Acupuncture for lumbar spinal stenosis: A systematic review and meta-analysis

Kun Hyung Kim\textsuperscript{a,b}, Tae-Hun Kim\textsuperscript{c}, Byung Ryul Lee\textsuperscript{a,b}, Jae Kyu Kim\textsuperscript{a,b}, Dong Wuk Son\textsuperscript{d}, Sang Weon Lee\textsuperscript{d}, Gi Young Yang\textsuperscript{a,b,*}

\textsuperscript{a} Division of Clinical Medicine, School of Korean Medicine, Pusan National University, Yangsan, South Korea
\textsuperscript{b} Department of Acupuncture and Moxibustion Medicine, Korean Medicine Hospital, Pusan National University, Yangsan, South Korea
\textsuperscript{c} College of Korean Medicine, Gachon University, Seongnam, South Korea
\textsuperscript{d} Department of Neurosurgery, School of Medicine, Pusan National University, Yangsan, South Korea

Received 23 February 2013; received in revised form 13 July 2013; accepted 11 August 2013
Available online 20 August 2013

KEYWORDS
Acupuncture; Lumbar spinal stenosis; Systematic review; Complementary and alternative medicine

Summary
Objectives: Lumbar spinal stenosis (LSS) negatively affects patients’ quality of life. No systematic review evaluating the effects and safety of acupuncture for this population is available. We aimed to evaluate evidence indicating the effectiveness and safety of acupuncture for LSS.

Methods: We searched five English-language databases (EMBASE, MEDLINE, CENTRAL, CINAHL, and AMED) and one Chinese database (CAJ) for randomised controlled trials (RCTs) and non-randomised controlled clinical trials (CCTs) of needle acupuncture for LSS. CCTs were analyzed only in terms of safety and intervention-related information.

Results: Six RCTs (n = 582) and six CCTs, which were all from China and reported in Chinese, were included. High or uncertain risk of bias and clinical heterogeneity due to different acupuncture techniques were observed. All RCTs compared different combinations or techniques of acupuncture. None of the included studies mentioned safety issues. Acupuncture combined with other interventions and/or with additional stimulation increased the number of improved patients compared with acupuncture alone or relatively simpler stimulation (n = 582; relative risk, 1.16; 95% confidence interval 1.08–1.25). Pain intensity, overall symptoms, and functional outcomes related to LSS and quality of life showed significantly favourable improvement in the treatment group compared with the control group, which lasted for up to 6 months post-treatment.

* Corresponding author at: Division of Clinical Medicine, School of Korean Medicine, Pusan National University, Yangsan 626-870, South Korea, Tel.: +82 51 510 5963; fax: +82 55 360 5519.
E-mail address: iampnukh@gmail.com (G.Y. Yang).
Conclusions: We found no conclusive evidence of the effectiveness and safety of acupuncture for LSS because of high or uncertain risk of bias and the limited generalisability of the included studies. Future trials using rigorous methodology, appropriate comparisons and clinically relevant outcomes should be conducted.

© 2013 The Authors. Published by Elsevier Ltd. Open access under CC BY-NC-ND licence.

Contents

Introduction .............................................................................................................. 536
Materials and methods ..................................................................................... 536
Search and study selection .................................................................................. 536
Results .................................................................................................................. 536
Study characteristics ......................................................................................... 537
Risk of bias in the RCTs ..................................................................................... 537
Study interventions used in all included studies ............................................... 540
Outcome results in the RCTs ............................................................................. 540
Adverse events .................................................................................................. 540
Discussion .......................................................................................................... 541
Implications for future research ...................................................................... 542
Implications for clinical practice ....................................................................... 542
Conclusion ......................................................................................................... 542
Conflict of interest statement .......................................................................... 543
Acknowledgments ............................................................................................. 543
Appendix A. Characteristics of included RCTs .................................................. 543
Appendix B. Summary of acupuncture techniques used in the controlled clinical trials .......................................................... 551
Appendix C. ......................................................................................................... 554
References ......................................................................................................... 555

Introduction

Degenerative lumbar spinal stenosis (LSS) is a chronic condition characterised by anatomical narrowing of the spinal canal, debilitating symptoms (pain and/or numbness in the back and legs, neurogenic claudication, postural exacerbation or palliation of pain/numbness), limited daily function, and impaired quality of life.\(^1\,2\) LSS is considered to be the leading cause of spinal surgery among elderly patients over 65 in the U.S.\(^3\) A recent population-based study revealed that diagnosed LSS is associated with a substantial burden of illness and that there is a need to manage the associated pain and ambulation deficits experienced by patients with LSS.\(^4\)

A series of conservative treatments for LSS, including non-steroidal anti-inflammatory drugs (NSAIDs), physical treatments, exercises, and epidural steroid injections, is available. However, the long-term use of NSAIDs, which are often present in the management of LSS patients, may be associated with an increased risk of cardiovascular and gastrointestinal events. Frequent local steroid injection at epidural, deep paravertebral, and facet joints may increase risk of infection.\(^2\) Overall, most conservative treatments are not founded on firm clinical evidence and have their own adverse effects, despite the treatments’ prioritised role in the non-surgical management of patients with LSS.\(^2\,5\,6\)

When conservative treatments over 3–6 months do not work well in symptomatic LSS, surgical interventions can be considered as a feasible treatment option.\(^7\) However, in one study, patient satisfaction between surgical and non-surgical interventions were similar at a 10-year follow-up, suggesting shared decision-making and the incorporation of individual patients’ preferences when deciding treatment intervention.\(^8\)

Acupuncture is commonly used for managing low back pain or other chronic pain.\(^9\,10\) One small survey revealed that acupuncture was one of the most preferred treatment options of physical therapists for LSS in Canada.\(^11\) The willingness of patients with low back pain to continue acupuncture treatments has been observed, which may reflect a possible preference for acupuncture in patients with spinal disorders.\(^12\,13\) However, little reliable information regarding the role of acupuncture in managing patients with LSS is available. Given the patients’ possible preference for acupuncture to treat spinal disorders, assessing the evidence of acupuncture for patients with LSS may be timely and relevant. Therefore, this study aimed to systematically evaluate current evidence of the effects and safety of acupuncture in patients with LSS.

Materials and methods

Search and study selection

An electronic search was conducted in five English-language databases and a Chinese database (see Table 1 for searched databases and search terms). There were no language restrictions in the study. We did not confine the search term to randomised controlled trials (RCTs) due to an expected scarcity of studies related to this topic. Clinical trials that had a comparator group but did not randomise patient
Table 1  Databases and search terms.

<table>
<thead>
<tr>
<th>Database</th>
<th>Dates*</th>
</tr>
</thead>
<tbody>
<tr>
<td>English</td>
<td></td>
</tr>
<tr>
<td>CENTRAL</td>
<td>Cochrane library 2013, issue 1</td>
</tr>
<tr>
<td>MEDLINE</td>
<td>1949 to February 2013</td>
</tr>
<tr>
<td>EMBASE</td>
<td>1966 to February 2013</td>
</tr>
<tr>
<td>CINAHL</td>
<td>From the inception to February 2013</td>
</tr>
<tr>
<td>AMED</td>
<td>1985 to February 2013</td>
</tr>
<tr>
<td>Chinese</td>
<td></td>
</tr>
<tr>
<td>CAJ</td>
<td>1980 to February 2013</td>
</tr>
</tbody>
</table>

Search terms

<table>
<thead>
<tr>
<th>Intervention</th>
<th>Condition</th>
</tr>
</thead>
<tbody>
<tr>
<td>Acupuncture, needling, needle, meridian, electrical stimulation</td>
<td>Spinal stenosis, lumbar stenosis, claudication</td>
</tr>
</tbody>
</table>

* First search was performed in the Cochrane library 2011, issue 4 for CENTRAL and up to November 2011 in 5 other databases for abstract submission (see Kim et al.: P04.50. Acupuncture for lumbar spinal stenosis: a systematic review. BMC Complementary and Alternative Medicine 2012;12(Suppl. 1):P320).

allocation or that had an inadequate randomisation process (e.g., the allocation of patients based on hospital record number or visit days) were regarded as non-randomised controlled clinical trials (CCTs) in our review. RCTs and CCTs comparing the effectiveness of acupuncture using acupuncture needles that penetrate certain points on the body (e.g., classical acupuncture points, trigger points, or local tenderness) for any form of control intervention were eligible. Studies with acupuncture-related interventions that do not penetrate the skin (e.g., moxibustion, acupressure, or laser acupuncture) or that include the injection of herbal extracts or any other substances into acupuncture points were excluded. Only RCTs were assigned to the analysis of effectiveness. CCTs were used in the analysis of safety and other intervention-related information.

One review author performed search studies using both English- and Chinese-language databases. The screening and selection of eligible studies were performed by the first author and checked by another author. Data extraction was performed by the first author and checked by two co-authors. The "risk of bias" criteria of Cochrane systematic reviews was used in the analysis. Risk of bias assessment was independently performed by two authors. Disagreements were resolved by discussion.

We sought to determine whether the eligible RCTs measured "core outcomes" that are clinically important in patients with LSS. We defined core outcomes as pain intensity, walking capacity, back-specific function, quality of life, work disability, and patient global assessment.

A meta-analysis was performed using RevMan software (Review Manager Version 5.1 for Windows; The Nordic Cochrane Centre, Copenhagen). Effect estimations were calculated as the standardised mean difference (SMD) for continuous outcomes or as relative risk (RR) for dichotomous outcomes. Random-effect models were employed to consider possible clinical heterogeneity among the included studies.

