REVIEW ARTICLE

Acupuncture for Acute Postoperative Pain after Back Surgery: A Systematic Review and Meta-analysis of Randomized Controlled Trials

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Abstract

Objectives: Acupuncture is commonly used as a complementary treatment for pain management. However, there has been no systematic review summarizing the current evidence concerning the effectiveness of acupuncture for acute postoperative pain after back surgery. This systematic review aimed at evaluating the effectiveness of acupuncture treatment for acute postoperative pain (≤1 week) after back surgery. Methods: We searched 15 electronic databases without language restrictions. Two reviewers independently assessed studies for eligibility and extracted data, outcomes, and risk of bias. Random effect meta-analyses and subgroup analyses were performed.

Results: Five trials, including 3 of high quality, met our inclusion criteria. The meta-analysis showed positive results for acupuncture treatment of pain after surgery in terms of the visual analogue scale (VAS) for pain intensity 24 hours after surgery, when compared to sham acupuncture (standard mean difference $\delta = 0.67$ ($0.104$ to $0.31$), $P = 0.0003$), whereas the other meta-analysis did not show a positive effect of acupuncture on 24-hour opiate demands when compared to sham acupuncture (standard mean difference $-0.23$ ($-0.58$ to $0.13$), $P = 0.21$).

Conclusion: Our systematic review finds encouraging but limited evidence for the effectiveness of acupuncture treatment for acute postoperative pain after back surgery. Further rigorously designed clinical trials are required.

Key Words: acupuncture, pain, back surgery, systematic review, meta-analysis

INTRODUCTION

Rates of back surgery in the United States are the highest in the world¹ and continue to rise steadily.² Over the last
few years, billions of dollars have been spent worldwide on surgery for people with chronic low back pain, and thousands of research articles have been dedicated to the subject. The most common reason for back surgery is the persistent low back pain caused by intervertebral disk herniation, spinal stenosis, or spondylolisthesis. Unfortunately, acute postoperative pain after back surgery remains a common problem. A high prevalence of moderate or severe pain on the first day following surgery as did 30% to 64% of back or spine surgery patients.

Pain management after back surgery is a very important element of patient care. Various opioid analgesics have been used for postoperative pain management, including morphine, hydromorphone, meperidine, or fentanyl. However, unwanted opioid side effects, such as nausea and vomiting, are frequently observed. More importantly, patients with fewer side effects experience more satisfaction. Therefore, the need for safe, effective therapies for pain management after back surgery has become evident.

Acupuncture is commonly used for pain management. Numerous studies have shown that acupuncture is safe and cost-effective compared to routine care. The primary goal of acupuncture treatment after back surgery is pain reduction. However, there has been no systematic review summarizing the current evidence concerning the effectiveness of acupuncture for acute postoperative pain after back surgery. For this reason, we conducted a systematic review of randomized controlled trials (RCTs) to evaluate critically, whether acupuncture is effective in relieving acute postoperative pain (<1 week) after back surgery.

**METHODS**

**Information Sources and Search Strategy**

Using the COSI model, the following electronic databases were searched from their inception to December 2012, without restrictions on language: the Cochrane Central Register of Controlled Trials (CENTRAL), EMBASE, MEDLINE, PubMed, the Allied and Complementary Medicine Database (AMED), CINAHL, Chinese databases (including the China Knowledge Resource Integrated Database (CNKI), Wanfang Data and VIP), a Japanese database (the Japan Science and Technology Information Aggregator Electronic database), and Korean databases (including DBpia, the Korean traditional knowledge portal, NDSL, OASIS and RISS). We also manually searched gray literature.

The following key search terms were used: “(acupuncture OR acup* OR acupressure OR electroacupuncture OR auricular acupuncture OR laser acupuncture OR scalp acupuncture) AND (spinal surgery OR spine surgery OR back surgery OR lumbar surgery OR lumbar operation OR vertebra surgery OR thoracolumbar surgery OR FBSS OR “failed back surgery syndrome” OR laminectomy OR discectomy OR foraminotomy OR spinal fusion OR vertebroplasty)”.

**Study Selection**

**Types of Studies.** RCTs of acupuncture as a treatment option for pain after back surgery were included. Relevant dissertations and abstracts were also included. The titles and abstracts of the searched articles were read by a single primary researcher (YHC) who was trained in search and systematic review for 3 years. If the articles were not written in English, we primarily reviewed them through their English abstracts. They were translated into English prior to screening by a commercial service, if we had troubles with language comprehension. The articles that were then potentially to be included in our review were checked by 2 independent reviewers (YHC, CKK).

