain disability 3) Psychological distress Hospital Anxiety and Depression Scale 4) Spine flexion, fingertip-to-floor distance 5) Complications: minor not serious adverse events occurred in 3 patients in the acupuncture group	Acupuncture plus physiotherapy was superior to physiotherapy alone regarding pain intensity, disability, and psychological distress at the end of the treatment. Compared to sham acupuncture plus physiotherapy, acupuncture (plus physiotherapy) reduced only psychological distress. At 9 mos, the superiority of acupuncture plus physiotherapy compared to physiotherapy alone became less and acupuncture plus physiotherapy was not different from sham plus physiotherapy
Li and Shang, 1997 ²⁵	156 patients with LBP of varying duration (between 2 days and 8 yrs). Age between 20 and 71 yrs, 80 males and 76 females Setting: outpatient clinic in a hospital. Hebei Province, China	1) Manual acupuncture plus cupping. Treatment was given every other day (except for acute back pain which was treated daily) up to 10 treatments 2) Manual acupuncture alone	Overall assessment (see description in He, 1997 ²⁴)	Manual acupuncture plus cupping technique is better than manual acupuncture alone for treating LBP
Lopacz and Gralewski, 1979 ²⁹	34 male patients from a neurology department with LBP for 1 mo or more. Age: mean 42 yrs (ranged from 25–52).	1) Acupuncture: 4 needles close to spine, 10 mins, 4 treatments, 8 days, plus pharmacotherapy 2) Placebo, suggestion, new Swedish method for pain relief, same 4 points echoencephalography, 10 mins, 4 treatments, 8 days, plus pharmacotherapy	Global improvement: very good, good, doubtful, unchanged, and worsening	The therapeutic results were better both immediately and after a series of acupuncture. The difference in the results of treatment was statistically significant in the patients with longest duration of pains (>3 mos)

(Table Continues)

problem was the quality of reporting, which did not allow us to judge the following items: method of randomization (15 trials), concealment of allocation (16 trials), baseline differences (18 trials), cointerventions (18 trials), and compliance (17 trials). Of the 7 trials published in Japanese, 4 were of higher^{16–18,21} and 3 were of lower methodologic quality. All 5 trials published in Chinese were of lower methodologic quality.

■ Results

Study Selection

Our searches resulted in the identification of 68 in CENTRAL, 49 reports in MEDLINE, and 85 in EMBASE. We obtained hard copies of 40 articles, but excluded 17 because they did not meet our inclusion criteria. In addi-

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
MacDonald <i>et al</i> , 1983 ⁴⁹	17 patients with chronic LBP for at least 1 yr, no relief from conventional treatments Demographics: not reported. Setting: London, UK	1) Superficial needling: subcutaneous (4 mm) 30-gauge needle insertion at trigger points (no. of trigger points unknown). 5–20 mins, maximum of 10 treatments in 10 wks. Electrical impulses 700 μ s at 2 Hz if manual stimulation failed 2) Placebo transcutaneous electrical stimulation: electrodes connected to dummy apparatus, maximum 10 treatments in 10 wks	1) Pain relief 2) Pain intensity 3) Activity 4) Physical signs 5) Severity and pain area	Needling achieved better responses than the placebo in all 5 measures. Four of the 5 intergroup differences were statistically significant
Mendelson <i>et al</i> , 1983 ⁵⁰	95 patients with chronic LBP; mean age: 54 yrs, 37 males and 40 females Setting: Prince Henry's and Alfred Hospitals, Melbourne, Australia	1) Traditional Chinese acupuncture, twice weekly, 4 wks 2) Sham acupuncture, intradermal injection of 2% lidocaine at nonacupuncture, nontender sites, then acupuncture needles superficially into the infiltrated areas for 30 mins without stimulation, twice weekly, 4 wks	1) Pain intensity 2) Pain relief 3) McGill Pain Questionnaire 4) Disability (method not described)	Patients receiving acupuncture had a greater but not significantly different reduction in pain rating scores compared to those receiving placebo. Similarly, no significant difference was found between the 2 groups based on self-assessment of disability
Meng <i>et al</i> , 2003 ³⁹	55 patients with chronic nonspecific LBP (>12 wks) and older than 60 yrs. Mean age: 71 yrs, 22 male and 33 female Setting: Private surgeries clinics of the Hospital for Special Surgery at the New York Presbyterian Hospital, New York	1) Acupuncture plus standard therapy: acupuncture twice a week for 5 wks. Between 10 and 14 needles were used per session. Needle retention was 20 mins 2) Standard therapy alone: primary physician for 5-wk intervention period: NSAIDs, aspirin, nonnarcotic analgesic. Continue back exercise (physical therapy) or home exercise regimen. Prohibited: narcotics, muscle relaxants, TENS, epidural steroid injections, and trigger point injections	1) Back specific functional status: modified Roland Disability Questionnaire 2) Pain intensity 3) Complications	Our data indicate that acupuncture plus standard therapy does decrease back pain and disability in older patients compared to standard therapy alone in a clinically and statistically significant manner
Molsberger <i>et al</i> , 2002 ⁴⁰	186 patients with LBP longer than 6 wks, with average pain score greater than 50 mm (max 100 mm) during the last week. Age between 20 and 60 yrs Gender: 97 males and 89 females Setting: Inpatients in the Hospital, Dusseldorf, Germany	1) Verum acupuncture plus conventional orthopedic therapy. All patients received 12 acupuncture treatments, 3/wk, each lasting for 30 mins 2) Sham acupuncture plus conventional orthopedic therapy. 12 sham acupuncture treatments, 3/wk, each lasting 30 mins. Sham acupuncture was standardized to 10 needles applied superficially (depth of insertion was less than 1 cm) at defined nonacupuncture points of the lumbar region, and 5 needles on either side of the back 3) Conventional orthopedic therapy: daily physiotherapy, physical exercises, back school, mud packs, infrared heat therapy. On demand, they received 50 mg diclofenac up to 3 times a day.	1) Pain intensity 2) At least 50% reduction in pain intensity 3) Effectiveness of treatment: excellent, good, satisfactory, and failed 4) Schober and finger-to-floor distance 5) Complications	Together with conservative orthopedic standard therapy, acupuncture helps to decrease pain intensity directly after treatment and patients rating of the acupuncture treatment is significantly better than that of the standard therapy alone. The therapeutic effect lasts for at least 3 mos after the end of treatment

(Table Continues)

