

# The Effectiveness of Acupuncture in the Management of Acute and Chronic Low Back Pain

A Systematic Review Within the Framework of the Cochrane Collaboration Back Review Group

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**Study Design.** A systematic review of randomized controlled trials.

**Objectives.** To evaluate the efficacy and effectiveness of acupuncture for the management of nonspecific low back pain.

**Summary of Background Data.** Acupuncture is one of the oldest forms of therapy, but little is known about the effectiveness of acupuncture for low back pain.

**Methods.** Randomized controlled trials were done to assess the effectiveness of all types of acupuncture treatment, which involves needling for subjects with nonspecific low back pain. Two reviewers blinded with respect to authors, institution, and journal independently assessed the methodologic quality of the studies. Because data were statistically and clinically too heterogeneous, a qualitative review was performed. The evidence was classified into four levels: strong, moderate, limited, or no evidence.

**Results.** Eleven randomized controlled trials were included. Overall, the methodologic quality was low. Only two studies met the preset “high quality” level for this review. No study clearly evaluated acupuncture for acute low back pain. The results indicate that there was no evidence showing acupuncture to be more effective than no treatment. There was moderate evidence indicating that acupuncture is not more effective than trigger-point injection or transcutaneous electrical nerve stimulation, and there was limited evidence that acupuncture is not more effective than placebo or sham acupuncture for the management of chronic low back pain.

**Conclusions.** Because this systematic review did not clearly indicate that acupuncture is effective in the management of back pain, the authors would not recommend acupuncture as a regular treatment for patients with low back pain. There clearly is a need for more high-quality randomized controlled trials. [Key words: acupuncture, Cochrane Collaboration, effectiveness, low back pain, systematic review] **Spine 1999;24:1113–1123**

Low back pain (LBP) is a major health problem in Western industrialized countries and a major cause of medical expenses, work absenteeism, and disablement.<sup>31</sup> Although LBP usually is a self-limiting and benign dis-

ease that tends to improve spontaneously over time,<sup>36</sup> a large variety of therapeutic interventions are available for its management.<sup>26</sup> However, the effectiveness claimed for most of these interventions has not been convincingly demonstrated and, consequently, the therapeutic management of LBP varies widely.

Acupuncture, one of the oldest forms of therapy, has its roots in ancient Chinese philosophy. Traditional Chinese medicine 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 in the body. In classical acupuncture theory, it is believed that all disorders are reflected at specific points either on the skin surface or just beneath it. Vital energy circulates throughout the body along the so-called meridians, which have either yin or yang characteristics. A correct choice for needling among the 361 classical acupuncture points located on these meridians is believed to restore the balance in the body.

When the needles have been placed successfully, the patient is supposed to experience a sensation known as *teh chi*, 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. In addition to needling, acupuncture often includes techniques such as moxibustion and cupping.

Since acupuncture was 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.<sup>16</sup>

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. Acupuncturists also use trigger points, which have no fixed locations and are found by eliciting tenderness at the site of most pain.

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Acupuncture commonly includes manual stimulation of the needles, but various adjuncts often are used in modern forms of the therapy including electrical acupuncture (with an electrical stimulator connected to the acupuncture needle), injection acupuncture (with herbal extracts injected into acupuncture points), and acupuncture with moxibustion (the burning of the moxa herb, *Artemisia vulgaris*, at the end of the needle).<sup>16</sup>

It is still not clear what exact mechanisms underlie the action of acupuncture. According to traditional Chinese medicine, acupuncture promotes the flow of *qi* (life force energy), thereby balancing the human body system. Western scientific research has proposed mechanisms for the effect of acupuncture in relieving pain. It has been suggested that acupuncture might act according to principles enunciated by 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, diffuse noxious inhibitory control (DNIC), implies that noxious stimulation of heterotopic body areas modulates the pain sensation originating in areas where a subject feels pain. There also is some evidence that acupuncture may stimulate the production of endorphins, serotonin and, acetylcholine in the central nervous system, enhancing analgesia.<sup>4,27</sup>

Although the effectiveness of acupuncture in the management of chronic pain has been reviewed systematically before,<sup>28</sup> no reviews have focused specifically on the effectiveness of acupuncture for LBP. The current review summarizes the available scientific evidence on the effectiveness of acupuncture for both acute and chronic LBP.

## ■ Objectives

This systematic review aimed to determine if acupuncture is an effective method of management for nonspecific LBP. The following comparisons were investigated:

1. Acupuncture compared with no treatment
  - a. Acupuncture in addition to baseline medication or treatment compared with baseline medication or treatment alone
  - b. Acupuncture treatment only, as compared with a group not receiving any intervention
2. Acupuncture compared with placebo or sham treatment
  - a. Acupuncture compared with needle attachment to skin surface (placebo: needle that does not penetrate the skin)
  - b. Acupuncture compared with needling prick on skin surface (sham: needles placed in an area close to but not in acupuncture points)
3. Acupuncture compared with conventional treatment

## ■ Methods

**Criteria for Including Studies in This Review.** *Types of Studies.* Only randomized controlled trials (RCTs) were in-

cluded in this review. Nonrandomized controlled clinical trials and trials controlled before and after studies were excluded.

*Types of Participants.* Randomized controlled trials that involved subjects with nonspecific LBP were included, but RCTs that included subjects with LBP caused by specific pathologic entities such as infection, metastatic diseases, neoplasm, osteoporosis, rheumatoid arthritis, or fractures were excluded. Patients with subacute LBP (12 weeks or less), chronic LBP (more than 12 weeks), or both were included.