**Types of Participants.** The clinical trials involving back surgery patients were included. There were no restrictions related to the reason for the back surgery, the site of the back surgery, the type of back surgery, age, or gender. We included patients within 1 week that had passed after back surgery regarding as acute postoperative pain.

**Types of Interventions/Controls.** Acupuncture is defined as a collection of procedures involving penetration of the skin with needles to stimulate certain points on the body, known as acupoints following the meridian theory of traditional Chinese medicine. Other means of stimulating the acupoints, including lasers, ultrasound, and electricity, may also be used. Thus, our study mainly considered the effects of acupuncture with needling at acupoints or other stimulations with non-needling on acupoints (including lasers, ultrasound, electricity, and etc.). We included classical acupuncture, electro-acupuncture, acupoint electronic stimulation, acupressure, auricular acupuncture, auricular acupressure, scalp acupuncture, laser acupuncture, and abdominal acupuncture. We also included trials that compared
acupuncture plus a conventional therapy (ie, regular care or routine rehabilitation) with conventional therapy alone. We excluded needling on nonacupuncture sites or acupuncture plus herbal medicine. Controls included sham/placebo acupuncture, (eg, nonpenetrating on acupoints or superficial penetrating on nonacupoints)17-19 no treatment, and conventional therapy for pain after back surgery (eg, drugs, rehabilitation, etc.).

**Outcome Measures.** We considered any pain-related measures, such as the visual analogue scale (VAS) and opiate demands. We also considered the general safety aspects, that is, adverse events of acupuncture as secondary outcomes.

**Data Extraction and Quality Assessment**

Data were independently extracted by two reviewers (YHC, BCS) and were blinded to the results of the other reviewer. The reviewers collected data related to the methodologies of the studies, the identification of outcome measurements, the results, and the final conclusions. Through the use of Cochrane’s tool for assessment of risk of bias, each study’s methodological quality was quantitatively evaluated. Cochrane’s risk of bias tool consists of seven domains: (1) random sequence generation, (2) allocation concealment, (3) blinding of participants and personnel, (4) blinding of outcome assessment, (5) incomplete outcome data, (6) selective reporting, and (7) other bias. The instructions in the Cochrane handbook were followed. In this study, the 7th other risk of bias was assessed as a low risk, if baseline characteristics were properly reported and not different between treatment and control groups. Any discrepancies were resolved through discussion to reach a consensus or by consulting the third reviewer (MSL). We considered trials high quality if we assessed the risk of bias to be low in more than four of the seven domains. Therefore, this study should be interpreted as a weighted analysis of high-quality trials.

**Data Synthesis**

Meta-analyses were analyzed using the Cochrane Collaboration software (Review Manager [RevMan] version 5.1; The Nordic Cochrane Centre, The Cochrane Collaboration, Copenhagen, Denmark). The 95% confidence interval (CI) and the standard mean difference (SMD) were calculated in the meta-analysis if the data were continuous. The 95% CI and the risk estimate (relative risk; RR) were calculated if the data were dichotomous. The variance of the change was imputed using a correlation factor of 0.4, as suggested by the Cochrane Collaboration. We then pooled data from across the studies using random effects models if excessive statistical heterogeneity did not exist. We assessed statistical heterogeneity using the chi-square test and the Higgins I² test. If any kinds of heterogeneity exist, we conducted subgroup analysis or sensitivity analysis additionally for more comprehensive understanding of meta-analysis. Formal funnel plots were planned for assessing the publication bias, if over 10 trials were included in the same meta-analysis. However, we were not able to carry out this assessment, due to the small number of trials included in the meta-analysis.

**RESULTS**

**Study Description**

Figure 1 shows details of the trial selection process. We identified 1,515 publications. We excluded 1,464 studies after screening the abstracts and titles. Fifty-one articles were fully evaluated. We subsequently excluded 46 additional articles, 29 of which described studies that were uncontrolled and 4 of which described studies that were not randomized. Six RCTs were excluded, four of which related to anesthesia effects during surgery, one of which involved nonacupuncture sites, one of which involved acupuncture plus herbal medicine. Whereas 7 RCTs were also excluded, two of which involved chronic postoperative pain and five of which involved indistinguishable from acute/chronic postoperative pain. Those studies are summarized in Appendix 1. Consequently, 5 RCTs met our inclusion criteria. Three trials studied acupuncture versus sham acupuncture, 1 trials studied acupuncture versus conventional therapy, and 1 trial studied acupuncture plus conventional therapy versus conventional therapy. The key data are summarized in Table 1. There were 3 Taiwanese studies, 1 German study, and 1 Chinese study. Three trials were 2-parallel-arm group design studies, and 2 trials were 3-parallel-arm group design studies.