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Sakai <i>et al</i> , 1998 ²⁰	26 patients with nonspecific LBP of variable duration. Mean age: 51 yrs; 7 males and 19 females Setting: outpatients in a University Hospital, Tokyo, Japan	1) Needling points were selected from lumbar area and lower extremities. Manual acupuncture technique such as needle retention and sparrow pecking technique were performed. Electroacupuncture was applied in some cases. Patients were treated twice a week for 2 wks, <i>i.e.</i> , 4 sessions in total 2) Oral medication that includes NSAIDs and/or kampo medicine (Chinese herbs)	1) Pain relief 2) JOA score rated by the physician	Both groups improved, and there was no difference between the 2 groups
Sakai <i>et al</i> , 2001 ²¹	68 patients with LBP (at least 2 wks) and age 20 yrs or older. Mean age: 37 yrs; 35 females and 29 males Setting: outpatients in a University Hospital, Tokyo, Osaka, Kyoto and Tsukuba (Japan)	1) Needling points were chosen by palpation in the lumbar area. Two points were used bilaterally, in total 4 points, twice a week for 2 wks. Electrostimulation at a frequency of 1 Hz was applied for 15 mins 2) TENS: Same points as above. Patients were treated twice a week for 2 wk, <i>i.e.</i> , four sessions in total.	1) JOA score rated by the physician 2) Pain relief 3) Complications	Both groups improved, but there was no significant difference between groups in any parameter
Takeda and Nabeta, 2001 ²²	20 students of acupuncture college who were suffering from lumbago. Duration of pain: mean 40.4 mos in distal group and 81.0 mos in local group. Mean age: 26.4 yrs in distal group and 35.8 yrs in local group; 17 males and 3 females Setting: Acupuncture College in Osaka, Japan	1) Distal point technique: sham acupuncture in local lumbar area plus real acupuncture in distal points in lower extremity. Participants were treated once a week for 3 wks 2) Local points technique: real acupuncture in local lumbar area plus sham acupuncture at the acupoints in lower extremity: acupuncturist mimicked needle insertion: tapped head of needle guide tube, then gesture of needling was performed. Participants were treated once a week for 3 wks	1) Pain intensity 2) Function: activity of daily living score; 8 questions about difficulty of specific actions 3) Finger-to-floor distance.	There is no difference between the effects of lumbar area needling and those of distal point needling
Thomas and Lundberg, 1994 ⁵¹	43 patients with nociceptive LBP for 6 mos or more, restriction of trunk or hip movement due to pain, restriction of ADL, muscle spasm Demographics and patients characteristics: not reported Setting: outpatient clinic at the Karolinska Hospital, Stockholm, Sweden	1) Acupuncture: 3 different modes of acupuncture: a) manual stimulation; b) low frequency (2 Hz); and c) high frequency (80 Hz) electrical stimulation of needles. Six local points, 10 sessions of 30 mins 2) Waiting list controls, no treatment	1) Pain: no. of words from chart of 83 words describing pain intensity 2) Global improvement: improved, no change, worse 3) Functional status 4) Goniometry of the lumbar spine	After 6 wks, patients receiving acupuncture were statistically significant better than the control group on measures of pain, global improvement, and mobility. The same results were observed at 6 mos, but only for the group that received low frequency electroacupuncture (Table continues)

tion, we retrieved 16 hard copies of studies published in Japanese and 11 published in Chinese, but excluded 9 and 6, respectively, because they did not meet our inclusion criteria. We contacted the primary authors of 8 trials to obtain additional information that was not reported in the published study. Six responded to our requests, all from the Japanese language trials.

Clinical Relevance

It should be noted that there was an enormous variance in the way the reviewers judged the 5 items of clinical relevance. This occurred because different pairs of reviewers assessed the 35 trials, and each reviewer has a different background and training. In addition, there were no clear instructions of what should constitute a

Table 1. Continued

Study	Participants and Settings	Interventions	Outcomes	Conclusions
Tsukayama <i>et al</i> , 2002 ⁴¹	20 patients with LBP of at least 2 wks and over 20 yrs old. Mean age: 45 yrs; 3 males and 16 females Setting: private clinic in Tsukuba, Japan	1) Acupuncture: points selected by tenderness and palpable muscle bands detected on the lower back and the buttock. Four points bilaterally (8 in total). Electrostimulation was applied to the inserted needles. Press tack needles were inserted after electroacupuncture at 4 of the 8 chosen points and left <i>in situ</i> for several days. Twice a week for 2 wks 2) TENS: applied in the same manner as in the acupuncture group. After each session, a poultice containing methyl salicylic acid, menthol, and antihistamine was prescribed to be applied at home in between treatments to the low back region. Twice a week for 2 wks	1) Pain intensity 2) JOA score 3) Complications	The results of the present trial showed a significant between group difference in pain relief in favor of acupuncture
Von Mencke <i>et al</i> , 1988 ³⁰	65 patients with lumbago and/or ischias, no relief after conventional treatment Age and gender: not described Setting: secondary care	1) Manual acupuncture, traditional meridian acupuncture, or trigger points 2) Sham acupuncture: no traditional acupuncture or trigger points	1) Pain intensity 2) Global improvement 3) Schober test 4) Laségue test	The difference in improvement between typically and atypically treated patients was highly significant
Wang, 1996 ²⁶	492 patients with LBP of unknown duration. Mean age: 48% were older than 40 yrs; 231 males and 261 females Setting: not reported; Wanuatoo, Southwest Pacific Ocean	1) Local treatment plus cupping. Treatments were given daily up to 10 treatments 2) Distal treatment plus electrical stimulation	Overall assessment: 'cure,' 'effective,' 'no significant change'	Local acupuncture treatment plus cupping is more effective than the distal treatment plus electrical stimulation
Wu, 1991 ²⁷	150 patients with acute low back pain. Age between 20 and 55 yrs; 105 males and 45 females Setting: outpatients in a hospital in Morocco	1) SI3 point treatment 2) Extra 29 (EX-UE7) treatment Manual acupuncture technique (no electrostimulation) was used. Strong Teh Chi sensation was obtained combined with lumbar spine movement until symptom relieved. No mention of the duration of the treatment	Global assessment: 'cure,' 'marked effective,' 'effective,' 'no change'	Acupuncture point SI 3 is more effective than the point Yaotongxue
Yeung <i>et al</i> , 2003 ⁴²	52 patients with chronic LBP (>6 mos) with or without radiation. Mean age: 53 yrs; 9 males and 43 females Setting: outpatient clinic in a hospital in Hong Kong.	1) Electroacupuncture: 3/wk for 4 wks, all patients also received exercise therapy, the same as in the control group 2) Standard group exercise program, that consisted of an hourly session each week for 4 consecutive wks, and comprised back strengthening and stretching exercises. In addition, patients were advised on spinal anatomy and body mechanics, back care and postural correction, lifting and ergonomic advice, and behavioral modification, as well as a series of home exercises	1) Pain: numerical rating scale for 'average' and for 'worst' pain intensity during the last week 2) Disability: the Aberdeen LBP scale 3) Complications	Significantly better scores in the NRS and Aberdeen LBP scale were found in the exercise plus electroacupuncture group immediately after treatment, at 1 mo follow-up, and at 3 mos follow-up

LBP = low back pain; TENS = transcutaneous electrical nerve stimulation; VAS = visual analogue scale; JOA = Japan Orthopedic Association; ADL = activities of daily living.