*Types of Interventions.* Articles evaluating acupuncture treatment that involved needling were included in this review. Either traditional acupuncture in which the needles are inserted at classical meridian points or contemporary acupuncture in which the needles are inserted at nonmeridian or trigger points were included in the review. Studies were included regardless of the source of stimulation (*e.g.*, manual or electrical). Studies in which the acupuncture treatment did not involve needling, such as acupressure or laser acupuncture, were excluded. The control interventions were placebo acupuncture, other therapeutic interventions, or no treatment.

*Types of Outcome Measures.* Randomized controlled trials were included that used at least one of the four primary outcome measures that the current authors considered to be the most important: pain intensity (VAS), a global measure (overall improvement, proportion of patients recovered, subjective improvement of symptoms), functional status (Roland-Morris Disability Questionnaire, Oswestry Scale), and return to work (return to work status, number of days off work). Physiologic outcomes of physical examination (*e.g.*, range of motion, spinal flexibility, degrees of straight leg raising, or muscle strength), generic health status (as assessed by the Medical Outcome Study Short Form-36 [SF-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.** Relevant RCTs meeting the inclusion criteria for this review were identified in the following steps:

1. Computer-aided search of the MEDLINE (1966–1996), EMBASE (1988–1996), and Cochrane Complementary Medicine Field databases using the search strategy recommended by the Editorial Board of the Cochrane Back Review Group.<sup>3,30</sup>
2. Screening of references in relevant reviews and RCTs identified in Step 1
3. Screening of the Cochrane Library 1997, Issue 1
4. Citation tracking of the RCTs identified in Steps 1 to 3, using the Science Citation Index.

**Methods of the Review.** *Study Selection.* One reviewer (MvT) generated the MEDLINE and EMBASE search strategies and downloaded the author, title, keywords, and abstract of all the identified studies into a computer file. Two reviewers (DC and MvT) then independently reviewed the information to identify trials that might potentially meet the inclusion criteria. Full articles describing these trials were obtained, and the same reviewers independently applied the selection criteria to the studies. Consensus was used to solve disagreements concerning

**Table 1. Methodologic Quality Criteria List**

Patient selection			
a. Were the eligibility criteria specified?	Yes	No	Don't know
b. Treatment allocation			
1) Was the method of randomization described and adequate?	Yes	No	Don't know
2) Was the treatment allocation concealed?	Yes	No	Don't know
c. Were the groups similar at baseline regarding the most important prognostic indicators?	Yes	No	Don't know
Intervention			
d. Were therapeutic and control interventions operationalized?	Yes	No	Don't know
e. Was the care provider blinded?	Yes	No	Don't know
f. Was controlled for co-interventions which could explain the results?	Yes	No	Don't know
g. Was the compliance rate (in each group) unlikely to cause bias?	Yes	No	Don't know
h. Was the patient blinded?	Yes	No	Don't know
Outcome measurement			
i. Was the outcome assessor blinded?	Yes	No	Don't know
j. Was at least one of the primary outcome measures applied?	Yes	No	Don't know
k. Was there a description of adverse effects?	Yes	No	Don't know
l. Was the withdrawal/drop-out rate unlikely to cause bias?	Yes	No	Don't know
m. Timing of follow-up measurements			
1) Was a short-term follow-up measurement performed?	Yes	No	Don't know
2) Was a long-term follow-up measurement performed?	Yes	No	Don't know
n. Was the timing of the outcome assessment in both groups comparable?	Yes	No	Don't know
Statistics			
o. Was the sample size for each group described?	Yes	No	Don't know
p. Did the analysis include an intention-to-treat analysis?	Yes	No	Don't know
q. Were the point estimates and measures of variability presented for the primary outcome measures?	Yes	No	Don't know

the final inclusion of RCTs, and a third reviewer was consulted if disagreements persisted.

**Methodologic Quality Assessment.** The methodologic quality of each RCT was assessed independently by two reviewers, who were blinded with respect to authors, institution, and journal. This blinding was performed by an independent person not involved in the review. Consensus was used to resolve disagreements, and a third reviewer was consulted if disagreements persisted.

The methodologic quality of the RCTs was assessed according to the criteria list (Table 1) recommended in the method guidelines of the Cochrane Back Review Group for systematic reviews.<sup>30</sup> Only the 10 items reflecting the internal validity of the RCTs (criteria B1, B2, C, E, F, G, H, I, L, N) were used in the meta-analysis to assess the methodologic quality of the RCTs. Each criteria was scored as “yes,” “no,” or “don't know.”

Seven of the eight English language studies were assessed by the two principal reviewers (DC and MvT). Because one of the English language studies was known by these reviewers,<sup>22,23</sup> that study was assessed by two other reviewers (BK and WD) to maintain the goals of blinding. For practical reasons, the German<sup>34,35</sup> (BK and MvT) and French<sup>6</sup> (BK and WD) studies also were assessed by one or two other experienced reviewers. The Polish study<sup>20</sup> was assessed by one reviewer (MvT) with the help of an individual whose first language was Polish.

**Data Extraction.** Two reviewers blinded to author, institution, and journal independently extracted the data on the primary outcome measures (pain intensity, a global measure, functional status, and return to work) and secondary outcome measures (physical measures, generic health status, and other symptoms such as medication use and side effects).

Data on the characteristics of the study population were extracted: type, location, and duration of LBP; age and gender; and acupuncture and reference interventions such as type of intervention, frequency, intensity, duration, and setting.

The authors of the original studies were not contacted for more information because all but one RCT were published before 1990.