Results

Of 289 screened articles, a total of 12 trials (six RCTs and six CCTs) were included in the qualitative synthesis. Six RCTs were included in the main analysis. CCTs were used only for safety and intervention analyses. The detailed study selection processes are shown in Fig. 1.

Study characteristics

All included trials were conducted in China and reported in the Chinese language. The number of participants ranged from 60 to 154 in RCTs and from 59 to 172 in CCTs. Most RCTs were two-arm parallel studies, except for one study that employed four arms, consisting of different acupuncture methods. All but one trial incorporated radiographic evidence, such as the results of magnetic resonance imaging or computed tomography, into the diagnosis of LSS or eligibility criteria. Traditional Chinese medicine (TCM) diagnosis was used for individual prescriptions for acupuncture regimen in three RCTs. However, the results were not reported separately, and no subgroup analyses according to different TCM diagnoses were conducted. Thus, whether TCM diagnosis made a difference in the clinical outcomes of different TCM diagnosis groups could not be assessed further in our review. The outcomes measured in the RCTs included the response rate (the number of improved patients), overall assessment scores, spinal function scores, pain visual analogue scale (VAS) scores, and quality of life (WHO Quality of Life-BREF (WHOQOL-BREF)).

All included RCTs assessed a response rate that had been defined as the number of patients in each predefined category, incorporating overall evaluations of each patient’s symptoms and functional disability as measured by an assessor. We converted the three-point (cured, improved, or not improved) or four-point (completely cured, much improved, somewhat improved, or not improved) Likert scale of response rates into a dichotomous scale to calculate the number of improved patients (i.e., improved or not improved) by merging the numbers of patients in the cured and improved groups. Three RCTs measured overall assessment scores that were defined as a measurement of various clinically relevant domains, as follows: symptoms in the lower back and legs, physical examination results, bladder function, and radiological abnormalities of the lumbar spine. Another trial defined items for overall assessment scores as activities of daily life, emotional status, and physical status. The rest of the trials did not clearly describe the components that the authors intended to measure. Four RCTs assessed spinal function scales that had been illustrated as a modified instrument based on the Japanese Orthopaedic Association’s scales. Details of the study information are provided in Tables 2 and 3 (see Appendix A for the full details of the included RCTs).
Table 2  Summary characteristics of included RCTs.

<table>
<thead>
<tr>
<th>First author (year)</th>
<th>Sample size</th>
<th>Interventions</th>
<th>Outcomes (follow-up periods)</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen (2009)&lt;sup&gt;18&lt;/sup&gt;</td>
<td>(1) 60 (30/30)</td>
<td>Electroacupuncture plus bloodletting therapy versus electroacupuncture alone. Once daily for 20 days</td>
<td>Response rate (post-treatment)</td>
<td>Significantly favored combined treatments</td>
</tr>
<tr>
<td>Ji (2011)&lt;sup&gt;19&lt;/sup&gt;</td>
<td>(1) 126 (64/62)</td>
<td>Manual acupuncture plus oral herbal decoction versus manual acupuncture alone. Once daily for 10 days</td>
<td>(1) Response rate (post-treatment) (2) Average lumbar assessment scores (post-treatment)</td>
<td>Both outcomes significantly favored combined treatments</td>
</tr>
<tr>
<td>Kou (2011)&lt;sup&gt;20&lt;/sup&gt;</td>
<td>(1) 154 (77/77)</td>
<td>Manual acupuncture with warm-dredging techniques versus manual acupuncture with simple insertion. Once daily for 20 days</td>
<td>(1) Response rate (post-treatment) (2) Pain VAS for back and leg (up to 6 months) (3) Overall assessment scores (up to 6 months) (4) Spinal function scores (up to 6 months) (5) Quality of life scores (up to 6 months)</td>
<td>All outcomes other than response rate significantly favored augmented acupuncture with warm-dredging techniques</td>
</tr>
<tr>
<td>Lu (2012)&lt;sup&gt;21&lt;/sup&gt;</td>
<td>(1) 60 (30/30)</td>
<td>Manual acupuncture with warm-promoting techniques versus manual acupuncture with simple insertion. Once daily for 20 days</td>
<td>(1) Response rate (2) Overall assessment scores (up to 6 months) (3) Spinal function scores (up to 6 months) (4) Quality of life scores (up to 6 months)</td>
<td>All outcomes significantly favored augmented acupuncture other than response rate, overall assessment scores at post-treatment, and spinal function scores at 6-month follow up</td>
</tr>
<tr>
<td>Chen (2011)&lt;sup&gt;22&lt;/sup&gt;</td>
<td>(1) 120 (30/30/30/30)</td>
<td>Manual or Electroacupuncture including BL32 stimulation versus those without BL 32 stimulation. Once daily for 30 days</td>
<td>(1) Response rate (post-treatment) (2) Overall assessment scores (post-treatment)</td>
<td>All outcomes significantly favored acupuncture with BL32 stimulation</td>
</tr>
<tr>
<td>Li (2012)&lt;sup&gt;23&lt;/sup&gt;</td>
<td>(1) 62 (32/30)</td>
<td>Manual acupuncture with thick silver needle insertion on BL32 plus warm-needle techniques versus warm-needle techniques alone. Twice a week for 5 weeks</td>
<td>(1) Response rate (post-treatment) (2) Spinal function scores (post-treatment)</td>
<td>All outcomes significantly favored silver needle insertion on BL32</td>
</tr>
</tbody>
</table>

RCT, Randomised controlled trial; VAS, visual analogue scale.
Acupuncture for lumbar spinal stenosis: A systematic review and meta-analysis

539

Figure 1 PRISMA flowchart of study selection. RCT, Randomised controlled trial; LSS, Lumbar spinal stenosis; CCT, Controlled clinical trial.

<table>
<thead>
<tr>
<th>Study</th>
<th>Sample size (M/F)</th>
<th>Intervention</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang (2011)</td>
<td>67 (35/32)</td>
<td>Electroacupuncture on SP6 versus manual stimulation on EX-B2 points. Once daily for 10 days</td>
</tr>
<tr>
<td>Jing (2011)</td>
<td>150 (75/75)</td>
<td>Deep versus conventional needling on EX-B2 points. Once daily for 28 days</td>
</tr>
<tr>
<td>Huang (1995)</td>
<td>59 (37/22)</td>
<td>Deep insertion of GV3 and GB30 with manual and electrical stimulation plus oral herbal decoction versus conventional needling with manual and electrical stimulation alone. Once per two days for 10 sessions</td>
</tr>
<tr>
<td>Lin (2007)</td>
<td>152 (88/64)</td>
<td>Combined treatments (manual acupuncture, acupressure, oral herbal decoction) versus intravenous injection of herbal medicine. Once daily for 30 days. Self-performed low back massage and exercise in both groups</td>
</tr>
<tr>
<td>Li (2009)</td>
<td>78 (41/37)</td>
<td>Deep insertion of BL25 with manual and electrical stimulation versus mechanised spinal distraction device and oral Fenbid tablet (ibuprofen; dose not reported). Once daily for 30 days</td>
</tr>
<tr>
<td>Pan (2011)</td>
<td>172 (97/75)</td>
<td>Combined treatments (manual acupuncture, acupressure, oral herbal decoction) versus intravenous injection of herbal medicine. Once daily for 30 days. Self-performed low back massage and exercise in both groups</td>
</tr>
</tbody>
</table>

CCT, Controlled clinical trial.
Table 4 Risk of bias of included RCTs.

<table>
<thead>
<tr>
<th>Study</th>
<th>Random sequence generation</th>
<th>Allocation concealment</th>
<th>Participant blinding</th>
<th>Assessor blinding</th>
<th>Incomplete outcome data</th>
<th>Selective outcome reporting</th>
<th>Other sources of bias</th>
</tr>
</thead>
<tbody>
<tr>
<td>Chen (2009)18</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Ji (2010)19</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Low</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Kou (2011)20</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Lu (2012)21</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Chen (2011)22</td>
<td>Unclear</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
<tr>
<td>Li (2012)23</td>
<td>Low</td>
<td>Unclear</td>
<td>High</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Unclear</td>
<td>Low</td>
</tr>
</tbody>
</table>

Domains of risk of bias assessment were based on Cochrane risk of bias assessment.15 RCT, Randomised controlled trial; Low, low risk of bias; High, high risk of bias; Unclear, unclear risk of bias.

Risk of bias in the RCTs
All RCTs had generally high or uncertain risk of bias, except in the domains of random sequence generation. No studies reported whether allocation concealment was attempted. All studies had high risk of performance bias due to the unblinded nature of open comparison and did not report whether the outcome assessors were blinded. Four RCTs19–22 did not mention whether dropout or loss of follow-up occurred during the study; thus, uncertain risk of bias was given in the domain of incomplete outcome reporting. No studies provided information about any discrepancy between the original trial protocol and the reported results or trial registration number. As a result, uncertain risk of bias was given in the domain of selective outcome reporting. Risk of bias of each RCT is illustrated in Table 4 and Appendix A.

Study interventions used in all included studies
Comparisons were made between acupuncture combined with related techniques (cupping or herbal medicine) and acupuncture alone,18,19 acupuncture with warming stimulation technique and acupuncture with ordinary stimulation technique,20,21 and acupuncture with BL32 points and acupuncture without BL32 points.20,23 No placebo- or sham-controlled RCTs or RCTs comparing acupuncture with conventional non-surgical or surgical treatments were found.