“yes” or “no” response for each question. As a consequence, the assessment of clinical relevance of each individual trial is subjective and difficult to analyze in the context of this systematic review. Table 3 shows the im-

provement in pain for each treatment group and for each duration of low back pain. The average improvement in pain with acupuncture for acute low back pain was 52% (based on 2 studies), 32% for chronic (16 studies), and

Table 2. Methodological Quality Assessment of Included Trials

Study	A	B	C	D	E	F	G	H	I	J	K	Summary Scores and Comments
Araki <i>et al</i> , 2001 ¹⁶	Y	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Score = 10 (high)
Carlsson and Sjolund, 2001 ³⁴	Y	Y	DK	Y	N	Y	DK	DK	Y/N*	Y	Y	Score = 7 at 1 mo (follow-up = 100%), score = 6 at 3 and 6 mos (follow-up = 64% and 54%, respectively) (high)
Ceccherelli <i>et al</i> , 2002 ³⁵	Y	DK	Y	DK	N	Y	DK	DK	Y	Y	Y	Score = 6 (high)
Cherkin <i>et al</i> , 2001 ³⁶	Y	DK	Y	N	N	Y	Y	Y	Y	Y	Y	Score = 8 (high)
Coan <i>et al</i> , 1980 ⁴³	Y	Y	DK	N	N	N	DK	N	N	N	N	Score = 2 (low)
Ding, 1998 ²³	DK	N	DK	Y	N	N	DK	DK	Y	Y	N	Score = 3 (low)
Edelist <i>et al</i> , 1976 ⁴⁴	DK	DK	DK	Y	N	Y	DK	Y	DK	DK	DK	Score = 3 (low)
Garvey <i>et al</i> , 1989 ³⁷	Y	DK	DK	Y	N	Y	Y	Y	Y	Y	Y	Score = 8 (high). Baseline characteristics are not shown. Groups are very different in size.
Giles and Muller, 1999 ³²	DK	Y	DK	N	N	Y	DK	N	N	Y	N	Fatal flaw = 52% dropout during treatment period in the acupuncture group.
Giles and Muller, 1999 ⁴⁵	Y	Y	Y	N	N	DK	Y	DK	N	Y	Y	Score = 6; 39% drop out at 9 wks (low). No adjustment for multiple comparisons
Grant <i>et al</i> , 1999 ³³	Y	Y	N	N	N	Y	Y	DK	Y	Y	N	Fatal flaw = baseline differences in main outcome measures. VAS (range 0–200) at baseline in acupuncture group = 140 and in the TENS group = 101.
Gunn <i>et al</i> , 1980 ⁴⁶	N	DK	DK	N	N	DK	DK	DK	Y	N	N	Score = 1 (low). No baseline values for pain. Cointerventions were allowed and not standardized or monitored.
He, 1997 ²⁴	DK	N	Y	Y	N	N	DK	DK	N	Y	DK	Score = 3 (low)
Inoue <i>et al</i> , 2000 ¹⁷	Y	Y	DK	Y	N	Y	Y	Y	Y	Y	Y	Score = 9 (high)
Inoue <i>et al</i> , 2000 ¹⁸	Y	Y	DK	Y	N	Y	Y	Y	Y	Y	Y	Score = 9 (high)
Kerr <i>et al</i> , 2003 ⁴⁷	Y	DK	DK	Y	N	Y	DK	DK	N	Y	N	Score = 4 (low). Cointerventions might have influenced the results. Patients followed: 76% in the short and 66.7% in the intermediate follow-ups
Kittang <i>et al</i> , 2001 ²⁸	N	DK	N	DK	DK	Y	Y	Y	Y	Y	Y	Score = 6 (high). Baseline differences in 3 factors: days of sick leave previous year, previous attendants at back schools, and use of pain killers
Kurosu, 1979 ¹⁹	DK	DK	DK	N	N	DK	DK	Y	DK	Y	DK	Score = 2 (low)
Li and Shang, 1997 ²⁵	DK	N	DK	Y	N	N	DK	DK	N	Y	DK	Score = 2 (low)
Lehmann <i>et al</i> , 1986 ⁴⁸	DK	DK	DK	N	N	N	Y	DK	N	Y	N	Score = 2 (low). Follow-up: 77% immediately after and 61% after 6 mos
Leibing <i>et al</i> , 2002 ³⁸	Y	Y	Y	Y	N	Y	Y	DK	N	Y	DK	Score = 7 (high). Dropout rate: 24% in the short-term and 37% in the long-term follow-ups
Lopacz and Gralewski, 1979 ²⁹	DK	DK	DK	N	N	N	Y	DK	Y	Y	Y	Score = 4 (low)
MacDonald <i>et al</i> , 1983 ⁴⁹	DK	DK	Y	Y	N	DK	DK	DK	Y	DK	Y	Score = 4 (low)
Mendelson <i>et al</i> , 1983 ⁵⁰	DK	DK	Y	Y	N	Y	DK	DK	Y	Y	N	Score = 5 (low). Crossover study
Meng <i>et al</i> , 2003 ³⁹	Y	Y	Y/N†	N	N	N	Y	DK	Y	Y	Y	Score = 7 (for pain outcomes). Score = 6 (important baseline difference in function (acupuncture group: 9.8 and control group: 11.8) (high)
Molsberger <i>et al</i> , 2002 ⁴⁰	Y	Y	Y	Y	N	Y	DK	Y	Y/N‡	Y	Y	Score = 9, immediately after and 8 in the short-term (dropout rate at 3 mos was 34%) (high). Blinding was between verum and sham acupuncture, but not between verum and nothing
Sakai <i>et al</i> , 1998 ²⁰	DK	DK	N	N	N	DK	DK	DK	N	N	DK	Score = 0 (low)
Sakai <i>et al</i> , 2001 ²¹	Y	Y	Y	N	N	Y	Y	Y	Y	Y	N	Score = 8 (high)
Takeda and Nabeta, 2001 ²²	Y	DK	DK	Y	N	N	DK	Y	Y	Y	DK	Score = 5 (low)
Thomas and Lundberg, 1994 ⁵¹	DK	DK	Y	N	N	DK	N	Y	DK	Y	Y	Score = 4 (low). We get different results when we reanalyzed using the data from the figures
Tsukayama <i>et al</i> , 2002 ⁴¹	Y	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Score = 9 (high) Outcome assessor was blinded, but patient was not. So it is possible that the blindness was broken, especially because the outcomes are subjective
Von Mencke <i>et al</i> , 1988 ³⁰	DK	DK	DK	Y	N	N	N	N	N	N	N	Score = 2 (low)
Wang, 1996 ²⁶	DK	N	DK	Y	N	N	DK	DK	N	DK	DK	Score = 1 (low)
Wu, 1991 ²⁷	N	N	DK	Y	N	N	DK	Y	N	Y	DK	Score = 3 (low)
Yeung <i>et al</i> , 2003 ⁴²	DK	Y	Y	N	N	Y	Y	Y	Y	Y	Y	Score = 8 (high). Outcome assessor was blinded, but patient was not. So it is possible that the blindness was broken, especially because the outcomes are subjective. One of the few studies that adjusted for confounders in the analysis. But small sample size did not account for attention effects
Total Yes	17	14	14	18	0	19	15	15	20	28	16	
Total No	3	5	3	15	34	10	2	3	12	4	10	
Total DK	15	16	18	2	1	6	18	17	3	3	9	