**Analysis.** The results of each RCT were plotted as point estimates (*i.e.*, odds ratios with corresponding 95% confidence intervals for discrete outcomes, and mean and standard deviation for continuous outcomes). Statistical homogeneity was formally tested.

According to the reviewers, the studies were clinically heterogeneous with respect to the type and duration of the disorder, the interventions (types of acupuncture), and the outcomes. Furthermore, the outcomes were poorly presented in 6 of the 11 studies (as reflected by the six negative scores to item Q of the criteria list) in such a way that pooling was not possible. Therefore, it was decided not to pool the data statistically, but to perform a qualitative review (best evidence synthesis) by attributing various levels of evidence to the effectiveness of acupuncture, taking into account the methodologic quality and the outcome of the original studies:

Level 1: Strong evidence—provided by generally consistent findings in multiple, relevant, high-quality RCTs

Level 2: Moderate evidence—provided by generally consistent findings in one relevant, high-quality RCT and one or more relevant low-quality RCTs

Level 3: Limited evidence—provided by generally consistent findings in one or more relevant low-quality RCTs

Level 4: No or conflicting evidence—if there were no RCTs or if the results were conflicting.

An RCT was considered to be of higher quality if more than 5 of the 10 validity items scored positively. The literature was considered to be conflicting if less than one third of the studies were either positive or negative for a specific outcome measure. The findings of each study were assessed by the blinded reviewers to be positive, neutral, negative, or unclear (if the results

**Table 2. Internal Validity Items**

Reference	B1	B2	C	E	F	G	H	I	L	N
Coan et al <sup>5</sup>	+	+	-	-	-	-	-	-	-	-
Duplan et al <sup>6</sup>	-	?	+	-	-	+	+	+	+	+
Edelist et al <sup>7</sup>	?	?	?	-	-	+	+	+	+	?
Garvey et al <sup>10</sup>	+	?	?	+	-	+	+	+	+	+
Gunn et al <sup>12</sup>	-	-	+	-	-	+	-	-	+	+
Lehmann et al <sup>17,18</sup>	?	?	?	-	+	+	-	-	-	+
Lopacz and Gralewski <sup>20</sup>	?	?	?	-	+	?	-	-	+	+
MacDonald et al <sup>21</sup>	?	?	+	-	-	+	+	?	+	?
Mendelson et al <sup>22,23</sup>	+	?	?	-	-	+	+	+	-	+
Thomas and Lundberg <sup>29</sup>	?	?	+	-	-	+	-	?	?	+
Von Mencke et al <sup>34,35</sup>	?	?	?	-	-	-	+	+	-	+

+ = yes; - = no; ? = don't know.

B1. Was a method of randomization performed?

B2. Was the treatment allocation concealed?

C. Were the groups similar at baseline regarding the most important prognostic indicators?

E. Was the care provider blinded?

F. Was controlled for co-interventions which could explain the results?

G. Was the compliance rate (in each group) unlikely to cause bias?

H. Was the patient blinded?

I. Was the outcome assessor blinded?

L. Was the withdrawal/drop-out rate unlikely to cause bias?

N. Was the timing of the outcome assessment in both groups comparable?

were poorly presented or there was a major flaw in the study design). The reviewers' conclusions about the studies' findings were based on the methodologic quality and sample size of the studies and on the statistical significance of the results from the primary outcome measures. These conclusions were made independently of those reported by the authors.

Subgroup analyses were conducted for these symptoms:

1. Subacute low back pain (12 weeks or less) and chronic low back pain (more than 12 weeks)
2. Low back pain without radiation compared to low back pain with radiation.

A sensitivity analysis was conducted to compare RCTs of lower methodologic quality with RCTs of higher methodologic quality, using different cutoff points. Higher quality was defined as a validity score of 5, 6, or 7 out of a possible 10 on the internal validity items. A sensitivity analysis was conducted in which all "don't know" scores on the validity items were assumed to be "yes" in one analysis and "no" in another analysis.

## ■ Results

### Study Selection

The MEDLINE search (1966–1996) identified 25 studies and the EMBASE search (1988–1996) identified 31 studies as potentially eligible. Because 4 studies were found in both databases, the total number of studies identified in MEDLINE and EMBASE was 52. After reviewing the information on authors, title, abstract, and keywords, both reviewers considered 27 studies to be potentially eligible for review. Reviews of the full articles reporting these 27 studies resulted in agreement that 8 articles met the eligibility criteria.<sup>5,10,12,17,18,21,29,35</sup> The two studies by Lehmann et al<sup>17,18</sup> reported on the same study, and 16 articles did not meet the eligibility criteria. One of these 16 studies was an RCT on acupuncture for LBP,<sup>19</sup> but it was excluded because the acupuncture

treatment did not involve needling. The other 15 articles were not reports of RCTs. The reviewers disagreed about three articles, of which two were included after the decision of a third reviewer.<sup>22,23</sup> One study was excluded because the acupuncture treatment did not involve needling.<sup>13</sup> The two articles by Mendelson et al.<sup>22,23</sup> reported on the same study. A search of the Cochrane Complementary Medicine Field database identified two additional studies that met the inclusion criteria.<sup>7,20</sup> Examination of the studies on acupuncture for LBP in the reviews of Richardson and Vincent<sup>25</sup> and Ter Riet et al<sup>28</sup> resulted in the identification of one additional study.<sup>6</sup> Screening of the Cochrane Library did not reveal any additional studies. In summary, a total of 11 RCTs on acupuncture for nonspecific LBP were identified that met the criteria for inclusion in this review.