All included trials combined local and distal acupuncture points. Four RCTs18,20–22 and one CCT25 used the local point EX-B2, which is located near the nerve roots of the lumbar vertebrae. Most of the included studies used traditional acupuncture points. None of the included studies considered myofascial trigger points as acupuncture points, although trigger points were needed in two RCTs.18,20 None of the included studies reported the treatment context or information related to the practitioner’s qualification or training, despite the relatively invasive methods (deeper and stronger stimulation with acupuncture). In CCTs, intravenous injections of herbal medicine,27,28 the use of a spinal distraction device, and oral ibuprofen at unknown doses28 served as control interventions. Further details of the interventions in the RCTs and CCTs are provided in Appendices A and B, respectively.

Outcome results in the RCTs
The number of improved patients was significantly higher for acupuncture combined with related therapies or acupuncture with additional stimulation than for acupuncture alone or acupuncture with simple stimulation based on a post-treatment assessment (4 RCTs; n = 582, RR 1.16, 95% CI 1.08–1.25; I² = 0%) (Fig. 2). A painVAS for the back and legs showed small but significant benefits for acupuncture with warm-dredging technique (a type of needle manipulation technique) compared with acupuncture with simple insertion based on treatment (1 RCT; n = 154, SMD −0.32, 95% CI −0.64 to 0.00) and 6-month follow-up (SMD −0.82, 95% CI −1.15 to −0.49) assessments, but not at the 3-month follow-up (SMD −0.05, 95% CI −0.37 to 0.26). The overall assessment scores significantly favoured acupuncture with additional therapies or stimulations over acupuncture alone or with ordinary techniques based on post-treatment (3 RCTs; n = 340, SMD −0.66, 95% CI −0.88 to −0.44; I² = 0%), 3-month follow-up (2 RCTs; n = 214, SMD −0.77, 95% CI −1.07 to −0.47; I² = 10%), and 6-month (2 RCTs; n = 214, SMD −0.74, 95% CI −1.02 to −0.46; I² = 0%) assessments. Spinal function scores for acupuncture methods that included additional or stronger stimulation improved significantly compared with the scores for acupuncture using ordinary techniques based on post-treatment (4 RCTs; n = 396, SMD −1.18, 95% CI −1.79 to −0.58; I² = 86%), 3-month follow-up (2 RCTs; n = 214, SMD −0.65, 95% CI −0.93 to −0.38; I² = 0%), and 6-month follow-up (2 RCTs; n = 214, SMD −0.30, 95% CI −0.57 to −0.02; I² = 4%) assessments, with a decreasing tendency of effect estimation. The same trend was noted for quality of life scores (2 RCTs of 214 patients for all measurements; SMD −0.90, 95% CI −1.18 to −0.61; I² = 0% post-treatment; SMD −0.59, 95% CI −0.87 to −0.32; I² = 0% at 3-month follow-up; SMD −0.71, 95% CI −0.99 to −0.44; I² = 0% at 6-month follow-up). Core outcomes were addressed in certain RCTs (i.e., pain intensity20 back-specific function20,21,23 and quality of life20,21). None of the included studies separately reported walking capacity, work-related disability, or patient global assessment. More forest plots are provided in Appendix C.

Adverse events
None of the included studies provided reports on adverse events.
Thus, in the included RCTs, the number of acupuncture sessions and specific acupoints varied. This lack of uniformity makes it difficult to draw conclusions about the optimal number of sessions and acupoints. However, some common themes emerged, such as the inclusion of a control group to assess the efficacy of acupuncture, the use of standardized outcome measures, and the reporting of adverse events. These features are essential for the reliability of the trials' results.

Discussion

In this study, we found that current evidence for the use of acupuncture in patients with LSS is limited, due to the scarcity of existing clinical trials and high risk of bias in various aspects, which impedes the reliability of the trials' results. Different acupuncture combinations and stimulation techniques were compared in six RCTs, which did not compare the role of acupuncture with existing surgical or conservative treatments. Thus, the value and clinical relevance of these trials may be doubtful when considering acupuncture as an add-on to existing conventional treatment options or as a standalone treatment. Acupuncture with additional stimulation or with other related techniques produced better results than the ordinary stimulation of acupuncture alone, although high risk of bias and substantial clinical heterogeneity should be seriously considered when interpreting the results of meta-analyses. The follow-up periods were relatively shorter (at best, 6 months) than in trials testing various surgical or non-surgical interventions for LSS, which assessed 2-year outcomes after treatment intervention. Therefore, the longer term effects of acupuncture could not be assessed in our analyses. The outcomes (e.g., response rates, overall assessment scores, and spinal function scores) incorporated multidimensional aspects of clinically important symptomatic or functional changes, which should have been measured and reported separately for a clear understanding and clinically relevant analyses of the obtained benefits. For instance, walking capacity has been regarded as a key outcome for patients with LSS. However, none of the included RCTs reported walking capacity separately. None of the recommended outcomes for disability (i.e., the Oswestry Disability Index (ODI) or the Roland-Morris Disability Questionnaire (RMDQ)) was assessed in the included studies, which may make it difficult to compare the results with the data of other studies that have used ODI or RMDQ. The safety of acupuncture was not addressed in any of the included RCTs or CCTs. All trials were conducted in China, using intensive treatment sessions and strong stimulation methods. Consequently, the generalisability of the evidence found in this study may be seriously limited given different treatment contexts or cultural backgrounds, and the feasibility and acceptability of the trials' results may not be the same in other countries. A lack of trials from Western countries may also deserve further attention because this lack may imply a potential difference in practice characteristics and research priorities between China and countries other than China or unidentified barriers to the design and implementation of acupuncture trials for LSS in Western countries.

No information was available on preferences or expectations regarding acupuncture compared with conventional treatments in any of the included RCTs. Empirical evidence showed that patients' expectations of acupuncture treatment positively influenced treatment outcome in patients with chronic pain. Preferences among patients in musculoskeletal trials were found to be associated with treatment effects. Given that shared decision-making for the management of LSS is necessary when considering surgery and other conservative care, patients' preferences for acupuncture should be addressed in future RCTs, and these preferences' influence on treatment outcome should be investigated.

Interestingly, all the included studies employed fixed or semi-fixed acupuncture regimens, which might imply that commonly acceptable core acupuncture points for the treatment of LSS could be developed. However, we do not know whether these studies sufficiently represent current acupuncture techniques used in other clinical situations in which different techniques might be used. Whether individualised acupuncture treatments or a selection of acupuncture points, based on a classification of the traditional diagnostic framework, is effective may be of interest for future study. Various acupuncture techniques with additional stimulation techniques or combined with other ancillary techniques were tested in all included studies. This clinical heterogeneity suggests the need for further investigation into whether these regimes are clinically valid in different contexts, which is an important consideration when designing acupuncture intervention for future clinical trials. Various approaches, including practitioner surveys, expert consensus, and clinical trials, may be required to develop optimal acupuncture techniques for this condition.

The safety of acupuncture may be a prerequisite when considering acupuncture as a viable non-surgical treatment option for LSS. Empirical evidence suggests that acupuncture is generally safe when performed by qualified practitioners.
of reports on adverse events and on the qualifications of the involved practitioners in all of the included studies does not allow us to determine the safety of acupuncture for LSS. Because this research found that deeper insertion and stronger stimulation methods were employed for LSS, particular attention should be paid to avoiding deep-tissue infection or neurological complications. Although acupuncture for lower back pain or neck pain that is performed by physicians was found to be a low-risk intervention in a large prospective study conducted in Germany, certain case studies have reported infectious events or neurological complications after acupuncture treatments. A large, well-conducted observational study aiming to provide safety data on the use of acupuncture for LSS, with high-quality reporting on harm observed during clinical studies, is required to generate reliable evidence for the safety of acupuncture for this condition.

The possible acupuncture mechanisms used for LSS might be of interest. One experimental study reported that manual acupuncture stimulation at a point on the lumbar muscle was correlated with increased blood flow in the sciatic nerve, suggesting a role for vasodilatory nerve fibres mediated by neurotransmitters stimulated by acupuncture. Another study postulated the possible involvement of the activation of cholinergic nerves to increase blood flow in the sciatic nerve after the electrical stimulation of the pudendal nerve in rats, which was inhibited by the administration of atropine. As ischemic nerve impairment by the presence of stenosis and nerve-root compression is believed to be a possible cause of neurogenic claudication and other disabling symptoms of LSS, these findings may deserve further exploration. Systemic and local anti-inflammatory actions of manual and electroacupuncture, mediated by efferent vagus nerve activation and inflammatory macrophage deactivation, may also be related to the possible benefit of acupuncture for patients with LSS because inflammation at the interface between the nerve root and the compressing tissue may be responsible for symptoms of LSS. Endogenous opioid peptides in the central nervous system might play a role in the analgesic effects of acupuncture in patients with LSS. However, the hypotheses regarding the mechanism of acupuncture that are suggested above are not fully understood and need future research.