*Y (1 mo); N (3 and 6 mos).

†Y (pain), N (function).

‡Y (immediately after), N (short-term follow-up).

Y = yes; N = no; DK = don't know.

Table 3. Improvement in Pain

Treatment Group	Acute	Chronic	Unknown/Mixed
Acupuncture			
No. of studies	2	16	8
Average improvement	52%	32%	51%
Standard deviation	39%	24%	19%
Minimum	25%	-17%	22%
Maximum	80%	62%	77%
No treatment			
No. of studies		6	
Average improvement		6%	
Standard deviation		25%	
Minimum		-33%	
Maximum		42%	
Sham/placebo			
No. of studies	1	6	3
Average improvement	22%	23%	25%
Standard deviation		22%	17%
Minimum		-19%	6%
Maximum		44%	37%
Other treatments			
No. of studies	1	6	3
Average improvement	79%	25%	99%
Standard deviation		19%	73%
Minimum		0%	41%
Maximum		50%	181%

51% for unknown or mixed durations of pains (8 studies). The average improvement of pain with no treatment was 6% (6 studies). The average improvement of pain with sham or placebo therapies was 22% for acute (1 study), 23% for chronic (6 studies), and 25% for unknown or mixed durations of pain (3 studies).

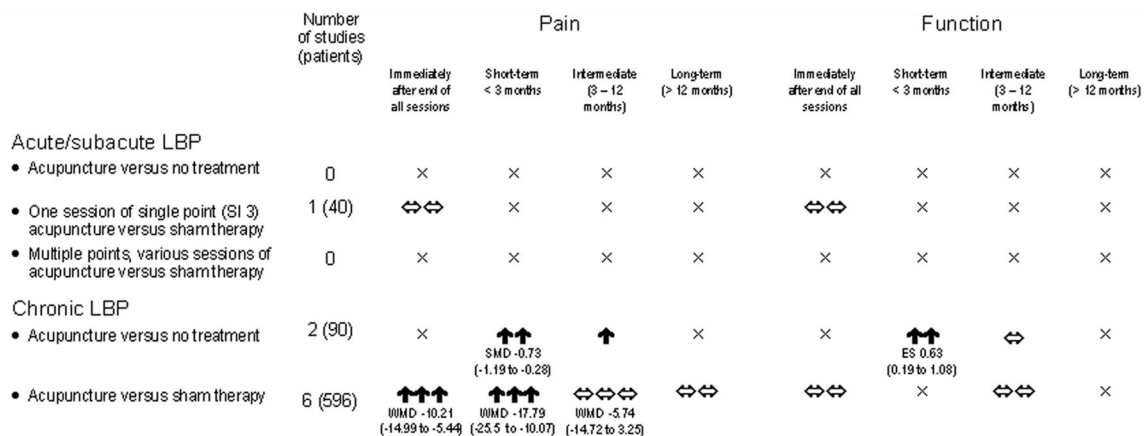
Adequacy of Acupuncture

In all trials, acupuncture was judged to be adequate for the population they included.

Primary Analyses

1. Acupuncture compared to no treatment, placebo, or sham therapy (Figure 1).

- a. Acupuncture *versus* no treatment for acute low back pain: there is no evidence because we did not find any RCT for this comparison.
- b. Acupuncture *versus* sham therapy for acute low back pain: we found only 1 RCT, and it used only 1 session of bilateral acupuncture on the SI3 acupoint. Therefore, there is moderate evidence (1 higher quality trial, 40 people)¹⁶ that there is no difference in pain and function between 1 session of acupuncture on the SI3 acupoint bilaterally and sham needling of the same point immediately after the session.
- c. Acupuncture *versus* no treatment for chronic low back pain: the pooled analysis of 2 lower quality trials (90 people)^{43,51} shows that acupuncture is more effective than no treatment for patients with chronic low back pain for short-term pain relief, with a, SMD of -0.73 (95% CI -1.19 to -0.28). There is limited evidence (1 lower quality trial, 40 people)⁵¹ that acupuncture is also more effective at intermediate follow-up for outcomes of pain. The pooled analysis of 2 lower quality trials (90 people)^{43,51} shows that acupuncture is more effective than no treatment for patients with chronic low back pain in short-term functional improvement, with an effect size of 0.63 (95% CI 0.19-1.08). There is limited evidence (1 lower quality trial, 40 people)⁵¹ that there is no difference at the intermediate-term follow-up in functional outcome between acupuncture and no treatment.
- d. Acupuncture *versus* sham therapy for chronic low back pain: 6 trials (3 higher and 3 lower quality) measured pain outcomes,^{34,38,40,47,48,50} and 1 higher and 2 lower quality trials measured functional outcomes.^{38,48,50} Of 5 trials that measured pain immediately after the end of the sessions, 4 trials could be pooled.^{38,40,47,50} The pooled analy-



AC: Acupuncture; SMD: Standardized Mean Difference; WMD: Weighted Mean Difference; ES: Effect Size; (↑) Limited, (↑↑) moderate or (↑↑↑) strong evidence that acupuncture is more effective than the control treatment; (↔) Limited, (↔↔) moderate or (↔↔↔) strong evidence that there is no difference between acupuncture and the control treatment; (↓) Limited, (↓↓) moderate or (↓↓↓) strong evidence that acupuncture is less effective than the control treatment; × No trial for that comparison was found in this systematic review; ? Contradictory findings

Figure 1. Meridian acupuncture compared to no treatment, placebo, or sham therapy.

