

Acupuncture for functional recovery after stroke: a systematic review of sham-controlled randomized clinical trials

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∞ See related commentary by Wu, page 1711

ABSTRACT

Background: Acupuncture is frequently advocated as an adjunct treatment during stroke rehabilitation. The aim of this review was to assess its effectiveness in this setting.

Methods: We searched 25 databases and 12 major Korean traditional medicine journals from their inception to October 2009. We included randomized controlled trials, with no language restrictions, that compared the effects of acupuncture (with or without electrical stimulation) with sham acupuncture. We assessed the methodologic quality of the trials using the Cochrane risk-of-bias criteria and the PEDro (Physiotherapy Evidence Database) scale.

Results: Ten of 664 potentially relevant studies met our inclusion criteria. For acute and subacute stages after stroke, we included seven trials. A meta-analysis of the five studies that assessed functionality did not show a significant difference in favour of acupuncture, with high heterogeneity. A post-hoc sensitivity analysis of three trials with low risk of bias did not show beneficial effects of acupuncture on activities of daily living at the end of the intervention period ($n = 244$; standard mean difference 0.07, 95% confidence interval [CI] -0.18 to 0.32 ; $P = 0\%$) or after follow-up ($n = 244$; standard mean difference 0.10, 95% CI -0.15 to 0.35 ; $P = 0\%$). For the chronic stage after stroke, three trials tested effects of acupuncture on function according to the Modified Ashworth Scale; all failed to show favourable effects.

Interpretation: Our meta-analyses of data from rigorous randomized sham-controlled trials did not show a positive effect of acupuncture as a treatment for functional recovery after stroke.

Acupuncture is often used as an adjunct to mainstream rehabilitation after stroke. It involves the insertion of an acupuncture needle into the skin at certain points of the body. Acupuncture is claimed to be effective for a wide range of conditions, such as pain, musculoskeletal disorders and several neurologic diseases.¹ Possible mechanisms of its effects on neurologic conditions include stimulation of neuronal cell proliferation,² facilitation of neural plasticity,³ reduction of the post-ischemic inflammatory reaction⁴ and prevention of neuronal apoptosis.⁵

Before acupuncture can be recommended for routine use, we require evidence from rigorous randomized clinical trials. In acupuncture trials, it is difficult to allow blinding of the treatment allocation.⁶ A placebo must be indistinguishable from the real treatment and inert.⁶ “Sham” is used to describe any control procedure that is used to blind treatment allocation in clinical trials of acupuncture.⁶ Several sham procedures are now available, such as the use of penetrating acupuncture on nonacupuncture points, superficial puncture of the skin on acupuncture points and nonpenetration on acupuncture points with sham needle devices.⁶

Several reviews assessing the effects of acupuncture for stroke have been published. However, some did not include all of the relevant articles published in Asian countries; others included interventions other than acupuncture; and several were not systematic. We conducted a systematic review to critically evaluate all of the currently available randomized sham-controlled trials of acupuncture as an adjunct to mainstream stroke rehabilitation.

Methods

Data sources

We searched the following databases from their inception through October 2009: MEDLINE, AMED, British Nursing Index, CINAHL, EMBASE, PsycINFO, the Cochrane Library (2009; issue 4), and Asian journals and 12 major Korean traditional medicine journals (Appendix 1, available at www.cmaj.ca/cgi/content/full/cmaj.091113/DC1). We used the following search terms: (acupuncture OR acu*) AND (stroke OR apoplexy OR cva OR cerebrovascular attack OR cerebrovascular accident OR cerebrovascular* OR cerebral infarction OR cerebral hemorrhage OR cerebral*). (Details about our search strategy for each database are shown in

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Appendix 2, available at www.cmaj.ca/cgi/content/full/cmaj.091113/DC1). We also searched our own files manually for relevant articles. Hard copies of all articles were obtained and read in full. No language restrictions were imposed. We included dissertations and abstracts, provided they contained sufficient detail for critical evaluation.

Study selection

Two of us (J.C.K., B.C.S.) independently identified eligible articles. Disagreements were resolved through discussion with the other authors. All prospective clinical studies of needle acupuncture (with or without electrical stimulation) as an adjunct treatment for functional recovery after stroke were considered. Randomized clinical trials involving patients of any age or sex with ischemic or hemorrhagic stroke in the acute, subacute or chronic stage were eligible. Stroke had to have been diagnosed by means of computed tomography or magnetic resonance imaging, or clinically according to the World Health Organization definition.⁷

Eligible trials were included regardless of time of treatment or the length of the treatment period. The control interventions were either sham acupuncture (acupuncture with or without needle penetration at the acupuncture points or non-acupuncture points) or subliminal acupuncture (electro-stimulation using electrodes attached to the skin).⁸

Outcome measures

The outcome measures we considered were those related to neurologic deficit, activities of daily living (i.e., Barthel Index or Fugl-Meyer Assessment), motor recovery and quality of life. In addition, we recorded adverse events.