**Table 3. Descriptive Items**

Reference	A	D	J	K	M1	M2
Coan et al <sup>5</sup>	+	-	+	-	+	+
Duplan et al <sup>6</sup>	+	+	+	-	+	-
Edelist et al <sup>7</sup>	-	+	+	-	+	-
Garvey et al <sup>10</sup>	+	+	+	+	+	-
Gunn et al <sup>12</sup>	+	+	+	-	+	+
Lehmann et al <sup>17,18</sup>	+	+	+	+	+	+
Lopacz and Gralewski <sup>20</sup>	-	+	+	-	+	-
MacDonald et al <sup>21</sup>	+	+	+	-	+	-
Mendelson et al <sup>22,23</sup>	-	+	+	-	+	-
Thomas and Lundberg <sup>29</sup>	+	+	+	-	+	+
Von Mencke et al <sup>34,35</sup>	+	+	+	-	+	-

+ = yes; - = no; ? = don't know.

A. Were the eligibility criteria specified?

D. Were therapeutic and control interventions operationalized?

J. Were the most important outcome parameters applied?

K. Was there a description of adverse effects?

M1. Was a short-term follow-up measurement performed?

M2. Was a long-term follow-up measurement performed?



**Table 4. Statistical Items**

Reference	O	P	Q
Coan et al <sup>5</sup>	+	–	–
Duplan et al <sup>6</sup>	+	+	–
Edelist et al <sup>7</sup>	+	+	–
Garvey et al <sup>10</sup>	+	+	–
Gunn et al <sup>12</sup>	+	+	+
Lehmann et al <sup>17,18</sup>	+	+	–
Lopacz and Gralewski <sup>20</sup>	+	+	+
MacDonald et al <sup>21</sup>	+	+	–
Mendelson et al <sup>22,23</sup>	–	–	+
Thomas and Lundberg <sup>29</sup>	–	+	+
Von Mencke et al <sup>34,35</sup>	+	–	+

+ = yes; – = no; ? = don't know

O. Was the sample size for each group described?

P. Did the analysis include an intention-to-treat analysis?

Q. Were point estimates and measures of variability presented for the primary outcome measures?

### Methodologic Quality

Tables 2–5 show the scores on the methodologic criteria list. There was disagreement between the reviewers concerning 51 of 190 scores (27%). After the consensus meeting, 16 of the disagreements were not resolved, and a third reviewer made a final decision, taking into account the comments of the reviewers who disagreed.

Overall, the number of validity items with a positive score was low. Only two studies<sup>6,10</sup> met the preset high-quality level requiring a score greater than 50%. Most studies lacked information on one or more validity items. In particular, information was lacking on items B1, B2, C, E, F and I, meaning that the randomization procedure was not adequately described, that it was unclear if the groups were similar at baseline, that the care provider was not blinded, that co-interventions were neither avoided nor subjected to control, and that the outcome assessor was not blinded.

Information also was lacking in most studies on some of the descriptive and statistical items, particularly items K, M2, and Q, indicating that adverse effects were not described, that there was no long-term follow-up measurement, and that the results were presented poorly.

### Study Characteristics

The study characteristics are provided in detail in Table 6. There were three studies comparing acupuncture to no treatment,<sup>5,12,29</sup> two studies comparing acupuncture to conventional treatment,<sup>10,17,18</sup> and eight studies comparing acupuncture to a placebo or sham acupuncture.<sup>6,7,10,17,18,20–23,34,35</sup> Seven studies took place in a secondary care setting,<sup>6,7,12,17,18,20,21,34,35</sup> and in four studies the setting was not specified.<sup>5,10,22,23,29</sup> Six studies included patients with chronic LBP.<sup>5,12,17,18,21–23,29</sup> Three studies included a mix of patients with acute, subacute, and chronic LBP,<sup>6,20,34,35</sup> and two studies did not specify the duration of the reported conditions.<sup>7,10</sup> Five studies included a mix of LBP patients with and without radiation.<sup>12,17,18,21,29,34,34</sup> In four studies, it was not

specified whether patients with or without radiating symptoms were included,<sup>5,7,20,22,23</sup> and only two studies reported on LBP with<sup>6</sup> or without<sup>10</sup> radiation. The sample sizes were very small, ranging from 17 to 100 subjects. Basic information on age and gender of the study population was missing in 6 of the 11 studies.<sup>7,10,17,18,21,29,34,34</sup>

The acupuncture treatment varied widely in type and length, and in only three studies was stimulation performed until the chi was reached. A description of the (adequate) training and experience of the acupuncturists was given in only four studies.<sup>5,17,18,22,23,29</sup>

### Best-Evidence Synthesis

Subgroup analyses had been planned for acute *versus* chronic LBP and for LBP with radiation *versus* LBP without radiation. However, the planned subgroup analyses could not be performed because no study clearly evaluated acute LBP and because 9 of the 11 studies included either a mixed population who had LBP with and without radiation or did not specify whether the subjects had radiating symptoms.

**Acupuncture Versus No Treatment.** Three studies were identified that compared acupuncture to no treatment.<sup>5,12,29</sup> In two of these studies, the reference group consisted of patients on a waiting list,<sup>5,29</sup> and in one study the additional value of acupuncture over a standard clinical regimen was compared with the standard clinical regimen alone.<sup>12</sup> All three studies were of lower methodologic quality (Table 5), and the conclusions of the reviewers were contradictory. Thus, there was conflicting evidence on the effectiveness of acupuncture compared with no treatment.