	Number of studies (patients)	Pain				Function			
		Immediately after end of all sessions	Short-term < 3 months	Intermediate (3 – 12 months)	Long-term (> 12 months)	Immediately after end of all sessions	Short-term < 3 months	Intermediate (3 – 12 months)	Long-term (> 12 months)
Acute/subacute LBP									
• Acupuncture versus Naproxen 500mg twice daily for 10 days	1(57)	⇔⇔	⇔⇔	⇔⇔	×	×	×	×	×
• Acupuncture + moxibustion + Chinese herbal medicine versus Chinese herbal medicine alone	1 (100)	×	×	×	↑	×	×	×	↑
Chronic LBP									
• Acupuncture versus spinal manipulation	1 (68)	↓	×	×	×	↓	×	×	×
• Acupuncture versus massage	1(172)	⇔⇔	×	×	↓↓↓	↓↓↓	×	×	↓↓↓
• Acupuncture versus celecoxib, rofecoxib or paracetamol	1 (72)	⇔	×	×	×	⇔	×	×	×
• Acupuncture versus TENS	2 (56)	?	×	⇔	×	⇔⇔	×	⇔	×
• Acupuncture versus self-care education	1 (184)	⇔⇔	×	×	⇔⇔	⇔⇔	×	×	⇔⇔
• Acupuncture + other therapy* versus other therapy alone	4 (289)	↑↑↑↑ SMD -0.76 (-1.02 to -0.5)	↑↑↑↑ SMD -1.1 (-1.62 to -0.58)	↑↑↑↑ SMD -0.76 (-1.14 to -0.38)	×	↑↑↑↑ SMD -0.95 (-1.27 to -0.63)	↑↑↑↑ SMD -0.95 (-1.37 to -0.54)	↑↑↑↑ SMD -0.55 (-0.92 to -0.18)	×

Ac: Acupuncture; NSAIDs: non-steroidal anti-inflammatory drugs; *other therapy may include exercises, NSAIDs, aspirin, non-narcotic analgesic, mud packs, infrared heat therapy, back care education, ergonomics or behavioural modification; SMD: Standardized Mean Difference; (↑) Limited, (↑↑) moderate or (↑↑↑) strong evidence that acupuncture is more effective than the control treatment; (⇔) Limited, (⇔⇔) moderate or (⇔⇔⇔) strong evidence that there is no difference between acupuncture and the control treatment; (↓) Limited, (↓↓) moderate or (↓↓↓) strong evidence that acupuncture is less effective than the control treatment; × No trial for that comparison was found in this systematic review; ? Contradictory findings

Figure 2. Meridian acupuncture compared to another intervention or added to other interventions.

sis (2 higher and 2 lower quality RCTs, 314 people) shows that acupuncture is more effective than sham therapy with a WMD of -10.21 (95% CI -14.99 to -5.44). The trial not included in the meta-analysis⁴⁸ included 36 people and found a trend that acupuncture was better than sham therapy, but failed to reach statistical significance. This trial could not be pooled with the other studies because of the scale they used to measure pain and the way they analyzed the results. For short-term measures of pain, there is strong evidence (2 higher quality trials, 138 people)^{34,40} that acupuncture is more effective than sham therapy for patients with chronic low back pain, with a WMD of -17.79 (95% CI -25.5 to -10.07). There are 3 trials (2 higher and 1 lower quality, 255 people) that assessed intermediate-term pain.^{34,38,48} All 3 trials found a trend that acupuncture was better than sham therapy, but without statistical significance. It was possible to pool 2 of these studies, showing a WMD of -5.74 (95% CI -14.72 – 3.25). The only exception was the analysis adjusted for baseline values conducted by Carlsson and Sjolund that showed a statistically significant effect ($P = 0.007$) in favor of acupuncture over sham therapy. For long-term measures of pain, there is moderate evidence (1 higher quality trial, 51 people)³⁴ that there is no difference between acupuncture and sham therapy for chronic low back pain. For measures of function taken immediately after the end of the sessions, there is moderate evidence (1 higher and 2 lower quality trials, 316 people)^{38,48,50} that there is

no difference between acupuncture and sham therapy. For measures of function taken at intermediate-term follow-up, there is moderate evidence (1 higher and 1 lower quality trial, 204 people)^{38,48} that there is no difference between acupuncture and sham therapy for patients with chronic low back pain. There is no evidence from RCTs on the effectiveness of acupuncture for patients with chronic low back pain for functional measures at short or long-term follow-ups.

2. Acupuncture compared to another intervention (Figure 2).
 - a. Acupuncture *versus* other interventions for acute low back pain: there is moderate evidence (1 higher quality trial, 57 people)²⁸ that there is no difference immediately after, at the short-term, or at the intermediate-term follow-ups between acupuncture and Naproxen 500 mg, taken twice daily for 10 days, in measures of pain (VAS).
 - b. Acupuncture *versus* other interventions for chronic low back pain: compared to spinal manipulation, there is limited evidence (1 lower quality trial, 68 people)^{4,5} that acupuncture is less effective for measures of pain and function immediately after the end of the sessions. Compared to massage, there is moderate evidence (1 higher quality trial, 172 people)³⁶ that there is no difference immediately after the sessions in pain between acupuncture and massage, but there is a statistically significant difference in favor of massage at the long-term follow-up. For measures of function, massage was statistically significantly more effective than acupuncture immedi-

ately after the end of the sessions, but there was only a marginally statistically significant difference in favor of massage at the long-term follow-up. However, differences in effect were only small (moderate evidence). Compared to celecoxib, rofecoxib, or paracetamol, there is limited evidence (1 lower quality trial, 72 people)⁴⁵ that there is no difference immediately after the end of the sessions in measures of pain and function. There is conflicting evidence (2 trials, 56 people)^{41,48} on the effectiveness of acupuncture compared to TENS for patients with chronic low back pain for pain measured immediately after the end of the sessions: 1 higher quality trial with a small sample size⁴¹ found a statistically significant difference in favor of acupuncture over TENS, whereas 1 lower quality trial⁴⁸ found no difference. There is limited evidence (1 lower quality trial, 36 people)⁴⁸ that there is no difference at the intermediate-term follow-up in pain between acupuncture and TENS for patients with chronic low back pain. There is moderate evidence (1 higher and 1 lower quality trial, 56 people)^{41,48} that there is no difference immediately after the end of the sessions in functional ability between acupuncture and TENS, and there is limited evidence that there is no difference at the intermediate-term follow-up.⁴⁸ Finally, compared to self-care education, there is moderate evidence (1 higher quality trial, 184 people)³⁶ that there is no difference immediately after the end of the treatments and at the long-term follow-up in pain and function between acupuncture and self-care education.