The limitations of this systematic review should be addressed. First, only different acupuncture combinations or different stimulations were compared; no placebo control or active comparators that reflect current surgical or non-surgical treatment options for LSS were used in the RCTs. Thus, we could not identify the specific efficacy or comparative effectiveness of acupuncture for LSS. Second, the RCTs in our review were conducted only in China and reported in the Chinese language. Thus, the generalisability of this review to other countries is limited, and non-Chinese-speaking readers cannot access the included studies. Regarding the latter issue, we provide a brief summary of the included studies in English. Third, although statistical heterogeneity was minimal for the meta-analyses of each outcome, the clinical heterogeneity between each trial was significant due to the different treatment interventions and comparisons. Thus, quantitative assessment by meta-analysis may not be the best option to understand the current evidence of acupuncture for LSS, and the effect estimates reported in this review should be interpreted with caution.

Implications for future research

More methodologically sound RCTs should be conducted to evaluate the effectiveness and safety of acupuncture in patients with LSS. Comparisons should be made between acupuncture and conventional conservative management or surgical treatments or between acupuncture in combination with conventional care and conventional care alone to measure the relative benefits of acupuncture compared with existing treatment options. Patient characteristics that might be related to treatment outcomes, such as expectation of and preference for acupuncture treatments, and types of traditional Asian medicine diagnosis may be worth exploring to identify potential influences on treatment effects. Potential determinant factors that may be associated with clinical heterogeneity regarding current acupuncture techniques for LSS should also be investigated. Safety information should be addressed with international standards of reporting harm (i.e., consolidated standards of reporting trials (CONSORT)) in future RCTs and in prospective observational studies.

Implications for clinical practice

The current evidence found in this review is seriously limited by high or uncertain risk of bias. Acupuncture may be recommended if patients have a preference for or willingness to receive acupuncture. Deeper insertion, stronger stimulation, or acupuncture combined with other TCM interventions have yielded benefits compared with ordinary acupuncture alone. However, no particular acupuncture technique could be recommended due to the limited generalisability of the study results. Acupuncture may sustain beneficial effects for up to 6 months. However, the long-term effectiveness of acupuncture is uncertain. Little safety data is available for acupuncture used to treat patients with LSS. Although acupuncture was found to be a safe treatment method when performed by a competent medical practitioner, care should be taken when performing deep needling to avoid infection or unintentional organ penetration.

Conclusion

This review found inconclusive evidence for the effectiveness of acupuncture in patients with LSS. Acupuncture with additional stimulation or in combination with other related techniques may be beneficial compared with ordinary acupuncture therapy alone. However, those results should be interpreted with caution due to high risk of bias and substantial clinical heterogeneity. All included studies were conducted in China. Thus, the findings of the review may not be generalisable to other countries or different clinical contexts. Little information is available regarding whether add-on or standalone uses of acupuncture are beneficial compared with conventional treatment options for the management of LSS. The safety of acupuncture for LSS could not be assessed in this review due to poor reporting.
quality. Further well-designed RCTs with clinically relevant comparisons and outcomes should be conducted.

**Conflict of interest statement**

None declared.

**Acknowledgments**

This work (study) was supported by Korea Institute of Oriental Medicine (KIOM, grant # K13273). We thank Dr. Tae Young Choi for her helpful assistance in searching the Chinese studies.

**Appendix A. Characteristics of included RCTs**

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Chen (2009) [18]</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design and risk of bias</strong></td>
<td>Design: parallel RCT</td>
</tr>
<tr>
<td></td>
<td>Language: Chinese</td>
</tr>
<tr>
<td></td>
<td>Random sequence generation: low (random number table)</td>
</tr>
<tr>
<td></td>
<td>Allocation concealment: unclear (information not reported)</td>
</tr>
<tr>
<td></td>
<td>Patient blinding: high (active comparator trial)</td>
</tr>
<tr>
<td></td>
<td>Practitioner blinding: unclear (information not reported)</td>
</tr>
<tr>
<td></td>
<td>Incomplete reporting of outcomes: low (number of patients at the assessment are the same as allocated)</td>
</tr>
<tr>
<td></td>
<td>Selective reporting of outcomes: unclear (study protocol is not available)</td>
</tr>
<tr>
<td></td>
<td>Other sources of bias: low</td>
</tr>
<tr>
<td><strong>Patient</strong></td>
<td>Setting: 60 inpatients and outpatients in TCM hospital, Haikou, China</td>
</tr>
<tr>
<td></td>
<td>Age: EA combined with bloodletting therapy/EA alone = mean 68 years (range 56—75 years)/mean 66 years (range 58—70 years)</td>
</tr>
<tr>
<td></td>
<td>Men/women: EA combined with bloodletting therapy (12/18)/EA alone (14/16)</td>
</tr>
<tr>
<td></td>
<td>Duration of symptoms: EA combined with bloodletting therapy/EA alone = range 2 months to 5 years/range 3 months to 4 years</td>
</tr>
<tr>
<td></td>
<td>Western Diagnosis of lumbar spinal stenosis: symptomatic patients were confirmed as LSS cases by CT or MRI</td>
</tr>
<tr>
<td></td>
<td>TCM classification: No details reported</td>
</tr>
<tr>
<td></td>
<td>Major eligibility criteria: Degenerative LSS by Criteria of diagnosis and therapeutic effects of diseases and syndromes in traditional Chinese medicine (中国针灸疗法标准)</td>
</tr>
<tr>
<td><strong>Intervention</strong></td>
<td>EA combined with bloodletting therapy group</td>
</tr>
<tr>
<td></td>
<td>(1a) Style of acupuncture: TCM style</td>
</tr>
<tr>
<td></td>
<td>(1b) Reasoning for treatment provided: based on historical context and literature sources</td>
</tr>
<tr>
<td></td>
<td>(1c) Extent to which treatment was varied: fixed formula used</td>
</tr>
<tr>
<td></td>
<td>(2a) Number of needle insertions per subject per session (mean and range where relevant): at least 18</td>
</tr>
<tr>
<td></td>
<td>(2b-1) Names (or location if no standard name) of points used: Local points (located on the depression inferior to the spinous process at the level of 3rd to 5th lumbar and 1st sacral vertebrae. EX-B2 at the level of 4th to 5th lumbar vertebrae, BL54, GB30) and distal points (BL40, BL57, GB34, GB40, tender points)</td>
</tr>
<tr>
<td></td>
<td>(2b-2) (uni/bilateral): bilateral EX-B2, distal points at the affected side(s) depending on each patients’ condition</td>
</tr>
<tr>
<td></td>
<td>(2c) Depth of insertion: To the neural foramina evoking radiating sensation for lumbosacral region. EX-B2 (to the direction of intervertebral space until the presence of radiating sensation), BL54 (2—2.5 cun), GB30 (3—3.5 cun), BL40, BL57, GB34 (1—1.5 cun), GB40 (0.5—1.0 cun)</td>
</tr>
<tr>
<td></td>
<td>(2d) Response sought: electrical stimulation until muscle contraction within the patients’ pain thresholds and manual stimulation to elicit radiating sensation or muscle contraction</td>
</tr>
<tr>
<td></td>
<td>(2e) Needle stimulation: electrical stimulation, continuous wave, 50—100 Hz, once daily (Governor vessel; bilateral EX-B2—BL54, GB30; GB34—GB40 to lateral leg pain; BL40—BL57 to posterior leg pain)</td>
</tr>
<tr>
<td></td>
<td>(2f) Needle retention times: 30 min</td>
</tr>
<tr>
<td></td>
<td>(2g) Needle type and specification: the diameter of 0.35 mm and the length of 1.5 cm piriform needles for lumbosacral region, the diameter of 0.35 mm and the length of 3 cun piriform needles for EX-B2</td>
</tr>
</tbody>
</table>
Appendix A (Continued)

(3a) Number of treatment sessions: 20
(3b) Frequency and duration of treatment sessions: 10 days treatment daily, 1 week off and 10 days treatment daily
(4a) Details of other interventions administered to the acupuncture group: bloodletting on venous congestion areas at the posterolateral side of the legs bilaterally (at standing position, using disposable injection needle, through puncturing vein, let blood outflow spontaneously) and on tender points at Governor Vessel and Bladder meridian at the level of 3rd lumbar to 5th lumbar and 1st sacral vertebrae, tender points at lower legs and BL 40 (using disposable injection needle, fire-cupping for 5 min right after needle insertion 3–5 times), once every 5 days, total 4 times
(4b) Setting and context of treatment: NR
(5) Description of participating acupuncturists: NR

Control group (EA alone)
(6a) Rationale for the control or comparator in the context of the research question: NR
(6b) Precise description of the control or comparator: electro-acupuncture without bloodletting.