**Characteristics of Included RCTs**

Table 1 shows the differences in the baseline characteristics of the treatment and control groups. Four studies reported no differences between the two
groups, whereas 1 study did not mention baseline imbalance.

All 5 studies included reported that treatments related to acupuncture were performed within 7 days after back surgery.

In outcome assessments, the VAS, opiate dose, or morphine dosage was used for pain intensity. Table 1 summarizes the details of the studies included.

**Study Quality**

The methodological quality of the RCTs was variable (Table 2). Two studies described a proper method of sequence generation. One study used a computerized randomization, and 1 other study used a randomization list. The other 3 studies did not clearly report how the allocation sequence was generated. Allocation was concealed in 2 studies. Participants blinding and personnel blinding were reported in 4 studies, and assessor blinding was reported in 3 studies. The risk of bias for incomplete outcome data was low in 2 studies, because details about dropouts and withdrawals were reported. In all, the 5 included RCTs had an unclear risk of bias in terms of selective reporting. Four studies were evaluated to be at low risk.
Table 1. Summary of Randomized Controlled Trials of Acupuncture for Acute Postoperative Pain after Back Surgery

| Author(s)   | Year | Country   | Reason for Surgery                                                                 | Sample Size (A:B:C) | Baseline Characteristics Difference of Treatment and Control Groups | AT Time before/after Surgery | Intervention                                                                                      |
|-------------|------|-----------|------------------------------------------------------------------------------------|---------------------|---------------------------------------------------------------------|-----------------------------|----------------------------------------------------------------------------------------------|
| Yeh         | 2011 | Taiwan    | Lumbar disk herniation, lumbar spinal stenosis, spondylolisthesis                  | 90 (30/30/30)       | No difference (gender, age, body weight, height, other chronic diseases, admitted diagnosis, number of lumbar surgeries, worst preoperative pain, average preoperative pain, operation duration, amount of blood loss) | 3 h after surgery           | (A) True AES (B) Sham AES (2 cm away from actual acupoints) (C) No treatment |
| Yeh         | 2010a| Taiwan    | Lumbar disk herniation, lumbar spinal stenosis, lumbar vertebra dislocation        | 94 (33/30/31)       | No difference (gender, age, employment, height, body weight, other chronic diseases, admitted diagnosis, lumber of lumbar surgeries, worst preoperative pain, average preoperative pain, preoperative systolic blood pressure, preoperative diastolic blood pressure, type of operation, operation duration, amount of blood loss) | 1 h before surgery 1 h after surgery 2 h after surgery | (A) True AES (B) Sham AES (2 cm away from actual acupoints) (C) No treatment |
| Wang        | 2000 | Germany   | Lumbar disk herniation                                                            | 132 (66/66)         | AT was conducted before and after corrective surgery for a total of 3-6 days | AT was conducted before and after corrective surgery for a total of 3-6 days | (A) Classic AT (B) Placebo AT (2 cm away from actual acupoints) |

Main Outcomes:
1. VAS (pain)
2. Opiate demands
3. Postoperative dose during first 24 h
Table 1. (Continued)

| Author (year) | Country | Reason for Surgery | Design | Sample Size (A: B:C) | Baseline Characteristics Difference of Treatment and Control Groups | AT Time before/after Surgery | Intervention |
|---------------|---------|--------------------|--------|----------------------|---------------------------------------------------------------|--------------------------------|--------------|
| AT vs. conventional therapy | Li (2008) | Lumbar disk herniation China | Parallel 2 arms | 90 (45/45) | No difference (Gender, age, course of disease (narrative only)) | 6 h after surgery 1-3 days after surgery (twice a day) 4-7 days after surgery (once a day) | (A) Abdominal AT | (B) Drugs (anti-inflammatory and analgesic) |
| AT plus conventional therapy vs. conventional therapy | Yeh (2010b) | Lumbar spine Taiwan (not reported details) | Parallel 2 arms | 74 (36/38) | No difference (gender, age, smoking, history of postoperative vomiting, history of spinal surgery, hypertension, diabetes, ASA class, operation duration, amount of blood loss, number of postoperative drains) | 1-3 days after surgery (four times) | (A) Auricular AT plus regular care | (B) Regular care alone |