3. Acupuncture added to an intervention compared to the intervention without acupuncture (Figure 2).
 - a. Addition of acupuncture to other interventions for acute low back pain: only 1 lower quality trial (100 people)²⁴ showed that there is limited evidence that the addition of acupuncture and moxibustion to Chinese herbal medicine is more effective than Chinese herbal medicine alone for a global measure of pain and function at the long-term follow-up.
 - b. Addition of acupuncture to other interventions for chronic low back pain: there are 4 higher-quality trials that assessed the effects of acupuncture added to other therapies and compared it to the other therapy alone (289 people).^{38-40,42} The other therapies included: exercises, NSAIDs, aspirin, nonnarcotic analgesic, mud packs, infrared heat therapy, back care education, ergonomics, or behavioral modification. The pooled analysis shows that the addition of acupuncture to other interventions is more effective than the other intervention alone for pain, measured immediately after the end of the sessions (4 higher quality trials, 289 people) with an SMD of -0.76 (95% CI -1.02 to -0.5), at the short-term follow-up (3 higher quality trials, 182 people) with an SMD of -1.1 (95% CI -1.62 to -0.58), and at

the intermediate-term follow-up (2 higher quality trials, 115 people) with an SMD of -0.76 (95% CI -1.14 to -0.38). These effects were also observed for functional outcomes immediately after the end of the sessions (3 higher quality trials, 173 people) with an SMD of -0.95 (95% CI -1.27 to -0.63), at the short-term follow-up with an SMD of -0.95 (95% CI -1.37 to -0.54), and at the intermediate-term follow-up with an SMD of -0.55 (95% CI -0.92 to -0.18).

Secondary Analyses

Other outcome measures were extracted for the purpose of complementing the conclusions based on the primary outcome measures.

1. Other outcome measures
 - a. Global measures of improvement: measures of global improvement included multiple-choice categorical scales (*e.g.*, improved, same, worse) or dichotomous options (*e.g.*, improved, not improved). In the case of multiple-choice categorical scales, we dichotomized the categories according to the principle of “improved” and “not improved.” The number of patients improved was divided by the total number of patients in that group. These results were in agreement with the result of the primary analyses; therefore, they do not change the conclusions and will not be discussed in this review.
 - b. Measures of work status: measures of work status were basically the number of people who returned or had not returned to work at follow-up. The pooled analysis of the 2 trials (1 higher and 1 lower quality, 58 people)^{34,48} that compared acupuncture to sham for chronic patients with low back pain failed to show a difference at the intermediate-term follow-up. Compared to TENS, there was 1 lower quality trial⁴⁸ that showed no difference in return-to-work at the intermediate-term follow-up.
 - c. Measures of physical examination: measures of physical examination basically included range of motion of the lumbar region measured, for example, by the finger-floor distance or Schober tests^{22,28,30,38,40,47,48,51} and a composite outcome measure based on physical examination.^{26,27,44} We compared the agreement between the results of physical examination with the results of pain and function in the trials that reported these data. There were 16 situations in which pain and physical examination were measured (*e.g.*, same trial, same comparison group, same follow-up, *etc.*). There was agreement in 13 situations and disagreement in 3. There were 9 situations in which functional outcomes and physical examination were measured (*e.g.*, same trial, same comparison group, same follow-up,

	Number of studies (patients)	Pain				Function or global improvement			
		Immediately after end of all sessions	Short-term < 3 months	Intermediate (3 – 12 months)	Long-term (> 12 months)	Immediately after end of all sessions	Short-term < 3 months	Intermediate (3 – 12 months)	Long-term (> 12 months)
Acute LBP									
• One session of dry-needling versus one session of trigger point injection with lidocaine	1(33)	×	×	×	×	↔↔	×	×	×
• One session of dry-needling versus one session of trigger point injection with lidocaine and steroid	1(34)	×	×	×	×	↔↔	×	×	×
• One session of dry-needling versus one session of cooling spray over trigger point area followed by acupressure	1(36)	×	×	×	×	↔↔	×	×	×
Chronic LBP									
• Superficial needling (4mm) at trigger points versus placebo TENS	1(17)	↑	×	×	×	↑	×	×	×
• Dry-needling added to a regimen of physiotherapy, occupational therapy and industrial assessments versus the regimen alone	1(56)	×	×	×	×	↑	↑	↑	×

Ac: Acupuncture
 (↑) Limited, (↑↑) moderate or (↑↑↑) strong evidence that dry-needling is more effective than the control treatment;
 (↔) Limited, (↔↔) moderate or (↔↔↔) strong evidence that there is no difference between dry-needling and the control treatment;
 (↓) Limited, (↓↓) moderate or (↓↓↓) strong evidence that dry-needling is less effective than the control treatment;
 × No trial for that comparison was found in this systematic review;
 ? Contradictory findings

Figure 3. Effects of dry-needling at trigger points.

etc.). There were 5 agreements and four disagreements.

d. Measures of complications: only 14 trials reported any measure of complications or side effects.^{21,28,32–34,36–42,47,48} The results for complications that happened during the treatment period showed that for a total of 245 patients who received acupuncture, there were only 13 minor complications (5%), whereas for 156 patients who received sham therapy, there were no complications (0%). In the group of 205 patients that received other interventions (e.g., TENS, NSAIDs, etc.), there were 21 reports of complications (10%). None of the complications were fatal or so serious that hospitalization was required.