Details of EA methods are the same as those in the treatment group

Outcomes
Total study duration: two set of 10 consecutive daily treatments and no follow-up data
Dropouts/withdrawals: information not reported
Outcome:
No definition for primary outcome and time-points. (However, only one outcome was reported.)
(1) Response rate (3-point scale; cured = complete resolution of low back and leg pain, complete functional recovery; effective = reduction of low back and leg pain with symptom recurrence after excessive activity; not effective = no changes on symptom and function) (post-treatment)

Notes

---

Study ID
Ji (2010)  

Design and risk of bias
Design: parallel RCT
Language: Chinese
Random sequence generation: low (random number table)
Allocation concealment: unclear (information not reported)
Patient blinding: high (active comparator trial)
Practitioner blinding: unclear (information not reported)
Incomplete reporting of outcomes: unclear (number of patients analyzed at post-treatment assessment were not reported)
Selective reporting of outcomes: unclear (study protocol is not available)
Other sources of bias: low

Patient
Setting: 126 Outpatients in Neck, Shoulder, Back and Lower extremity pain treatment center, Shandong, China
Age: Acupuncture combined with herbal medicine/Acupuncture alone = mean 50 years (range 23–82 years)/mean 54 years (range 27–81 years)
Men/women: Acupuncture combined with herbal medicine (36/28)/Acupuncture alone (33/29)
Duration of symptoms: Acupuncture combined with herbal medicine/Acupuncture alone = range 1 week to 12 years/range 1.5 week to 11 years
Western Diagnosis of lumbar spinal stenosis: (1) history of chronic low back pain, traumatic events or demanding physical works over 40 years; (2) chronic recurrent low back pain and sciatica or intermittent claudication (low back pain relieved with lumbar flexion posture and aggravated with lumbar extension; leg pain may present bilaterally or alternatively on both sides; leg and back pain/numbness/weakness present with standing or ambulation; pain aggravated after prolonged ambulation and relieved after rest; urinary incontinence in severe cases; (3) muscle atrophy of lower limb; decreased deep tendon reflexes; (4) spinal stenosis confirmed by plain radiographs, lumbar myelography, computed tomography/magnetic resonance imaging
TCM classification: three types of TCM classification were reported according to the symptoms, tongue and pulse diagnosis (wind-cold obstruction; kidney qi deficiency; qi deficiency and blood stagnation)
Major inclusion criteria: (1) LSS by Western diagnosis; (2) written informed consent for participation in the RCT
**Study ID** Ji (2010)\(^9\)

**Intervention**

**Acupuncture combined with herbal medicine**

1a) Style of acupuncture: TCM style
1b) Reasoning for treatment provided: based on historical context and literature sources
1c) Extent to which treatment was varied: Fixed formula used
2a) Number of needle insertions per subject per session (mean and range where relevant): 16 or 24 (bilaterally for back located points and uni- or bilaterally for lower-extremities)
2b) Names (or location if no standard name) of points used: Local points; BL23, BL24, BL54, BL28, GB29, GB30

Distal points; GB31, BL40, BL60, SP6, GB34, SP9
(2b-2) (uni/bilateral): bilaterally for back located points and uni- or bilaterally for lower-extremities
2c) Depth of insertion: NR
2d) Response sought: NR
2e) Needle stimulation: manual stimulation
2f) Needle retention times: 30 min
2g) Needle type and specification: NR
3a) Number of treatment sessions: 10
3b) Frequency and duration of treatment sessions: 10 days treatment daily
4a) Details of other interventions administered to the acupuncture group: herbal decoctions according to the TCM classification twice a day, total 10 days
4b) Setting and context of treatment: NR
5) Description of participating acupuncturists: NR

**Control group (acupuncture alone)**

6a) Rationale for the control or comparator in the context of the research question: NR
6b) Precise description of the control or comparator: same acupuncture method without herbal decoction treatment

**Outcomes**

Total study duration: 10 consecutive daily treatments and follow-up at 3 months post-treatment
Dropouts/withdrawals: information not reported
Outcome:
No definition for primary outcome and time-points.
(1) Response rate (3-point scale; cured = complete resolution of low back and leg pain, complete functional recovery; effective = reduction of low back and leg pain with symptom recurrence after excessive physical activity; not effective = no changes on symptom and function (post-treatment)
(2) Overall assessment scores (comprised of 6 items as follows: lumbar symptoms; lower extremity symptoms; physical examination of DTR, Babinski and SLR; lower extremity sensory function; bladder function; degree of lumbar curvature and instability)

**Notes**

**Study ID** Kou (2011)\(^10\)

**Design and risk of bias**

Design: parallel RCT
Language: Chinese
Random sequence generation: low (random number table)
Allocation concealment: unclear (information not reported)
Patient blinding: high (active comparator trial)
Practitioner blinding: unclear (information not reported)
Incomplete reporting of outcomes: unclear (number of patients analyzed at each time points were not reported)
Selective reporting of outcomes: unclear (study protocol is not available)
Other sources of bias: low

**Patient**

Setting: 154 patients in Shanghai, China (further details not reported).
Age: ranged 18—75 years (no significant between-group difference)
Men/women: Warm-dredging needling method (37/40), ordinary needling method (39/38)
Mean duration of symptoms: ranged one month to 11 years
Western Diagnosis of lumbar spinal stenosis: relevant criteria from Criteria of diagnosis and therapeutic effects of diseases and syndromes in traditional Chinese medicine (中国近现代中医治疗学)
TCM classification: no information reported
Major eligibility criteria: aged 18—75 years, LSS by Western diagnosis, cold-dampness and kidney qi deficiency by TCM classification
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Kou (2011)\textsuperscript{20}</th>
</tr>
</thead>
</table>

**Intervention**

**Warm-dredging needling method group:**

- (1a) Style of acupuncture: TCM style
- (1b) Reasoning for treatment provided: a special type of warm-dredging needling method based on historical context and literature sources
- (1c) Extent to which treatment was varied: Semi-fixed formula used (Core formula plus additional points according to the TCM classification)
- (2a) Number of needle insertions per subject per session (mean and range where relevant): at least 9 (uni- or bilateral not reported)
- (2b-1) Names (or location if no standard name) of points used: Local points; GV4, EX-B2 (tender points), BL23, BL20.
- (2b-2) Depth of insertion: NR
- (2d) Response sought: sensations towards the affected regions
- (2e) Needle stimulation: manual stimulation with warming techniques
- (2f) Needle retention times: 30 min
- (2g) Needle type and specification: NR
- (3a) Number of treatment sessions: 20
- (3b) Frequency and duration of treatment sessions: 10 days treatment daily, 3 days off and 10 days treatment daily
- (4a) Details of other interventions administered to the acupuncture group: NR
- (4b) Setting and context of treatment: NR
- (5) Description of participating acupuncturists: NR

**Control group (ordinary acupuncture technique)**

- (6a) Rationale for the control or comparator in the context of the research question: Traditional Chinese medicine, based on historical context
- (6b) Precise description of the control or comparator: ordinary needling method without manual warming stimulation, after de-qi, 30 min of retention

**Outcomes**

Total study duration: two set of 10 consecutive daily treatments and follow-up at 3 and 6 month post-treatment

Dropouts/withdrawals: information not reported

Outcome:

No definition for primary outcome and time-points.

1. Response rate (4-point scale; cured = complete symptom reduction or difference of 3 classes before and after treatments, markedly effective = substantial reduction of major symptoms or difference of 2 classes, effective = difference of one class; not effective = no changes on class; Class: Patients were classified as four groups according to their symptoms, spinal functions and quality of life scores.) (post-treatment, 3 months, 6months f/u)

2. Overall assessment scores (no clear definition for the outcome was provided) (post-treatment, 3 months, 6 months f/u)

3. Spinal function scores (Japanese Orthopedic Association Score) (post-treatment, 3 months, 6 months f/u)

4. WHQOL-BREF Quality of life scores (post-treatment, 3 months, 6 months f/u)

5. VAS for low back and leg pain (post-treatment, 3 months, 6 months f/u)
Study ID: Lu (2012)

**Design and risk of bias**
- Design: parallel RCT
- Language: Chinese
- Random sequence generation: low (random number table)
- Allocation concealment: unclear (information not reported)
- Patient blinding: high (active comparator trial)
- Practitioner blinding: unclear (information not reported)
- Incomplete reporting of outcomes: unclear (number of patients analyzed at each time points were not reported)
- Selective reporting of outcomes: unclear (study protocol is not available)
- Other sources of bias: low

**Patient**
- Setting: 60 Outpatients in Community Health Service Center in Shanghai, China
- Mean age (year, ±standard deviation): Warming-promotion acupuncture/normal acupuncture = 56.24 (±9.75)/55.03 (±7.82)
- Men/women: Warming-promotion acupuncture (11/19), normal acupuncture (10/20)
- Mean duration of symptoms (year, ±standard deviation): Warming-promotion acupuncture/normal acupuncture = 10.54 (±3.57)/11.08 (±4.24)
- Western Diagnosis of lumbar spinal stenosis: (1) history of chronic low back pain, traumatic events or demanding physical works over 40 years; (2) chronic recurrent low back pain and sciatica or intermittent claudication (low back pain relieved with lumbar flexion posture and aggravated with lumbar extension; leg pain may present bilaterally or alternatively on both sides; leg and back pain/numbness/weakness present with standing or ambulation; pain aggravated after prolonged ambulation and relieved after rest; urinary incontinence in severe cases; (3) muscle atrophy of lower limb; decreased deep tendon reflexes; (4) spinal stenosis confirmed by plain radiographs, lumbar myelography, CT/MRI
- TCM classification: three types of TCM diagnoses were reported according to the symptoms, tongue and pulse diagnosis (wind-cold obstruction; kidney qi deficiency; qi deficiency and blood stagnation)
- Major eligibility criteria: Aged 18–75 years, LSS by Western diagnosis, wind-cold obstruction and kidney qi deficiency by TCM classification

**Intervention**
- **Warming-promotion acupuncture group:**
  (1a) Style of acupuncture: TCM style
  (1b) Reasoning for treatment provided: a special type of warm-dredging needling method based on historical context and literature sources
  (1c) Extent to which treatment was varied: Semi-fixed formula used (Core formula plus additional points according to the TCM classification)
  (2a) Number of needle insertions per subject per session (mean and range where relevant): at least 9 (uni- or bilateral not reported)
  (2b-1) Names (or location if no standard name) of points used: Local points; GV4, EX-B2 (tender points), BL23, BL20
  (2b-2) (uni/bilateral): NR
  (2c) Depth of insertion: NR
  (2d) Response sought: sensations towards the affected regions
  (2e) Needle stimulation: manual stimulation with warming techniques, stimulation every 10 min during retention
  (2f) Needle retention times: 30 min
  (2g) Needle type and specification: NR
  (3a) Number of treatment sessions: 20
  (3b) Frequency and duration of treatment sessions: 10 days treatment daily, 3 days off and 10 days treatment daily
  (4a) Details of other interventions administered to the acupuncture group: NR
  (4b) Setting and context of treatment: NR
  (5) Description of participating acupuncturists: NR