Data extraction, quality and validity assessment

Two of us (J.C.K., B.C.S.) extracted data according to pre-defined criteria. The Cochrane risk-of-bias tool⁹ and the PEDro (Physiotherapy Evidence Database) scale¹⁰ were used to assess methodologic quality of the trials.

The same two authors independently assessed the quality of the acupuncture technique as described previously.¹¹ Disagreements were resolved by discussion with the other authors.

Statistical analysis

In the absence of clinical heterogeneity, we synthesized the results in a meta-analysis. We compared the mean change in outcome measures with baseline values to assess differences between the intervention and control groups. Weighted mean differences or standardized mean differences and 95% confidence intervals (CIs) were calculated. Where necessary, we contacted the primary authors of the trials to acquire or verify data. Differences compared with sham control were considered relevant. The variance of the change was inferred using a correlation factor of 0.5.¹² Cochrane's Q-test and *I*² were used to assess heterogeneity. Heterogeneity was assumed if the *p* value was less than 0.10 in the χ^2 test and the *I*² value was above 75%.⁹ In case of heterogeneity, we attempted to identify and explain the heterogeneity using subgroup analysis. Subgroup analysis was performed for subsets of studies and

stages of stroke. Where possible, we assessed publication bias using a funnel plot. Post hoc sensitivity analyses were performed to test the robustness of the overall effect.

Results

Study description

We identified 664 potentially relevant articles (Appendix 3, available at www.cmaj.ca/cgi/content/full/cmaj.091113/DC1). Ten studies, involving a total of 711 participants, met our inclusion criteria (Figure 1). Key data are summarized in Table 1.¹³⁻²² Seven trials included patients in the acute or subacute stage of stroke, and three included patients in the chronic stage. Eight trials were from Western countries and published in English.^{13-15,17,18,20-22} Two trials were from China and published in Chinese.^{16,19} Details of the treatment regimens are summarized in Appendix 4 (available at www.cmaj.ca/cgi/content/full/cmaj.091113/DC1).

Two trials used sham electro-stimulation on acupoints.^{14,15} The other eight used sham acupuncture:^{13,16-22} one trial used superficial acupuncture in the control procedure;¹³ four^{16,18,20,21} used nonpenetrating acupuncture on nonacupuncture points or real acupuncture points; and three^{17,19,22} used penetrating acupuncture on nonacupuncture points.

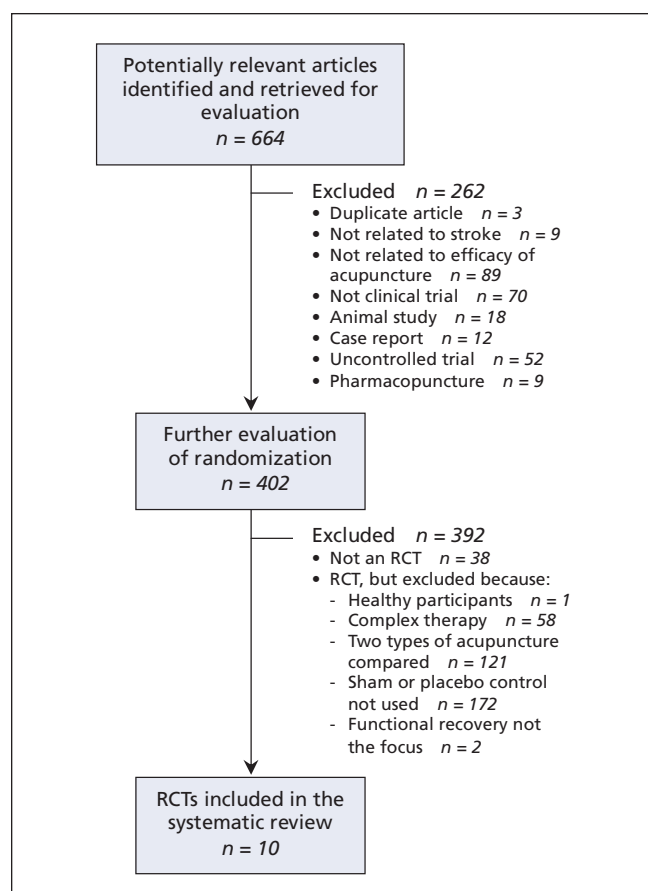


Figure 1: Selection of sham-controlled randomized clinical trials of acupuncture for functional recovery after stroke. RCT = randomized controlled trial.