**Acupuncture Versus Conventional Treatment.** Two studies were identified that compared acupuncture with conventional treatment.<sup>10,17,18</sup> The study by Garvey et al<sup>10</sup> was of higher methodologic quality and the study of Lehmann et al<sup>17,18</sup> of lower methodologic quality. The overall conclusion of the reviewers concerning both was neu-

**Table 5. Number of Internal Validity Items (B1, B2, C, E, F, G, H, I, L, N) Scored Yes, No or Don't Know**

Reference	Internal Validity Score			
	Yes	No	Don't Know	
Garvey et al <sup>10</sup>	7	(9)	1	2
Duplan et al <sup>6</sup>	6	(7)	3	1
Mendelson et al <sup>22,23</sup>	5	(7)	3	2
Edelist et al <sup>7</sup>	4	(8)	2	4
Gunn et al <sup>12</sup>	4	(4)	6	0
MacDonald et al <sup>21</sup>	4	(8)	2	4
Lehmann et al <sup>17,18</sup>	3	(6)	4	3
Lopacz and Gralewski <sup>20</sup>	3	(7)	3	4
Thomas and Lundberg <sup>29</sup>	3	(7)	3	4
Von Mencke et al <sup>34,35</sup>	3	(6)	4	3
Coan et al <sup>5</sup>	2	(2)	8	0

The values in parentheses refer to sensitivity analysis; number of validity items fulfilled if all "don't know" scores are positive.

**Table 6. Study Characteristics**

Study	Methods	Participants	Interventions	Outcomes	Notes
Coan et al <sup>5</sup>	RCT; randomization was carried out by having prepared in advance a small box with 50 identically sized pieces of paper, folded so that they could not be read. 25 had A and 25 had B written on them. The box was shaken and one of the pieces of paper was removed from the box blindly.	50 patients recruited via newspapers. Inclusion criteria: LBP for 6 months or more, no previous acupuncture treatments, no history of diabetes, infection or cancer, and not more than 2 back surgeries. Heterogeneous population regarding type and location of disorder.	Acupuncture tx: according to classical Oriental meridian theory. Electrical acupuncture in some patients. Acknowledged acupuncturists. Reference tx: waiting list controls; no treatment.	Results after 10 weeks in acupuncture and after 15 weeks in reference group: reduction in pain score (11-point scale), global improvement and ADL (4-point scale): acupuncture group 51%, 83% and 19% vs. reference group 2%, 31% and 0%. Inadequate treatment in 11 of the 50 patients treated with acupuncture.	Conclusion of authors 'positive'; conclusion of reviewers 'unclear'. Large number of drop-outs. Inadequate treatment group should have been included in intention-to-treat analysis. Difference in follow-up time.
Duplan et al <sup>6</sup>	RCT; randomization procedure not described.	30 hospital patients. Inclusion criteria: severe lumbosciatica, disc origin, no improvement after conventional medicine. Exclusion criteria: neurological involvement, cauda equina, tumor, post-surgical recurrence.	Acupuncture tx: 9 traditional acupuncture points, electronically detected, meridian, sterile needles inserted 2–3 mm, no manual or electrical stimulation, 5 treatments of 20 minutes. Training and experience of acupuncturists unknown. Reference tx: placebo acupuncture, 6 points, 5 treatments of 20 minutes.	Results: mean improvement in pain at rest and standing (VAS) after 6 days in acupuncture group 29% and 21%, in reference group 1% and 13%. Increase on Laseque test in acupuncture group of 13 degrees and in reference group 7 degrees. Improvement in Schober test and fingertip-floor distance 0.3 cm and 2.5 cm in acupuncture and –0.1 cm and 3 cm in reference group.	Conclusion of authors 'positive', conclusion of reviewers 'positive'. Control group seemed to have more severe complaints. Most differences tested within groups not between groups.
Edelist et al <sup>7</sup>	RCT; randomization procedure not described.	30 patients. Inclusion criteria: no improvement after conventional therapy including bed rest, analgesics, heat and physiotherapy. Patients were felt to have disc disease.	Acupuncture tx: manual insertion of 4 sterile needles into traditional acupuncture points until reaching 'te chi,' then electroacupuncture at 3–10 Hz for 30 minutes, 3 treatments in maximum 2 weeks. Training and experience of acupuncturists unknown. Reference tx: sham acupuncture, 4 needles placed in areas devoid of classic acupuncture points, no 'te chi'.	Results: no. of patients improved posttreatment on global measure (subjective) and physical examination (objective): acupuncture 7 (47%), 6 (40%) vs. reference 6 (40%), 5 (33%). Not significant.	Conclusion of authors 'neutral'. Conclusion of reviewers 'neutral'. Very small sample size, no. of patients randomized unknown.
Garvey et al <sup>10</sup>	RCT; computer-generated four-tier entry list.	63 patients. Inclusion criteria: non-radiating LBP, normal neurological examination, absence of tension signs, normal x-ray, persistent pain despite initial treatment of 4 weeks, being able to localize a point of maximum tenderness (trigger point).	Acupuncture tx: a single dry-needle stick with a 21-gauge needle after an isopropyl alcohol wipe. Training and experience of acupuncturists unknown. Reference tx: 1: injection with 1.5 ml of 1% lidocaine using a 1.5 inch, 21-gauge needle after an isopropyl alcohol wipe. 2: injection with 0.75 ml of 1% lidocaine and 0.75 ml of Aristospan using a 1.5 inch, 21-gauge needle after an isopropyl alcohol wipe. 3: 10-sec ethyl chloride spray from 6 inches away, followed by 20 sec acupressure using the plastic needle guard after an isopropyl alcohol wipe.	Results on global improvement (improved or not improved): no. (%) of patients improved after 2 weeks: acupuncture 11 (55%), lidocaine injection 4 (31%), lidocaine + steroid 5 (26%), acupressure 8 (50%).	Conclusion of authors 'positive'; conclusion of reviewers 'neutral'. Not traditional acupuncture.