**Control group (ordinary acupuncture technique)**
- (6a) Rationale for the control or comparator in the context of the research question: Traditional Chinese medicine, based on historical context
- (6b) Precise description of the control or comparator: ordinary needling method without manual warming stimulation, after achieving the de-qi sensation, 30 minutes of retention
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Lu (2012)\textsuperscript{21}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Outcomes</td>
<td>Total study duration: two set of 10 consecutive daily treatments and follow-up at 3 and 6 month post-treatment&lt;br&gt;Dropouts/withdrawals: information not reported&lt;br&gt;Outcome: No definition for primary outcome and time-points&lt;br&gt;(1) Response rate (4-point scale; cured = complete symptom reduction or difference of 3 classes before and after treatments, markedly effective = substantial reduction of major symptoms or difference of 2 classes, effective = difference of one class; not effective = no changes on class; Class: Patients were classified as four groups according to their symptoms, spinal functions and quality of life scores.) (post-treatment, 3 months, 6 months f/u)&lt;br&gt;(2) Overall symptom assessment scores (mean scores of 30 items measuring general ability of daily living, psychological status and general physical status by four-point scales (1—4) (post-treatment, 3 months, 6 months f/u)&lt;br&gt;(3) Spinal function scores (Japanese Orthopedic Association Score) (post-treatment, 3 months, 6 months f/u)&lt;br&gt;(4) WHOQOL-BREF Quality of life scores (post-treatment, 3 months, 6 months f/u)&lt;</td>
</tr>
<tr>
<td>Notes</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Chen (2011)\textsuperscript{22}</th>
</tr>
</thead>
<tbody>
<tr>
<td>Design and risk of bias</td>
<td>Design: parallel RCT&lt;br&gt;Language: Chinese&lt;br&gt;Random sequence generation: unclear (no details for randomisation methods)&lt;br&gt;Allocation concealment: unclear (information not reported)&lt;br&gt;Patient blinding: high (active comparator trial)&lt;br&gt;Practitioner blinding: unclear (information not reported)&lt;br&gt;Incomplete reporting of outcomes: unclear (number of patients analyzed at each time points were not reported)&lt;br&gt;Selective reporting of outcomes: unclear (study protocol is not available)&lt;br&gt;Other sources of bias: low</td>
</tr>
<tr>
<td>Patient</td>
<td>Setting: 120 inpatients and outpatients in Hubei, China&lt;br&gt;Mean age (year, ±standard deviation): BL32 EA group/BL32 MA group/ordinary EA/ordinary MA = 60.52 (±15.62)/63.60 (±14.89)/62.32 (±13.02)/62.04 (±12.78)&lt;br&gt;Men/women: BL32 EA group (11/19)/BL32 MA group (12/18)/ordinary EA (13/17)/ordinary MA (12/18)&lt;br&gt;Mean duration of symptoms (year, ±standard deviation): BL32 EA group/BL32 MA group/ordinary EA/ordinary MA = 6.54 (±3.45)/5.98 (±4.12)/6.35 (±3.14)/6.65 (±2.86)&lt;br&gt;Western Diagnosis of lumbar spinal stenosis: Criteria of diagnosis and therapeutic effects of diseases and syndromes in traditional Chinese medicine (中医辨证施治标准)&lt;br&gt;TCM classification: no information reported&lt;br&gt;Major eligibility criteria: (1) Aged at least 35 years, (2) history of chronic low back pain or traumatic events, (3) chronic recurrent low back pain and sciatica or intermittent claudication, (4) lumbar extension test positive (low back pain relieved with lumbar flexion posture and aggravated with lumbar extension), (5) patients may have sensory dysfunction on lower extremities, decreased DTR, muscle atrophy (especially 5th lumbar nerve and 1st sacral nerve-innervated areas), decreased dorsal flexion of toe, positive SLR, (6) spinal stenosis confirmed by plain radiography, CT and MRI</td>
</tr>
<tr>
<td>Intervention</td>
<td>BL32 needling group&lt;br&gt;(1a) Style of acupuncture: TCM style&lt;br&gt;(1b) Reasoning for treatment provided: based on historical context and literature sources&lt;br&gt;(1c) Extent to which treatment was varied: Fixed formula used&lt;br&gt;(2a) Number of needle insertions per subject per session (mean and range where relevant): 10 or 18 (bilaterally BL32 and EX-B2, otherwise, uni- or bilateral not reported)&lt;br&gt;(2b-1) Names (or location if no standard name) of points used: Local points; BL32, EX-B2 alongside at the level of 2nd to 5th lumbar vertebrae, GB30. Distal points; BL40, BL57, BL60</td>
</tr>
<tr>
<td>Study ID</td>
<td>Chen (2011)(^2)</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------</td>
</tr>
<tr>
<td></td>
<td>(2b-2) (uni/bilateral): bilaterally BL32 and EX-B2, otherwise, uni- or bilateral not reported</td>
</tr>
<tr>
<td></td>
<td>(2c) Depth of insertion: not clearly reported. Depth of needling depended on the degree of body fat of the patient.</td>
</tr>
<tr>
<td></td>
<td>(2d) Response sought: Radiating sensation on hips and lower extremities when insertion on both BL32. Electrical stimulation within individual pain thresholds</td>
</tr>
<tr>
<td></td>
<td>(2e) Needle stimulation: manual and electrical (BL32 and EX-B2)</td>
</tr>
<tr>
<td></td>
<td>(2f) Needle retention times: 30 min</td>
</tr>
<tr>
<td></td>
<td>(2g) Needle type and specification: 0.35 mm × 40 mm, 0.35 mm × 60 mm acupuncture needle</td>
</tr>
<tr>
<td></td>
<td>(3a) Number of treatment sessions: 30</td>
</tr>
<tr>
<td></td>
<td>(3b) Frequency and duration of treatment sessions: 30 days treatment daily</td>
</tr>
<tr>
<td></td>
<td>(4a) Details of other interventions administered to the acupuncture group: TDP apply on low back and buttock region</td>
</tr>
<tr>
<td></td>
<td>(4b) Setting and context of treatment: NR</td>
</tr>
<tr>
<td></td>
<td>(5) Description of participating acupuncturists: NR</td>
</tr>
</tbody>
</table>

**Control group (ordinary acupuncture without BL32 needling)**

|          | (6a) Rationale for the control or comparator in the context of the research question: based on historical context |
|          | (6b) Precise description of the control or comparator: (1) acupuncture on BL32 and the other points without electrical stimulation, (2) acupuncture without BL32 but on the other points with electrical stimulation, (3) acupuncture without BL32 but on the other points without electrical stimulation |

**Outcomes**

Total study duration: three set of 10 consecutive daily treatments and no follow-up data provided

Dropouts/withdrawals: information not reported

Outcome:

No definition for primary outcome and time-points

(1) Response rate (4-point scale; cured = complete resolution of low back and leg pain as well as related symptoms, complete functional recovery, no recurrence within 6 months; markedly effective = substantial reduction of low back and leg pain as well as related symptoms, significant functional recovery; effective = somewhat reduced low back and leg pain as well as related symptoms, functional recovery and intermittent aggravation of symptoms; not effective = no improvement (post-treatment))

(2) Spinal function scores (Japanese Orthopedic Association Score) (post-treatment)

**Notes**

<table>
<thead>
<tr>
<th>Study ID</th>
<th>Li (2012)(^3)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Design and risk of bias</strong></td>
<td>Design: parallel RCT</td>
</tr>
<tr>
<td></td>
<td>Language: Chinese</td>
</tr>
<tr>
<td></td>
<td>Random sequence generation: low (random number table)</td>
</tr>
<tr>
<td></td>
<td>Allocation concealment: unclear (information not reported)</td>
</tr>
<tr>
<td></td>
<td>Patient blinding: high (active comparator trial)</td>
</tr>
<tr>
<td></td>
<td>Practitioner blinding: unclear (information not reported)</td>
</tr>
<tr>
<td></td>
<td>Incomplete reporting of outcomes: unclear (number of patients analyzed at each time points were not reported)</td>
</tr>
<tr>
<td></td>
<td>Selective reporting of outcomes: unclear (study protocol is not available)</td>
</tr>
<tr>
<td></td>
<td>Other sources of bias: low</td>
</tr>
</tbody>
</table>

**Patient**

Setting: 64 Outpatients in Jing’an District Center Hospital of Shanghai, China.