AES, acupoint electrical stimulation (non-penetration); AT, acupuncture; EA, electro-acupuncture; VAS, visual analogue scale; ASA, the American Society of Anaesthesiologists.
of bias from other sources because baseline characteristics were properly reported and not different between the treatment and control groups. However, 1 study was evaluated to be at high risk of bias from other sources because there were baseline imbalances in VAS without consideration of adjustment between the two groups. In total, 3 studies were considered high in quality (low risk of bias), 1 study was considered medium in quality, and the other 1 study was considered low in quality.

### Descriptions of Acupuncture Treatment

All of the RCTs stated that the rationale for acupuncture point selection was drawn from traditional Chinese medicine theory (Table 3). Two studies used acupoint electrical stimulation with nonpenetration, 1 study used classic acupuncture with manual stimulation, 1 study used abdominal acupuncture with classic acupuncture, and 1 study used acupressure on the ear.

### Outcomes

**Acupuncture vs. Sham Acupuncture (3 RCTs).** Two RCTs evaluated the effect of acupoint electrical stimulation in comparison to sham acupoint electrical stimulation. The other 1 RCT reported the results of classic acupuncture versus sham acupuncture in terms of pain intensity as measured by VAS. In one study, the times at which the VAS were measured were before acupuncture, immediately after acupuncture, 0.5 hour after acupuncture, 1 hour after acupuncture, 2 hours after acupuncture, and 6 hours after acupuncture. In another study, the times at which pain was evaluated using the VAS scale were before surgery, 1 hour after surgery, and 24 hours after surgery.

### Table 2. Cochrane Risk of Bias of Included Randomized Clinical Trials

| First Author (Year) | Yeh (2011) | Yeh (2010a) | Wang (2000) | Li (2008) | Yeh (2010b) |
|---------------------|------------|-------------|-------------|-----------|------------|
| 1. Random sequence generation (selection bias) | L (computerized randomization) | U | U | U | L (randomization list) |
| 2. Allocation concealment (selection bias) | L (mentioned) | L (mentioned) | U | U | U |
| 3. Blinding of participants and personnel (performance bias) | L (patient blind) | L (patient blind) | U | U | U |
| 4. Blinding of outcome assessment (detection bias) | L (mentioned) | L (mentioned) | U | U | U |
| 5. Incomplete outcome data (attrition bias) | L (mentioned) | U | U | U | L (Mentioned) |
| 6. Selective reporting (reporting bias) | U | U | U | U | U |
| 7. Other bias | L | L | H | L | L |

Risk of bias: H, high risk of bias; L, low risk of bias; U, unclear.

### Table 3. Summary of Acupuncture Treatment Points and other Information Related to Acupuncture Treatment

| First Author (Year) | Acupuncture Method | Total Treatment (times) | Acupuncture Points | Deqi | Rationales for Acupuncture Points | Adverse Events |
|---------------------|--------------------|------------------------|--------------------|------|----------------------------------|---------------|
| Yeh (2011)          | AES                | 2                      | BL40, GB34, HT7, P6 | n.r. | TCM theory                       | No adverse effect |
| Yeh (2010a)         | AES                | 3                      | BL40, GB34, HT7, P6 | n.r. | TCM theory                       | n.r.          |
| Wang (2000)         | Classic AT with MS | 2–3                    | BL25, GB31, BL26, GB30, BL62, BL23, BL36, BL40, GB34 | n.r. | TCM theory                       | n.r.          |
| Li (2008)           | Abdominal AT with Classic AT | 10 | Standard points: CV12, CV9, CV6, CV4 Individualized: CV6 0.2 unit of length lateral (L2-3 surgery) CV5 0.2 unit of length lateral (L3-4 surgery) CV4 0.2 unit of length lateral (L4-5 surgery) Additive: KI11, ST25 (back pain) Ab7 (CV6 0.5 unit of length lateral), ST26, Ab4, Ab6 (Sciatica) ST28, ST24 (Low back pain) | n.r. | TCM theory | n.r. |
| Yeh (2010b)         | Auricular acupressure | 12 | TF4, AT3, AH9, CO4, CO5, CO18 | n.r. | TCM theory | n.r. |

AES, acupoint electrical stimulation (nonpenetration); AT, acupuncture; MS, manual stimulation; n.r., not reported; TCM, traditional Chinese medicine.
surgery, 2 hours after surgery, and 24 hours after surgery. In the third study, pain was evaluated 24 hours after surgery (Table 1).