Study	Methods	Participants	Interventions	Outcomes	Notes
Gunn et al <sup>12</sup>	RCT; randomized blocks, blocks defined by age and operation status; the first subject from each block was assigned to the acupuncture treatment	56 patients Inclusion criteria: males with LBP for at least 12 weeks, who had had 8 weeks of a standard clinic regimen Persistent disabling pain despite all traditional medical or surgical therapy and recovery deemed absent Exclusion criteria: psychosomatic or psychological problems Heterogeneous population regarding type and location of disorder	Acupuncture tx: standard clinical regimen plus acupuncture; nonmeridian, muscle motor points, 3–5 cm needles, direction of the needle perpendicular to the skin, mechanical stimulation by pecking and twirling, low voltage (9 V) electrical stimulation interrupted direct current or phasic current Training and experience of acupuncturists unknown Reference tx: standard clinical regimen (physiotherapy, remedial exercises, occupational therapy, industrial assessment)	Results of global improvement (4-point scale): no. of patients with good or total improvement at discharge and after 12 weeks in acupuncture group 18, 17 vs. 4, 4 in reference groups Significant At final follow-up (12–61 weeks) in acupuncture group 18 (62%) had returned to work and in reference group 4 (15%)	Conclusion of authors 'positive'; conclusion of reviewers 'neutral'
Lehmann et al <sup>17,18</sup>	RCT; block randomization, blocks defined by prior lumbar surgery	54 patients screened at orthopaedic clinic Inclusion criteria: chronic disabling LBP warranting the expense of inpatient treatment Exclusion criteria: candidates for lumbar surgery, pain less than 3 months, pregnancy, osteomyelitis of the spine, discitis, tumor, ankylosing spondylitis, vertebral fractures and structural scoliosis	Acupuncture tx: electroacupuncture, biphasic wave at 2–4 Hz, meridian, Hoku points and additional points were stimulated according to the patient's pattern of pain, twice weekly for 3 weeks A certified acupuncturist experienced in its application Reference tx: 1: TENS, pulse width of 250/sec at 60 Hz, 15 treatments in 3 weeks sub-threshold intensity, points of stimulation over the center of pain, experienced physiotherapist 2: placebo TENS, same as TENS but dead battery	Results: acupuncture significantly more relief of average pain posttreatment and after 6 months (36%, 43%) than both reference groups (7%, 3%, and 32%, 16%) No differences between reference groups Return to work after 6 months 53% in acupuncture and 61% in TENS and 44% in placebo TENS group	Conclusion of authors 'positive' for pain, 'neutral' for global measure and return to work, overall conclusion 'positive' Conclusion of reviewers 'neutral'
Lopacz and Gralewski <sup>20</sup>	RCT; randomization procedure not described	34 patients from a neurology department Inclusion criteria: low back pain for 1 month or more	Acupuncture tx: 4 needles close to spine, 0.5 cm 10% NaCl, 10 minutes, 4 treatments, 8 days, plus pharmacotherapy Training and experience of acupuncturists unknown Reference tx: placebo, suggestion, new Swedish method for pain relief, same 4 points echo-encephalograph, 10 minutes, 4 treatments, 8 days, plus pharmacotherapy	Results of global improvement (5-point scale): after 1 treatment and 4 treatments no. (%) improvement in acupuncture group 13 (72%), 13 (72%) and in reference group 3 (19%), 9 (56%)	Conclusion of authors 'neutral', conclusion of reviewers 'neutral' Very short term follow-up only Small sample size Polish language
MacDonald et al <sup>21</sup>	RCT; a stratified random process to divide the sexes as equally as possible between the two groups	17 patients referred from orthopaedic or rheumatological departments Inclusion criteria: chronic LBP for at least 1 year, no relief from conventional treatments	Acupuncture tx: subcutaneous (4mm) 30-gauge needle insertion at trigger points (no. of trigger points unknown) 5–20 minutes, maximum of 10 treatments in 10 weeks Training and experience of acupuncturists unknown Electroacupuncture (impulses 700 $\mu$ s at 2 Hz) if manual stimulation failed Reference tx: placebo acupuncture, electrodes connected to dummy apparatus, maximum 10 treatments in 10 weeks	Results: mean percentage reduction posttreatment in pain score (VAS), pain relief score (VAS), physical examination (presence of physical signs) and ADL (VAS): acupuncture group 57%, 77%, 97%, and 52% vs. reference group 23%, 30%, 29%, and 6% Significant	Conclusion of authors 'positive'; conclusion of reviewers 'neutral' Very small sample size, no. of treatments unknown, and follow-up time unknown

(Continues)