Age: Silver needle on BL32 points plus warm-needling therapy group/Warm-needling therapy alone group = mean 69 years (range 45–74 years)/mean 70 years (range 47–75 years)

Men/women: Silver needle on BL32 points plus warm-needling therapy group (24/9)/Warm-needling therapy alone group (23/7)

Duration of symptoms: Silver needle on BL32 points plus warm-needling therapy group/Warm-needling therapy alone group = range 3 months to 9 years/range 6 months to 10 years
Study ID | Li (2012)\textsuperscript{23}
---|---

Western Diagnosis of lumbar spinal stenosis: (1) history of chronic low back pain at least one month ago; (2) symptoms including pain at low back area, uni- or bilateral leg pain/numbness, lower skin temperature and/or sensory dysfunction, typical neurogenic claudication with walking capacity less than 500 meters, positive lumbar overtension test; (3) degenerative LSS confirmed by neuroimaging studies including CT and MRI

TCM classification: NR

Major eligibility criteria: Aged 40–75 years, LSS by Western diagnosis

### Intervention

**Silver needle on BL32 points plus warm-needling therapy group**

(1a) Style of acupuncture: TCM style

(1b) Reasoning for treatment provided: a penetrating technique of Ciliao (BL32) based on expert’s clinical experience and literature sources

(1c) Extent to which treatment was varied: Fixed formula used

(2a) Number of needle insertions per subject per session (mean and range where relevant): at least 10

(2b-1) Names (or location if no standard name) of points used: BL32, BL23, BL24, BL25, BL54, GB30, BL40, BL57, GB39

(2b-2) Uni/bilateral: Uni- or bilateral use of BL32 depended on ipsilateral or bilateral leg pain; For other acupuncture points, whether uni- or bilateral points were used was not reported

(2c) Depth of insertion: BL32 was needled until the practitioner felt that the needle reached the 2nd posterior sacral foramen. No information for other points

(2d) Response sought: NR

(2e) Needle stimulation: No manipulation for BL32 needling. Plain tonification and reduction technique and warm-needling technique (burning of attached moxibustion at the tip of acupuncture needle) for other points

(2f) Needle retention times: 12 min

(2g) Needle type and specification: Silver needle (1 mm of diameter and 11.5 cm of length) for BL32 and piriiform needle (0.45 mm of diameter and 75 mm of length) for other points

(3a) Number of treatment sessions: 10

(3b) Frequency and duration of treatment sessions: twice weekly for 5 weeks

(4a) Details of other interventions administered to the acupuncture group: NR

(4b) Setting and context of treatment: NR

(5) Description of participating acupuncturists: NR

**Warm-needling therapy alone group**

(6a) Rationale for the control or comparator in the context of the research question: Traditional Chinese medicine, based on historical context

(6b) Precise description of the control or comparator: the same needle stimulation except the BL32 point stimulation was used for comparator group

### Outcomes

Total study duration: 5-week treatment course and no follow-up data provided

Dropouts/withdrawals: information not reported

Outcome:

No definition for primary outcome and time-points

(1) Response rate (3-point scale; cured = complete resolution of low back and leg pain, no intermittent claudication, complete functional recovery; effective = reduction of low back and leg pain, no claudication after amputation of 500 meters, inability to tolerate excessive physical activity, ability to do light activity; not effective = symptom recurrence within one month, no change on intermittent claudication, gradual symptom exacerbation)

(3) Spinal function scores (Japanese Orthopedic Association Score) (post-treatment)

### Notes

### Appendix B. Summary of acupuncture techniques used in the controlled clinical trials

<table>
<thead>
<tr>
<th>Study</th>
<th>Details of acupuncture treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Huang (2011)</td>
<td>(1a) Style of acupuncture: TCM style&lt;br&gt;(1b) Reasoning for treatment provided: based on historical context and literature sources&lt;br&gt;(1c) Extent to which treatment was varied: Fixed formula used&lt;br&gt;(2a) Number of needle insertions per subject per session (mean and range where relevant): 6&lt;br&gt;(2b-1) Names (or location if no standard name) of points used: Local points: not used, Distal points: GV26, SP6, PC6, CV6 (bilaterally)&lt;br&gt;(2b-2) (uni/bilateral): mainly bilaterally&lt;br&gt;(2c) Depth of insertion: 2–3 cun for CV6 needling. Otherwise, not reported&lt;br&gt;(2d) Response sought: NR&lt;br&gt;(2e) Needle stimulation: manual stimulation&lt;br&gt;(2f) Needle retention times: NR&lt;br&gt;(2g) Needle type and specification: NR&lt;br&gt;(3a) Number of treatment sessions:10&lt;br&gt;(3b) Frequency and duration of treatment sessions: 10 days treatment daily&lt;br&gt;(4a) Details of other interventions administered to the acupuncture group: herbal decoctions according to the patient’s TCM diagnosis. One unit for every other day. Foot and legs bathing in 2500 ml of herbal decoction once daily for 10 days&lt;br&gt;(4b) Setting and context of treatment: NR&lt;br&gt;(5) Description of participating acupuncturists: NR&lt;br&gt;(6a) Rationale for the control or comparator in the context of the research question: based on historical context and literature sources&lt;br&gt;(6b) Precise description of the control or comparator: EX-B2 acupuncture with manual stimulation daily for 10 days</td>
</tr>
</tbody>
</table>

TCM, Traditional Chinese medicine; NR, not reported.

<table>
<thead>
<tr>
<th>Study</th>
<th>Details of acupuncture treatments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Jing (2011)</td>
<td>(1a) Style of acupuncture: TCM style&lt;br&gt;(1b) Reasoning for treatment provided: based on historical context and literature sources&lt;br&gt;(1c) Extent to which treatment was varied: Semi-fixed formula used&lt;br&gt;(2a) Number of needle insertions per subject per session (mean and range where relevant): at least 5&lt;br&gt;(2b-1) Names (or location if no standard name) of points used: Local points: EX-B2, BL23, BL52, GV3, BL17, BL54&lt;br&gt;Distal points: KI3, BL40, GV16, GV26, GB34, ST36, GB31, GB39, BL62&lt;br&gt;(2b-2) (uni/bilateral): NR&lt;br&gt;(2c) Depth of insertion: To the depth of neural foramina on EX-B2 needling. Otherwise, 25 mm for the rest of points.&lt;br&gt;(2d) Response sought: De-qi (radiating sensation on thigh region when EX-B2 needling)&lt;br&gt;(2e) Needle stimulation: manual. EX-B2 was not stimulated.&lt;br&gt;(2f) Needle retention times: 30 min except EX-B2.&lt;br&gt;(2g) Needle type and specification: 1.5 mm × 120 mm for EX-B2 needling. Otherwise, 0.30 mm × 40 mm for the rest of points.&lt;br&gt;(3a) Number of treatment sessions: 28&lt;br&gt;(3b) Frequency and duration of treatment sessions: 28 days daily&lt;br&gt;(4a) Details of other interventions administered to the acupuncture group: NR&lt;br&gt;(4b) Setting and context of treatment: NR&lt;br&gt;(5) Description of participating acupuncturists: NR&lt;br&gt;(6a) Rationale for the control or comparator in the context of the research question: based on historical context&lt;br&gt;(6b) Precise description of the control or comparator: EX-B2 on the level of lumbar 1st to 5th and selected from BL23, BL52, GV3, BL17, BL54, KI3, BL40, GV16, GV26, GB34, ST36, GB31, GB39, BL62 according to the patient’s TCM diagnosis, 0.30 mm × 40 mm needle inserted 25 mm in depth. Retention for 30 min with manual stimulation, total 28 sessions</td>
</tr>
</tbody>
</table>

TCM, Traditional Chinese medicine; NR, not reported.
TCM, Traditional Chinese medicine; NR, not reported.

### Table 1: Details of acupuncture treatments

<table>
<thead>
<tr>
<th>Study</th>
<th>Details of acupuncture treatments</th>
</tr>
</thead>
</table>
| Huang (1995) \(^{36}\) | (1a) Style of acupuncture: TCM style  
(1b) Reasoning for treatment provided: based on historical context and literature sources  
(1c) Extent to which treatment was varied: Fixed formula used  
(2a) Number of needle insertions per subject per session (mean and range where relevant): 6 or 11 (uni- or bilateral unclear)  
(2b-1) Names (or location if no standard name) of points used: Local points; GV3, GB30, BL25. Distal points; BL40, BL57, GB34  
(2b-2) (uni/bilateral): unclear  
(2c) Depth of insertion: 1–2 cun for GV3. Otherwise not reported  
(2d) Response sought: De-qi sensation (radiating sensation in both or unilateral low extremities). Radiating sensation to dorsal area when stimulating GB30.  
(2f) Needle retention times: 20–30 min  
(2g) Needle type and specification: the diameter of 0.25–0.35 mm, piriform acupuncture needles with 2–5 cun of length  
(3a) Number of treatment sessions: NR  
(3b) Frequency and duration of treatment sessions: acupuncture every other day, 10 times of treatment for 1 session, 5–7 days interval between sessions  
(4a) Details of other interventions administered to the acupuncture group: herb decoction. One unit daily, 10 times for 1 session, 5–7 days interval between sessions  
(4b) Setting and context of treatment: NR  
(5) Description of participating acupuncturists: NR  
(6a) Rationale for the control or comparator in the context of the research question: NR  
(6b) Precise description of the control or comparator: acupuncture on BL23, GB30, BL40, and EX-B2 on the level of affected vertebrae using piriform needles with the length of 0.25–0.35 mm and the diameter of 2–5 cun. Manual stimulation for eliciting the De-qi sensation or radiating sensation towards lower leg. O 6805 device, continuous wave, more than 200 per minute frequency for electrical stimulation. 20–30 min needle retention. Acupuncture every other day, 10 times for 1 session, 5–7 days interval between sessions. |
| Lin (2007) \(^{27}\)   | (1a) Style of acupuncture: TCM style  
(1b) Reasoning for treatment provided: based on historical context  
(1c) Extent to which treatment was varied: Fixed formula used  
(2a) Number of needle insertions per subject per session (mean and range where relevant): at least 4 (7, if needled bilaterally)  
(2b-1) Names (or location if no standard name) of points used: Local points; GV2, BL32, Distal points; SI3, BL62  
(2b-2) (uni/bilateral): NR  
(2c) Depth of insertion: NR  
(2d) Response sought: NR  
(2e) Needle stimulation: manually, every 10 min during needle retention  
(2f) Needle retention times: about 30 min  
(2g) Needle type and specification: NR  
(3a) Number of treatment sessions: 30  
(3b) Frequency and duration of treatment sessions: 30 days treatment daily  
(4a) Details of other interventions administered to the acupuncture group: Massage (rolling, pressing, holding, rubbing, touching, patting, etc.) from posterior to anterior, superior to inferior side, at the posterior side of leg on the bladder meridian, and at the ST31, GB31, SP10, ST36, GB34, ST41, KI1 for 45 min daily, shaking before ending. Herb decoctions 1 unit daily for 30 days  
(4b) Setting and context of treatment: encourage to rub low back, rub KI1 in hot water and low back exercise  
(5) Description of participating acupuncturists: NR  
(6a) Rationale for the control or comparator in the context of the research question: NR  
(6b) Precise description of the control or comparator: aescin 20 mg in 500 ml dextrose saline IV, salvia injection 10 ml in 250 ml 15% dextrose IV, once daily, 7 days per session, 3 days interval between each session, total 3 sessions |