Table 1: Summary of randomized sham-controlled trials included in systematic review of acupuncture for functional recovery after stroke

| Study | Study design | Patient population | Experimental treatment | Control treatment | Outcome measures |
|--------------------------------------|------------------------------|--|--|---|---|
| Acute to subacute stage | | | | | |
| Gosman-Hedstrom et al. ¹³ | Single-blind, parallel 3-arm | 104 patients; rehabilitation < 1 wk after stroke | (A) Acupuncture twice weekly for 10 wk + manual and electrical stimulation; follow-up at 3 d, 3 wk, 3 mo, 12 mo (<i>n</i> = 37) | (B) Sham acupuncture (placed superficially under the skin) without manual and electrical stimulation (<i>n</i> = 34) (C) Conventional stroke rehabilitation only (<i>n</i> = 33) | <ul style="list-style-type: none"> • Scandinavian Stroke Scale • Barthel Index • Sunnaas ADL Index • Nottingham Health Profile |
| Schuler et al. ¹⁴ | Single-blind, parallel 3-arm | 120 patients; rehabilitation 3–35 d after stroke | (A) Acupuncture twice weekly for 4 wk + electrical stimulation; follow-up at 4 wk and 6 mo (<i>n</i> = 41) | (B) Sham electro-acupuncture (surface electrodes on acupuncture points with visual stimulation) (<i>n</i> = 40) (C) Control (no additional treatment) (<i>n</i> = 39) | <ul style="list-style-type: none"> • European Stroke Scale • Barthel Index |
| Hopwood et al. ¹⁵ | Single-blind, parallel 2-arm | 105 patients; rehabilitation 4–10 d after stroke | (A) Acupuncture 3 times weekly for 4 wk + electro-acupuncture and scalp acupuncture (100 Hz electric stimulation); follow-up at 3, 6, 12, 24 and 52 wk (<i>n</i> = 57) | (B) Sham transcutaneous electrical nerve stimulation (with no current flow) (<i>n</i> = 48) | <ul style="list-style-type: none"> • Barthel Index • Motoricity Index • Nottingham Health Profile |
| Xie et al. ¹⁶ | Single-blind, parallel 2-arm | 64 patients; rehabilitation < 2 wk after stroke | (A) Electro-acupuncture once daily for 7–10 d (1 cycle) total 2 or 3 cycles; follow-up at 10 and 20 d (<i>n</i> = not reported) | (B) Sham acupuncture (nonpenetrating, at same acupoints) (<i>n</i> = not reported) | <ul style="list-style-type: none"> • National Institutes of Health Stroke Scale • Fugl–Meyer Assessment • Modified Barthel Index |
| Naeser et al. ¹⁷ | Double-blind, parallel 2-arm | 16 patients; rehabilitation for spasticity 1–3 mo after left hemisphere infarction | (A) Acupuncture 5 times weekly for 4 wk + electro-acupuncture and scalp acupuncture; follow-up at 4 wk (<i>n</i> = 10) | (B) Sham acupuncture (penetrating) + sham electrical stimulation (electrical stimulation not conducted) (<i>n</i> = 6) | <ul style="list-style-type: none"> • Boston Motor Inventory • Boston Motor Inventory with analysis of CT scan of lesion site |
| Park et al. ¹⁸ | Double-blind, parallel 2-arm | 116 patients; rehabilitation < 4 wk after stroke | (A) Acupuncture 9–12 treatments for 2 wk; follow-up at 2 wk (<i>n</i> = 56) | (B) Sham acupuncture (nonpenetrating on nonacupuncture points) (<i>n</i> = 60) | <ul style="list-style-type: none"> • Barthel Index • National Institutes of Health Stroke Scale • Motoricity Index • EQ-5D • Nottingham Extended Activities of Daily Living • Modified Ashworth Scale |
| Huang et al. ¹⁹ | Single-blind, parallel 3-arm | 120 patient; rehabilitation 14–90 d after ischemic stroke | (A) Electro-acupuncture (Back Shu) once daily 6 times weekly for 4 wk; follow-up at 4 wk (<i>n</i> = 40) (B) Electro-acupuncture (<i>n</i> = 40) | (C) Sham electro-acupuncture (penetrating on nonacupuncture points) (<i>n</i> = 40) | <ul style="list-style-type: none"> • Barthel Index • Neural Deficit score |
| Chronic stage | | | | | |
| Wayne et al. ²⁰ | Double-blind, parallel 2-arm | 33 patients; rehabilitation (upper extremities) > 6 mo after stroke | (A) Acupuncture twice weekly for 10 wk + manual (body and scalp) and electrical (body) stimulation; location of acupuncture (body or scalp) alternated weekly; follow-up at 12 wk (<i>n</i> = 16) | (B) Sham acupuncture (nonpenetrating), sham electro-acupuncture, sham scalp acupuncture (<i>n</i> = 17) | <ul style="list-style-type: none"> • Fugl–Meyer Assessment • Modified Ashworth Scale • Barthel Index • Nottingham Health Profile |
| Schaecher et al. ²¹ | Double blind, parallel 2-arm | 8 patients; rehabilitation 1.0–10.2 yr after stroke | (A) Acupuncture twice weekly for 10 wk + scalp acupuncture and electric stimulation; follow-up at 12 wk (<i>n</i> = 4) | (B) Sham acupuncture (nonpenetrating, no electrical stimulator) (<i>n</i> = 4) | <ul style="list-style-type: none"> • Upper limb function (Modified Ashworth Scale and range of motion) |
| Fink et al. ²² | Double blind, parallel 2-arm | 25 patients; rehabilitation for leg spasticity > 7 mo after stroke | (A) Acupuncture twice weekly for total of 8 sessions; follow-up at 4 wk and 3 mo (<i>n</i> = 13) | (B) Sham acupuncture (penetrating on nonacupuncture points) (<i>n</i> = 12) | <ul style="list-style-type: none"> • Modified Ashworth Scale • Clinical Global Impressions Scale (patient rating) • Hoffmann reflex |