**Table 6. (Continued)**

Study	Methods	Participants	Interventions	Outcomes	Notes
Mendelson et al <sup>22,23</sup>	RCT; random number method	100 patients Inclusion criteria: chronic low back pain, no compensation or litigation pending, no overt psychiatric disease	Acupuncture tx: traditional Chinese acupuncture, meridian, 8 needles, manual stimulation until reaching 'teh chi', 30 minutes with no further stimulation, twice weekly, 4 weeks A surgeon trained at the Chinese Traditional Medical Research Institute in Peking Reference tx: placebo acupuncture, intradermal injection of 2% lidocaine at nonacupuncture, nontender sites, then acupuncture needles for 30 minutes without stimulation., twice weekly, 4 weeks	Results: reduction in pain score (VAS) after 4 weeks in acupuncture group 40% vs. reference group 26% Not significant. Cross-over: reduction in pain score now acupuncture 19%, placebo 40% Significant Overall mean percentage decrease in pain score 26.1 for acupuncture and 21.8 for placebo Not significant	Conclusion of authors 'neutral' Conclusion of reviewers 'unclear'
Thomas and Lundberg <sup>29</sup>	RCT; randomization procedure not described	43 patients from 2 clinics Inclusion criteria: nociceptive LBP for 6 months or more, restriction of trunk or hip movement due to pain, restriction of ADL, muscle spasm Exclusion criteria: previous surgery, claudication, depression, neurosis, clinical examination not nociceptive	Acupuncture tx: manual stimulation of needles, low frequency (2 Hz) and high frequency (80 Hz) electrical stimulation of needles, 3 paraspinal points and 3-4 distal points, insertion 1-5 cm, rotation producing 'teh chi', 10 sessions of 30 minutes, 2 registered physiotherapists trained in acupuncture Reference tx: waiting list controls, no treatment	Results: randomization only for three modes of acupuncture vs. waiting list controls (WLC) The improvement in pain (no. of words from chart of 83 words describing pain intensity), global improvement (3-point scale) and functional status (VAS on 12 ADL) was in the acupuncture group after 6 weeks 2, 0.6 and 0.7 and in the WLC group -0.1, -0.1, and -0.8 After 6 months 2.1, 0.2 and 1.0 vs. -0.2, 0 and 0.3	Conclusion of authors 'positive' for pain, global measure and physical examination, neutral for functional status, overall conclusion of authors 'positive' Overall conclusion of reviewers 'positive' for acupuncture compared to WLC Randomization only for comparison acupuncture vs. WLC, not for different modes of acupuncture
Von Mencke et al <sup>34,35</sup>	RCT; randomization procedure not described	65 patients from an orthopedic clinic Inclusion criteria: lumbago and/or ischias, no relief after conventional treatment Exclusion criteria: neurological problems, scoliosis, concurrent treatment, acute disc prolapse or protrusion, chronic degenerative disorders, infection Heterogeneous population regarding type, location, and duration of disorder	Acupuncture tx: manual acupuncture, traditional meridian acupuncture or trigger points, rotation, insertion 0.2-3 cm, 6-12 needles 5-20 minutes, 8 treatments Training and experience of acupuncturists unknown Reference tx: sham acupuncture, no traditional acupuncture or trigger points	Results: after short-term follow-up, improvement in pain intensity (VAS) in acupuncture group 55% in reference group 37%, after long-term follow-up 44% vs. 30% Global improvement in 94% of acupuncture and 50% of reference group Increase in Schober test after short-term and long-term follow-up in acupuncture vs. reference group 6.4 and 7.8 vs. 2.7 and -0.9, for Lasegue's test 6.0 and 6.7 vs. 2.2 and 0.6.	Conclusion of authors 'positive' for all outcome measures and overall; overall conclusion of reviewers 'neutral'

tral, indicating that there was moderate evidence to show that acupuncture is not more effective than trigger point injection or transcutaneous electrical nerve stimulation (TENS).

**Acupuncture Versus Placebo or Sham Acupuncture.** Eight studies were identified comparing acupuncture to a placebo or sham acupuncture.<sup>6,7,10,17,18,20-23,34,35</sup> Of these, only two studies were of higher methodologic quality.<sup>6,10</sup> The reviewers' overall conclusion about the study of Duplan et al<sup>6</sup> was positive, although it was noted that the control group seemed to have reports of more severe conditions at baseline. The reviewers' overall conclusion concerning the study of Garvey et al<sup>10</sup> was neutral, although it should be noted that the usefulness of the acupuncture treatment used in this study is debatable. There

is conflicting evidence that acupuncture is more effective than placebo or sham acupuncture resulting from the contradictory outcomes of the two higher-quality studies. The reviewers' overall conclusion concerning five of the six low-quality studies was neutral, indicating that acupuncture was not more effective than placebo or sham acupuncture. In one study, the overall conclusion was unclear.

#### **Sensitivity Analysis**

If it had been assumed that all validity items scored as "don't know" met the current criteria for a positive score, then 9 of the 11 studies would have been of higher quality. However, the current authors' conclusions regarding the effectiveness of acupuncture compared with no treatment for chronic LBP would not change because



two of the three studies<sup>5,12</sup> would still be of lower methodologic quality and the results would be conflicting. Their conclusions regarding the effectiveness of acupuncture compared with conventional management of LBP would now point to strong evidence showing that acupuncture is not more effective than other conventional treatment (trigger point injection or TENS). Furthermore, their conclusions regarding the effectiveness of acupuncture compared with placebo or sham acupuncture for LBP would maintain that all eight studies were of higher quality, and that six had an overall conclusion of neutral. Thus, there would be strong evidence that acupuncture is not more effective than placebo or sham acupuncture for the management of LBP.

## ■ Discussion

Eleven RCTs were included in this systematic review. Overall, the number of validity items (used to assess the methodologic quality) with a positive score was low. Only two studies<sup>6,10</sup> met the preset higher quality level requiring a score higher than 50%. According to the results, there was no evidence to show that acupuncture is more effective than no treatment, moderate evidence to show that acupuncture is not more effective than trigger point injection or TENS, and limited evidence to show that acupuncture is not more effective than placebo or sham acupuncture for the management of chronic LBP.