2. Other comparisons:

a. Efficacy and effectiveness of dry-needling at trigger and motor points (Figure 3). There is limited evidence (1 lower quality trial, 17 patients) that superficial needling (4 mm) inserted at trigger points is better than placebo TENS.⁴⁹ Two randomized trials compared dry-needling with other interventions. There is limited evidence (1 lower quality trial, 56 people)⁴⁶ that a few sessions of dry-needling, added to a regimen of physiotherapy, occupational therapy, and industrial assessments, is better than the regimen alone immediately after, at the short-term, and the intermediate-term follow-ups. There is moderate evidence (1 higher quality trial, 34 people)³⁷ that there is no difference in short-term global improvement between 1 session of dry-needling and 1 session of trigger point injection with lidocaine and steroid, 1 session of trigger

point injection with lidocaine only, or 1 session of cooling spray over the trigger point area followed by acupressure.

b. Comparison between different techniques of acupuncture (Figure 4):

- i. For acute low back pain, 1 single session of bilateral needling of SI3 is better than 1 single session of needling of Yaotongxue (Extra 29, EX-UE 7) (1 lower quality trial, 150 patients)²⁷
- ii. For chronic low back pain, deep stimulation (1.5 cm in the muscle or in the trigger point) is better than superficial stimulation (2 mm in the subcutaneous tissue) immediately after the sessions and at the short-term follow-up (1 higher quality trial, 42 patients)³⁵
- iii. For chronic low back pain, the ancient needling technique is better than the regular needling technique at the short-term follow-up (1 lower quality trial, 54 patients)²³
- iv. For chronic low back pain, manual acupuncture has the same effects as electroacupuncture, both at the short and long-term follow-ups (1 higher quality trial, 34 patients)³⁴
- v. For low back pain of any duration, distal point needling is no different from local lumbar area needling for measures of pain, function, and range of motion (1 lower quality trial, 20 patients)²²
- vi. For low back pain of any duration, needle retention for about 10 minutes is better than removal immediately after insertion (1 lower quality trial, 20 patients)¹⁹

	Technique 1	Technique 2	Number of studies (patients)	Pain, function or global improvement			
				Immediately after end of all sessions	Short-term < 3 months	Intermediate (3–12 months)	Long-term (> 12 months)
For acute low-back pain	One single session of bilateral needling of SI 3	One single session of needling of Yaotongzue (EX 29, EX-UP 7)	1(150)	↑	×	×	×
For chronic low-back pain	Deep stimulation (1.5 cm)	Superficial stimulation (2mm)	1(42)	↑↑	↑↑	×	×
For chronic low-back pain	Ancient needling technique	Regular needling technique	1(54)	↑	×	×	×
For chronic low-back pain	Manual acupuncture	Electroacupuncture	1(34)	↔↔	↔↔	×	×
Low-back pain of any duration	Distal point needling	Lumbar area needling	1(20)	↔	×	×	×
Low-back pain of any duration	Needle retention for about 10 minutes	Removal immediately after insertion	1(20)	↑	×	×	×
Low-back pain of any duration	Local needling plus cupping	Distal treatment plus electrical stimulation	1(492)	×	↑	×	×
Low-back pain of any duration	Manual acupuncture plus cupping	Manual acupuncture alone	1(156)	↑	×	×	×

Ac: Acupuncture
 (↑) Limited, (↑↑) moderate or (↑↑↑) strong evidence that technique 1 is more effective than the technique 2;
 (↔) Limited, (↔↔) moderate or (↔↔↔) strong evidence that there is no difference between technique 1 and the technique 2;
 (↓) Limited, (↓↓) moderate or (↓↓↓) strong evidence that technique 1 is less effective than technique 2;
 × No trial for that comparison was found in this systematic review;
 ? Contradictory findings

Figure 4. Comparison between 2 techniques of acupuncture.

- vii. For low back pain of any duration, local needling plus cupping is more effective than distal treatment plus electrical stimulation (1 lower quality trial, 492 patients)²⁶
- viii. For low back pain of any duration, manual acupuncture plus cupping is better than manual acupuncture alone (1 lower quality trial, 156 patients)²⁵

In summary, the best technique of acupuncture is still to be determined, but the available high-quality randomized trials suggest that the best technique of acupuncture for low back pain includes deep stimulation (1.5 cm) instead of superficial stimulation (2 mm), and it seems that electrostimulation does not add any benefit to manual stimulation of the needles.

- c. Efficacy and effectiveness of acupuncture for mixed populations of acute/chronic low back pain: There were a few trials that did not specify the duration of the low back pain or that mixed acute with chronic patients.^{17–20,30} These trials will not be discussed because they do not change the conclusions of this review.

■ Discussion

Thirty-five RCTs covering 2861 patients were included in this systematic review. There were only 3 trials of acupuncture for acute low back pain that do not justify firm conclusions because of small sample sizes and low methodologic quality of the studies. There is some evidence that acupuncture may be better than no treatment or sham treatment for chronic low back pain. However, most studies have not found acupuncture to be more effective than other conventional treatments (e.g., analgesics, NSAIDs, TENS and self-care education) or “alternative” treatments (e.g., massage or spinal manipulation). The data suggest that both acupuncture and dry-needling may be useful adjuncts to other therapies for chronic low back pain.

Although the conclusions showed some positive results of acupuncture, the magnitude of the effects were generally small. The average pain reduction (measured by continuous scales such as the VAS) in the group that received acupuncture for chronic low back pain was 32% compared to 23% in those who received sham therapies and 6% in those who received no treatment. Furthermore, the terms used to express the strength of the evidence (strong, moderate and limited), as is standard in many systematic reviews, might be misinterpreted. These are relative terms and are often used to apply to a small number of “higher” quality studies. This may give the false impression that “strong” evidence means “definite” evidence, but this may not be the case.

Although efforts were made to find all published RCTs, some relevant trials might have been missed. Twenty of the 35 included RCTs were published in English, 7 in Japanese, 5 in Chinese, and 1 each in Norwegian, Polish, and German. Although no languages were excluded, the number of non-English journals indexed in electronic databases such as MEDLINE and EMBASE is limited. If additional trials are found, this review will be updated.

The methodologic quality of the included RCTs, although improving over the past several years, was poor. There were 2 studies with fatal flaws and 14 studies with higher and 19 studies with lower methodologic quality. The methodologic quality in the current review was defined by the internal validity criteria, which referred to characteristics of the study that might be related to selection, performance, attrition, and detection bias. It seems reasonable that in the authors’ qualitative synthesis, the best evidence would be provided by the higher quality studies, which are less likely to have biased results. Although the levels of evidence in this review may be considered arbitrary, it seems unlikely that a different rating system would have resulted in different conclusions.

The included studies were very heterogeneous in terms of population included, type of acupuncture administered, control groups, outcome measures, timing of follow-up, and presentation of data. Therefore, very few meaningful meta-analyses could be performed, and it was difficult to reach conclusions for most types of treatments.