---

TCM, Traditional Chinese medicine; NR, not reported; IV, intravenous injection.
<table>
<thead>
<tr>
<th>Study</th>
<th>Details of acupuncture treatments</th>
</tr>
</thead>
</table>
| Li (2009)²⁸   | (1a) Style of acupuncture: TCM style  
(1b) Reasoning for treatment provided: based on historical context and literature sources  
(1c) Extent to which treatment was varied: Fixed formula used  
(2a) Number of needle insertions per subject per session (mean and range where relevant): 5 or 8 (depends on unilateral or bilateral leg symptoms)  
(2b-1) Names (or location if no standard name) of points used: Local points; BL25 (bilaterally), Distal points; BL40, BL57, BL60 (ipsilaterally)  
(2b-2) (uni/bilateral): bilateral BL25, ipsilateral; BL40, BL57, BL60  
(2c) Depth of insertion: not clearly reported. Depth of needling depended on the degree of body fat of the patient  
(2d) Response sought: Radiating sensation on hips and lower extremities when insertion on both BL25. Electrical stimulation within individual pain thresholds  
(2e) Needle stimulation: manual and electrical stimulation. After De-qi, electrical stimulation added, using G6805, continuous wave, intensity within individual pain thresholds, for 25 min  
(2f) Needle retention times: 25 min  
(2g) Needle type and specification: Huato Pai acupuncture needles. 0.35 mm × 40 mm or 0.35 mm × 100 mm  
(3a) Number of treatment sessions: 30  
(3b) Frequency and duration of treatment sessions: once daily, total 30 sessions  
(4a) Details of other interventions administered to the acupuncture group: TDP apply on low back and buttock region  
(4b) Setting and context of treatment: NR  
(5) Description of participating acupuncturists: NR  
(6a) Rationale for the control or comparator in the context of the research question: NR  
(6b) Precise description of the control or comparator: traction with YHZ-V device, 10—40 g traction power, for 30 min, once daily, total 30 days. Encouraging self-exercise Fenbidi (ibuprofen) 1 capsule at a time, twice daily, total 30 days |
| Pan (2011)²⁹  | (1a) Style of acupuncture: TCM style  
(1b) Reasoning for treatment provided: based on historical context  
(1c) Extent to which treatment was varied: Fixed formula used  
(2a) Number of needle insertions per subject per session (mean and range where relevant): at least 4 (7, if needled bilaterally)  
(2b-1) Names (or location if no standard name) of points used: Local points; GV2, BL32, Distal points; SI3, BL62  
(2b-2) (uni/bilateral): NR  
(2c) Depth of insertion: NR  
(2d) Response sought: NR  
(2e) Needle stimulation: manually, every 10 min during needle retention  
(2f) Needle retention times: about 30 min  
(2g) Needle type and specification: NR  
(3a) Number of treatment sessions: 30  
(3b) Frequency and duration of treatment sessions: 30 days treatment daily  
(4a) Details of other interventions administered to the acupuncture group: Massage (rolling, pressing, holding, rubbing, touching, patting, etc.) from posterior to anterior, superior to inferior side, at the posterior side of leg on the bladder meridian, and at the ST31, GB31, SP10, ST36, GB34, ST41, K11 for 45 min daily, shaking before ending. Herb decoctions 1 unit daily for 30 days  
(4b) Setting and context of treatment: encourage to rub low back, rub K11 in hot water and low back exercise  
(5) Description of participating acupuncturists: NR  
(6a) Rationale for the control or comparator in the context of the research question: NR  
(6b) Precise description of the control or comparator: aescin 20 mg in 500 ml dextrose saline IV, salvia injection 10 ml in 250 ml 15% dextrose IV, once daily, 7 days per session, 3 days interval between each session, total 3 sessions |

TCM, Traditional Chinese medicine; NR, not reported; TDP, Teding Diancibo Pu irradiation (translated as special electromagnetic spectrum).
Appendix C.

Figure 3. Pain visual analogue scale scores for back and leg at post-treatment, 3-month and 6-month assessment.

Figure 4. Overall assessment scores at post-treatment, 3-month and 6-month assessment.

Figure 5. Spinal function scores at post-treatment, 3-month and 6-month assessment. In the study of Chen (2011)\textsuperscript{22}, four groups of acupuncture stimulation were merged into two for pairwise comparison between techniques with BL32 stimulation and those without them.
## Table 1: Quality of life at post-treatment, 3-month and 6-month assessment.

<table>
<thead>
<tr>
<th>Study or Subgroup</th>
<th>Experimental Mean</th>
<th>Experimental SD</th>
<th>Experimental Total</th>
<th>Control Mean</th>
<th>Control SD</th>
<th>Control Total</th>
<th>Weight</th>
<th>Std. Mean Difference</th>
<th>IV, Random, 95% CI</th>
<th>Std. Mean Difference</th>
<th>IV, Random, 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Post-tx</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kou 2011</td>
<td>55.13</td>
<td>4.8</td>
<td>77</td>
<td>62.6</td>
<td>10.18</td>
<td>77</td>
<td>71.5%</td>
<td>-0.93</td>
<td>[-1.27, -0.60]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lu 2012</td>
<td>53.67</td>
<td>8.91</td>
<td>30</td>
<td>64.5</td>
<td>16.69</td>
<td>30</td>
<td>28.5%</td>
<td>-0.80</td>
<td>[-1.33, -0.27]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>107</td>
<td></td>
<td></td>
<td></td>
<td>100.0%</td>
<td>-0.90</td>
<td>[-1.18, -0.61]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong></td>
<td>Tau² = 0.00;</td>
<td>Chi² = 0.18,</td>
<td>df = 1 (P = 0.67);</td>
<td></td>
<td>P² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect:</td>
<td>Z = 6.23 (P &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>3 mo f/u</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kou 2011</td>
<td>57.07</td>
<td>6.08</td>
<td>77</td>
<td>61.8</td>
<td>8.44</td>
<td>77</td>
<td>71.5%</td>
<td>-0.64</td>
<td>[-0.96, -0.32]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lu 2012</td>
<td>55.13</td>
<td>15.39</td>
<td>30</td>
<td>62.33</td>
<td>14.54</td>
<td>30</td>
<td>28.5%</td>
<td>-0.47</td>
<td>[-0.99, 0.04]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>107</td>
<td></td>
<td></td>
<td></td>
<td>100.0%</td>
<td>-0.59</td>
<td>[-0.87, -0.32]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong></td>
<td>Tau² = 0.00;</td>
<td>Chi² = 0.28,</td>
<td>df = 1 (P = 0.59);</td>
<td></td>
<td>P² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect:</td>
<td>Z = 4.24 (P &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>6 mo f/u</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Kou 2011</td>
<td>59.48</td>
<td>6.92</td>
<td>77</td>
<td>64.43</td>
<td>7.4</td>
<td>77</td>
<td>72.3%</td>
<td>-0.69</td>
<td>[-1.01, -0.36]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Lu 2012</td>
<td>55.7</td>
<td>14.66</td>
<td>30</td>
<td>65.87</td>
<td>10.94</td>
<td>30</td>
<td>27.7%</td>
<td>-0.78</td>
<td>[-1.30, -0.25]</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Subtotal (95% CI)</td>
<td></td>
<td></td>
<td>107</td>
<td></td>
<td></td>
<td></td>
<td>100.0%</td>
<td>-0.71</td>
<td>[-0.99, -0.44]</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Heterogeneity:</strong></td>
<td>Tau² = 0.00;</td>
<td>Chi² = 0.08,</td>
<td>df = 1 (P = 0.78);</td>
<td></td>
<td>P² = 0%</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Test for overall effect:</td>
<td>Z = 5.04 (P &lt; 0.00001)</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Favours experimental AT | Favours control AT

---

### References


42. Witt CM, Lao L, MacPherson H. Evidence on acupuncture safety needs to be based on large-scale prospective surveys, not single case reports. *Pain* 2011;152:2180.