Two trials showed favorable effects of acupoint electrical stimulation that were superior to those of sham acupoint electrical stimulation.

The pooled meta-analysis of data showed significant improvements in pain intensity for VAS 24 hours after surgery (2 studies, n = 123, SMD, −0.67; 95% CI of −1.04 to −0.31, P = 0.0003, heterogeneity: χ² = 0.01, df = 1 (P = 0.94); I² = 0%; Figure 2.1). In addition, the pooled meta-analysis of the data showed significant improvements in postoperative opiate dose demands during the first 24 hours after surgery (2 studies, n = 123, SMD, −0.77; 95% CI of −1.14 to −0.41, P = 0.0001, heterogeneity: χ² = 0.00, P = 0.96, and I² = 0%; Figure 2.2).

Acupuncture vs. No Treatment (2 RCTs). Two RCTs evaluated the effect of acupuncture electrical stimulation in comparison to no treatment. The points of time for measuring the VAS were before surgery, 1 hour after surgery, 2 hours after surgery, and 24 hours after surgery (Table 4).

The pooled meta-analysis of the data showed significant improvements in pain intensity for VAS 24 hours after surgery (2 studies, n = 124, SMD, −0.67; 95% CI of −0.76 to −0.58, P = 0.0001, heterogeneity: χ² = 0.00, df = 1 (P = 0.96); I² = 0%; Figure 2.2).
Acupuncture vs. Conventional Therapy (1 RCT). One RCT$^{35}$ evaluated the effect of acupuncture (abdominal acupuncture) in comparison with conventional therapy (drugs).

The points of time for measuring the VAS were before surgery, 1 week after surgery, 1 month after surgery, and 3 months after surgery.

There were no differences between the acupuncture and conventional therapy in terms of VAS for pain intensity before surgery and 1 week after surgery. However, the RCT showed acupuncture to be superior to conventional therapy in VAS for pain intensity 1 and 3 months after surgery (Table 4).

Acupuncture Plus Conventional Therapy vs. Conventional Therapy (1 RCT). One RCT$^{37}$ evaluated the effect of acupuncture plus conventional therapy (auricular acupuncture plus regular care) in comparison with conventional therapy (regular care alone).

The points of time for measuring the VAS were 2 hours after surgery, 24 hours after surgery, 48 hours after surgery, and 72 hours after surgery, whereas the points of time for measuring the morphine demands were during first 24 hours after surgery, during 24 hours to 48 hours after surgery, and during 48 hours to 72 hours after surgery.

However, the RCT$^{37}$ was not applicable for effect estimates because of the lack of data on standard deviation in the original paper (Table 4).

The Safety of Acupuncture

Only 1 RCT$^{38}$ reported adverse events associated with acupuncture or acupoint electrical stimulation and