The experience and training of the acupuncturists who gave the treatments were mentioned in a few studies. Some studies used a protocol of a fixed set of points for all patients, whereas others used a flexible protocol where the points were selected for each individual. Both methods are considered to be valid and were analyzed together in this systematic review.

No serious adverse events were reported in the trials included in this review. The incidence of minor adverse events was 5% in the patients submitted to acupuncture. In the literature, most of the reports of serious adverse events related to acupuncture are described as case reports. In the past years, various prospective studies were conducted, enabling the estimation of the true incidence of minor and major adverse events.

Melchart *et al* reported the largest prospective study, covering over 760,000 treatments delivered by 7050 German physicians over a 10-month period. They observed 6936 minor (incidence of 91 per 10,000 treatments) and 5 major adverse reactions (6 per 1,000,000 treatments), which included: exacerbation of depression (1 case), acute hypertensive crisis (1 case), vasovagal reaction (1 case), asthma attack with hypertension and angina (1 case), and 2 cases of pneumothorax.⁵²

The other prospective studies did not observe any major adverse reactions. Yamashita *et al* observed 65,482 treatments delivered by 84 therapists over a 6-year period in Japan. There were 94 cases of minor adverse events, with an incidence of 14 per 10,000 treatments, but this incidence was estimated using data from spontaneous reports of adverse event by the practitioner.⁵³ In another similar study by Yamashita *et al*, they forced practitioners to detect and report every acupuncture session, whether there were adverse reactions or not. Then, different incident rates of adverse reaction were obtained. A total of 391 patients were treated in 1441 sessions, involving a total of 30,338 needle insertions. The incidence of recorded systemic reactions in individual patients was: tiredness (8.2%); drowsiness (2.8%); aggravation of pre-existing symptoms (2.8%); itching in the punctured regions (1.0%); dizziness or vertigo (0.8%); feeling of faintness or nausea during treatment (0.8%); headache (0.5%); and chest pain (0.3%).⁵⁴

MacPherson *et al* observed 34,407 treatments delivered by 574 traditional Chinese acupuncturists in the UK over a 4-week period. There were 43 minor adverse events (incidence of 12.5 per 10,000 treatments).¹³ White *et al* observed 31,822 treatments delivered by 78 acupuncturists (physicians and physiotherapists) in the UK over a 21-month period. There were 43 minor adverse reactions (incidence of 13.5 per 10,000 treat-

ments).⁵⁵ Odsberg *et al* observed 9277 treatments delivered by 187 physiotherapists in Sweden over a 4-week period and recorded 2108 minor adverse reactions (incidence of 2272 per 10,000 treatments).⁵⁶ Ernst *et al* observed 3535 treatments delivered by 29 acupuncturists in Germany over a 13-month period and recorded 402 minor adverse reactions (incidence of 1100 per 10,000 treatments).⁵⁷

The great variation in incidence of minor adverse events is probably due to different definitions of adverse reaction, research designs, or styles of acupuncture in the various studies.

Because serious adverse events are rare, they continue to be reported in the form of case reports. Recently published systematic reviews of case reports showed that these serious complications may include infections (human immunodeficiency virus, hepatitis, bacterial endocarditis) caused by nonsterile needles and fatal tissue trauma (pneumothorax, cardiac tamponade, spinal cord injury).⁵⁸⁻⁶⁰ Furthermore, we have little information about the safety of acupuncture specifically for low back pain. We need more information about the safety of acupuncture that focuses on specific conditions.

■ Conclusions

Implications for Practice

There were only 3 heterogeneous trials of acupuncture for acute low back pain. Therefore, we could not reach a convincing conclusion, and there is a need for future studies to make recommendation in this area.

There is some evidence of the effects of acupuncture for chronic low back pain. Compared to no treatment, there is evidence for pain relief and functional improvement for acupuncture at shorter-term follow-ups. Compared to sham therapies, there is evidence for pain relief at shorter-term follow-up, but these effects were not maintained at the longer-term follow-ups, nor were they observed for functional outcomes. Compared to other conventional or "alternative" treatments, acupuncture is no better for measures of pain and function. There is evidence that acupuncture, added to other conventional therapies, relieves pain and improves function better than conventional therapies alone. According to these results, acupuncture may be useful as either a unique therapy for chronic low back pain or as an adjunct therapy to other conventional therapies. Although the conclusions show some positive results of acupuncture, the magnitude of the effects was generally small.

Although dry-needling appears to be a useful adjunct to other therapies for chronic low back pain, no clear recommendations can be made because of small sample sizes and low methodologic quality of the studies.

With respect to the different techniques of acupuncture, most studies were either small, of lower methodologic quality, or both; therefore, no clear recommendation could be made.

Implications for Research

Because most of the studies were of poor methodologic quality, there certainly is a need for future higher quality RCTs. Also, because many trials were poorly reported, we recommend that authors use the CONSORT statement as a model for reporting RCTs (www.consort-statement.org) and use the STRICTA criteria⁶¹ to report the interventions. Many trials could not be included in the meta-analyses because of the way the authors reported the results; therefore, we suggest that publications of future trials report means with standard deviations for continuous measures or the number of events and total patients analyzed for dichotomous measures. Future research should focus on areas where there are few or no trials, for example, acupuncture compared to no treatment, placebo, or sham for acute low back pain. Future studies should also have larger sample sizes, use a valid acupuncture treatment, and have both a short-term and a long-term follow-up (for chronic pain). From the available high-quality trials included in this review, deep stimulation seems to be the most promising acupuncture treatment. Future studies are needed that evaluate superior features of acupuncture. We suggest that publications of future trials report the proportion of patients who obtain a clinically important improvement in the groups being compared to facilitate a judgment about clinically important differences between the groups. Although an evaluation of costs was not the objective of this review, we suggest that future research assesses cost-effectiveness of acupuncture compared to other treatments.

Key Points

- Thirty-five RCTs covering 2861 patients were included in this systematic review.
- There is insufficient evidence to make any recommendations about acupuncture or dry-needling for acute low back pain.
- For chronic low back pain, results show that acupuncture is more effective for pain relief than no treatment or sham treatment, in measurements taken up to 3 months. The results also show that for chronic low back pain, acupuncture is more effective for improving function than no treatment in the short-term. Acupuncture is not more effective than other conventional and “alternative” treatments. When acupuncture is added to other conventional therapies, it relieves pain and improves function better than the conventional therapies alone. However, effects are only small.
- Dry-needling appears to be a useful adjunct to other therapies for chronic low back pain.

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