### Selection Bias

Although efforts were made to find all published RCTs, some relevant trials might have been missed. Eight of the 11 included RCTs were published in English, and one each was published in French, German, and Polish, respectively. There is some empirical evidence showing that exclusion of trials published in languages other than English might be associated with bias.<sup>8,11,24</sup> Although none of the languages were excluded, the number of journals published in languages other than English indexed in electronic databases such as MEDLINE and EMBASE is limited. If additional trials are found, this review will be updated.

### Blinding

Some empirical evidence<sup>14</sup> supports blinded assessment of the methodologic quality of RCTs (with respect to authors, journal, and institution) to prevent reviewer bias, but two recently published studies did not show any effect of blinding on the results of a meta-analysis.<sup>2,33</sup>

It is often difficult to achieve true blinding because experts usually are involved in the review process. The two principal reviewers who conducted the quality assessment and data extraction are experts in the field of LBP in primary care, but they had no specific knowledge or experience in the field of acupuncture. Although the study selection was nonblinded, the current authors believe that the blinded quality assessment still made sense. The English language study, for which these reviewers could not be blinded, was assessed by two other experienced reviewers.

Blinding is especially important if the reviewers have a conflict of interest. One remarkable finding in the current review was the notable difference between the overall conclusions of the (blinded) reviewers and the overall conclusions reached by the authors of the original studies. The authors of eight studies concluded that acupuncture was effective, whereas the reviewers concluded that there was a positive effect of acupuncture in only two studies. If a conflict of interest is likely to exist in a systematic review (*e.g.*, acupuncturists appraising the quality of a review on acupuncture), it is recommended that the studies be blinded for results and conclusions.

### Methodologic Quality

The methodologic quality of the included RCTs was extremely poor. 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. Studies with lower methodologic quality, as in this review, are supposed to have biased findings. It seems reasonable that in the authors' best-evidence synthesis, strong evidence can be provided only by higher quality studies, which are less likely to have biased results.

Although the levels of evidence in this review were arbitrary, it seems unlikely that a different rating system would have resulted in different conclusions. The sensitivity analysis shows that even when it is assumed that all criteria scored as "don't know" were fulfilled, there still is no strong evidence in favor of acupuncture. However, it is very unlikely that in the field of LBP all these uncertain criteria were met because, in general, the methodologic quality of RCTs in this field is low.<sup>15,32</sup>

### Levels of Evidence

Because the authors viewed the studies in this review as very heterogeneous clinically, they conducted a "best-evidence synthesis" rather than a meta-analysis (*i.e.*, statistical pooling of the data). There was a large variety in the type, location, and duration of LBP; the interventions (types of acupuncture); and the outcomes measured. Furthermore, the outcomes were poorly presented in 6 of the 11 studies to the extent that pooling was not possible. The levels of evidence used in the review were arbitrary because there still is no consensus on how to assess the strength of the evidence. Other levels of evidence might lead to different conclusions. Readers may apply their own rating system to see if the conclusions indeed change. However, it should be kept in mind that to avoid bias, a rating system ideally should be predefined and independent of the results from the studies included in the review.

### Validity of Treatment

The experience and training of the acupuncturists who gave the treatments were mentioned in a only few studies. None of the studies stated what that experience involved so far as years of practice, for example. Furthermore, in most studies the number of needles, number and

duration of sessions, and the duration of the intervention period were not specified. Some studies reported that the acupuncture points, the number of sessions, and the duration of treatment were individualized according to the pattern of the patient's pain.

From the scarce description of treatment included in most of the studies, it is difficult to evaluate whether the acupuncture treatment was valid or not. The validity of the acupuncture treatment might be related to its safety as well as its effectiveness. Serious adverse events have been associated with acupuncture such as infections (human immunodeficiency virus, hepatitis, subacute bacterial endocarditis) caused by nonsterile needles, or complications (pneumothorax, cardiac tamponade) caused by tissue trauma, but the incidence of adverse events is unknown.<sup>9</sup> A recent National Institutes of Health consensus report stated that one advantage of acupuncture is that the incidence of adverse effects is substantially lower than that of many other accepted medical interventions.

### Summary

A recent National Institutes of Health consensus panel concluded that there is clear scientific evidence to show that acupuncture is effective for postoperative dental pain, for nausea and vomiting caused by chemotherapy, and for pain after surgery and probably during pregnancy. However, the panel also concluded that sufficient scientific evidence of effectiveness is lacking concerning several other indications for which acupuncture frequently is used (e.g., chronic pain, asthma, and nicotine addiction). The results of this systematic review confirm that there is no convincing scientific evidence to show that acupuncture is effective in the management of acute and chronic LBP. However, because the studies in this review were of poor quality, the effectiveness of acupuncture for LBP remains unclear.

## Conclusions

### Implications for Practice

Because this systematic review did not clearly show that acupuncture is effective in the management of back pain, and because there are effective alternatives,<sup>32</sup> the authors do not recommend acupuncture as a regular treatment of patients with LBP.

### Implications for Research

Because most of the studies were of very poor methodologic quality, not meeting the current standards for conducting and reporting of RCTs,<sup>1</sup> there certainly is a further need for future high-quality RCTs. In particular, future studies should overcome most of the limitations of the RCTs presented in this review by using a study design that ensures a high internal validity. Future studies also should have larger sample sizes, should use a valid acupuncture treatment, and should have both a short-term and a long-term follow-up.

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