| Outcome of Subgroup | Number of Studies$^{ref}$ | Number of Patients | Effect Estimate (SMD [95% CI]) |
|---------------------|--------------------------|--------------------|-------------------------------|
| AT vs. sham AT      |                          |                    |                               |
| VAS (pain)          |                          |                    |                               |
| Before AT           | 1$^{36}$                 | 132                | −0.95 [−1.31, −0.59]          |
| Immediately after AT| 1$^{36}$                 | 132                | −2.91 [−3.40, −2.41]          |
| 0.5 h after AT      | 1$^{36}$                 | 132                | −4.74 [−5.42, −4.07]          |
| 1 h after AT        | 1$^{36}$                 | 132                | −5.68 [−6.45, −4.90]          |
| 2 h after AT        | 1$^{36}$                 | 132                | −6.95 [−7.87, −6.03]          |
| 6 h after AT        | 1$^{36}$                 | 132                | −9.82 [−11.07, −8.57]         |
| Before surgery      | 1$^{34}$                 | 60                 | NA                            |
| 1 h after surgery   | 1$^{34}$                 | 60                 | NA                            |
| 2 h after surgery   | 1$^{34}$                 | 60                 | NA                            |
| 24 h after surgery  | 2$^{34,38}$              | 124                | −0.67 [−1.04, −0.31]          |
| Opiate demands      |                          |                    |                               |
| Postoperative dose during first 24 h | 2$^{34,38}$              | 124                | −0.23 [−0.58, −0.13]          |
| AT vs. no treatment |                          |                    |                               |
| VAS (pain)          |                          |                    |                               |
| Before surgery      | 1$^{34}$                 | 60                 | NA                            |
| 1 h after surgery   | 1$^{34}$                 | 60                 | NA                            |
| 2 h after surgery   | 1$^{34}$                 | 60                 | NA                            |
| 24 h after surgery  | 2$^{34,38}$              | 124                | −0.69 [−1.06, −0.33]          |
| Opiate demands      |                          |                    |                               |
| Postoperative dose during first 24 h | 2$^{34,38}$              | 124                | −0.77 [−1.14, −0.41]          |
| AT vs. conventional therapy |                  |                    |                               |
| VAS (pain)          |                          |                    |                               |
| Before surgery      | 1$^{35}$                 | 90                 | 0.11 [−0.30, 0.52]            |
| 1 week after surgery| 1$^{35}$                 | 90                 | 0.16 [−0.26, 0.57]            |
| 1 month after surgery| 1$^{35}$               | 90                 | −0.94 [−1.38, −0.50]          |
| 3 months after surgery| 1$^{35}$             | 90                 | −0.08 [−0.50, 0.33]           |
| AT plus conventional therapy vs. conventional therapy | | | |
| VAS (pain)          |                          |                    |                               |
| 2 h after surgery   | 1$^{37}$                 | 74                 | NA                            |
| 24 h after surgery  | 1$^{37}$                 | 74                 | NA                            |
| 48 h after surgery  | 1$^{37}$                 | 74                 | NA                            |
| 72 h after surgery  | 1$^{37}$                 | 74                 | NA                            |
| Morphine demands    |                          |                    |                               |
| Postoperative dose during first 24 h after surgery | 1$^{37}$              | 74                 | NA                            |
| Postoperative dose 48 h-72 h after surgery | 1$^{37}$              | 74                 | NA                            |

AT, acupuncture; CI, confidence interval; NA, not applicable because of the lack of data on standard deviation in the original paper; SMD, standardized mean difference; VAS, visual analogue scale.
stated that there were no adverse events. None of others mentioned adverse events.

DISCUSSION
Strengths and Weaknesses
This is the first systematic review and meta-analysis of RCTs that has critically evaluated the totality of RCTs for testing the effectiveness of acupuncture for acute postoperative pain relief after back surgery. Through rigorous searches without limitations on language, we found 5 RCTs comparing sham, no treatment, and conventional therapy.

Because there has been no systematic review summarizing the current evidence concerning the effectiveness of acupuncture for acute postoperative pain after back surgery, we considered to include all of acupuncture intervention types such as acupuncture with penetrating or nonpenetrating on acupoints stimulation. We also included trials that compared acupuncture plus a conventional therapy (i.e., regular care) with conventional therapy alone. But we excluded at nonacupuncture sites or acupuncture plus herbal medicine, because these methods of acupuncture were not able to evaluate the effects of specific acupuncture treatment.

Clinical merit of this systematic review is that it evaluated the possibility that acupuncture may act as an alternative or complementary modality when conservative therapies present lesser effects on pain or considerable adverse events when managing acute postoperative pain conditions after back surgery. Also, this systematic review was conducted in accord with the QUOROM statement and the PRISMA statement.

Based on the Cochrane risk of bias assessment, the methodological quality was generally moderate (3 of the 5 were of high quality, but all of these were by the same author). In addition, 3 high-quality RCTs included in this review performed sample size estimation with appropriate power analysis. Whereas one trial included was of poor methodological quality in terms of the method of allocation concealment, blinding of participants and personnel, blinding of outcome assessment, and power analysis.

Most of the RCTs included were high-quality reports with respect to the revised standards for reporting interventions in clinical trials of acupuncture (STRICTA), especially for acupuncture techniques such as needle type, the depth of insertion, needle stimulation, and responses elicited.

However, the study designs of the RCTs included had some flaws in terms of several components of internal validity. First, the design for acupuncture compared to no treatments seems insufficient because it is difficult to control for nonspecific effects of acupuncture. Second, the design for acupuncture compared to conventional therapy is likely to have performance bias because it is not able to incorporate blinding properly. Third, the design for acupuncture compared to sham acupuncture also has questionable validity of using relevant sham control.

One of the most important questions is what methods of sham acupuncture are acceptable. There are various sham control methods which are penetrating minimal or superficial acupuncture, penetrating on nonacupoints, or a blunt tip touching the skin without penetration. However, there is still not enough evidence which design is the most appropriate sham control.

Moreover, although sham procedure is methodologically necessary to produce valid results such as reducing the performance bias, ethical issues are apparent. It is possible to effect critical ethic problem by sham control without usual medical care for reducing the patient’s pain that goes neglected.

Therefore, those study designs should have adhered more closely to the methodology of comparative effectiveness research (CER). CER is the direct comparison of existing interventions, aiming to determine which treatment works best for whom and under what circumstances. Accordingly, CER or pragmatic effectiveness trials that reflect clinical practice could find firm conclusion on effectiveness of acupuncture more clearly. Furthermore, CER could resolve the critical ethical issues.

Clinical Implications
Our meta-analysis of the pooled data on VAS for pain intensity showed superior effects of acupuncture during the first 24 hours after back surgery. In contrast, the meta-analysis of opiate demands did not show a positive effect of acupuncture. Despite the different results for the two pain outcomes, acupuncture seems to reduce acute postoperative pain in patients with back surgery. Yet, we could not find clear evidence on effectiveness of acupuncture for the following reason. First, the total numbers of RCTs and participants involved were too small to draw concrete conclusions on the therapeutic
effect of acupuncture. Second, the specific and convincing mechanisms of acupuncture are still being elucidated. Third, the time for measuring the VAS differed between some studies (See Table 1). Further, there was lack of observation as to long-term follow-up.

Nevertheless, acupuncture may be an easy accessible,48 convenient49,50 and economical way11 to control pain after back surgery in clinical field. In addition, acupuncture appears to be a relatively safe treatment.10,51,52 If performed by well-trained practitioners, the adverse events occur rarely when used for neck and lower back pain.53,54 However, occasional serious events continue to be reported in relation to the safety of acupuncture.55,56

In this systematic review, only 1 RCT38 reported no adverse events for acupuncture treatment. Acupuncture did not appear to be associated with serious adverse events, but the evidence is limited. Adverse events associated with the use of acupuncture for controlling acute postoperative pain after back surgery should be reported in future research in more detail and rigorously assessed by standardized monitoring.

Based on this review, our main finding is that acupuncture seems to be effective for pain after back surgery, based on 3 high-quality RCTs34,37,38 and two meta-analyses, but the effect of acupuncture on pain after back surgery is limited due to some methodological flaws.

CONCLUSIONS AND FUTURE RESEARCH

In this systematic review, rigorous searches were performed following PRISMA guidelines. We note here several points that must be addressed in future research. First, future trials should adhere more closely to the methodology of comparative effectiveness research because sham-acupuncture-controlled trials may lead to critical ethic problem and could not reflect clinical practice circumstances. Thus, larger pragmatic effectiveness trials to compare acupuncture with standard treatments should be conducted. Second, the acupuncture points used varied widely and were not consistent across studies. However, this is a key feature of traditional Chinese medicine and its individualized point selection. Nevertheless, clinical heterogeneity (by 6 checklist items) can be an issue of standardization and should be considered by adhering to the revised STRICTA guidelines41 in reporting of acupuncture trial. Third, the RCTs included in this systematic review had various control groups and outcome measures, which made it difficult to draw firm conclusions concerning the effects of acupuncture on outcomes after back surgery. Thus, more consistent and standardized outcome measures should be used in future trials. In addition, future trials should observe CONSORT and STRICTA guidelines41 in their study designs.

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AUTHOR CONTRIBUTIONS

YHC, CKN, KHH, and BCS contributed to the study conception and design. YHC and CKN performed search, determined the inclusion eligibility of trials, extracted data from the trials, and assessed the methodological quality of the trials. BCS provided a third assessment of the methodological quality of all trials. YHC, MSL, and BCS entered and organized the data, conducted the analyses, and drafted the manuscript. YHC, MSL, and BCS all contributed to check the analysis and interpretation of the data. YHC and BCS are the guarantors.

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**SUPPORTING INFORMATION**

Additional Supporting Information may be found in the online version of this article:

**Appendix S1.** Summary of 7 RCTs of 2 chronic and 5 unknown the time of acupuncture application trials after back surgery.