Note: ADL = activities of daily living, CT = computed tomography, EQ-5D = EuroQol quality-of-life assessment tool.

Study quality

The mean PEDro score was 6.6 (standard deviation [SD] 1.5), with a range of four to nine points (Table 2). The Cochrane risk of bias varied (Table 2). Only four studies reported appropriate sequence generation.^{13,15,18,20} Five trials used blinding of participants and assessors,^{17,18,20-22} three used blinding of participants only,^{14,16,19} and two used blinding of assessors only.^{13,15} Six trials assessed the outcome of more than 85% of the allocated participants at the last follow-up.^{13,15,17-19,21} Five trials mentioned that the outcomes were analyzed by intention-to-treat analysis.^{13-15,18,20} Incomplete outcome data were addressed adequately in six studies.^{13-15,18,20,21} Three trials reported details about allocation concealment, and all of them used adequate methods.^{15,18,20} Ethical approval was reported in four studies,^{13,15,18,22} and informed consent was described in seven.^{13-15,17,18,20,22} Success of blinding was assessed in five studies and found to be successful in all cases.^{17,18,20-22} The six studies with a high risk of bias^{14,16,17,19,21,22} showed a low quality score on the PEDro scale (mean score 5.7) compared with the other trials that had a low risk of bias (mean score 8.0). The degree of confidence in the quality of the acupuncture varied from 55% to 93% (mean 82.4%); there was good agreement between the two reviewers.

Outcome measures

Four trials tested the effects of acupuncture on neurologic deficits using the National Institutes of Health Stroke Scale,^{16,18} the European Stroke Scale¹⁴ or the Scandinavian Stroke Scale.¹³ One of the four studies showed positive therapeutic effects.¹⁶ Seven trials tested the effects of acupuncture on activities of daily living according to the Barthel Index,^{13,14,18,20} the modified Barthel Index^{15,16} or the Sunaas Index of Activities of Daily Living.¹³ Two of these studies (both from China) showed favourable effects on activities of daily living.^{16,19} Of the five trials that assessed the effects of acupuncture treatment on quality of life, none showed favourable effects.^{13,15,18,20,22}

Two of the seven trials that involved patients in the acute and subacute stages of stroke were excluded from the meta-analysis: one because it reported data as medians and interquartile ranges (IQRs)¹⁸ and the other because it did not focus on functional recovery and did not report numerical data.¹⁷ Our meta-analysis of the remaining five studies did not yield a significant difference in favour of acupuncture ($n = 368$; standard mean difference 0.47, 95% CI -0.02 to 0.96; $I^2 = 81\%$) (Figure 2A). A post-hoc sensitivity analysis that excluded the two trials from China with a high risk of bias^{16,19} failed to show significant effects of acupuncture ($n = 244$; standard mean difference 0.07,

Table 2: Quality assessment and internal validity of randomized clinical trials included in the systematic review

| Study | PEDro Scale items* | | | | | | | | | | | Cochrane risk of bias† | | | | | | Validity of acupuncture (quality/degree of confidence)‡ | Assessment of success of blinding |
|--------------------------------------|--------------------|---|---|---|---|---|---|---|---|---|---|------------------------|---|---|---|---|---|---|-----------------------------------|
| | A | B | C | D | E | F | G | H | I | J | K | L | M | N | O | P | Q | | |
| Gosman-Hedstrom et al. ¹³ | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | Y | U | Y | Y | Y | Y | 3/85 | NR |
| Schuler et al. ¹⁴ | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | U | U | Y | Y | Y | U | 0/- | NR |
| Hopwood et al. ¹⁵ | 1 | 1 | 1 | 1 | 0 | 0 | 1 | 1 | 1 | 1 | 1 | Y | Y | Y | Y | Y | Y | 3/90 | NR |
| Xie et al. ¹⁶ | 1 | 1 | 0 | 0 | 1 | 0 | 0 | 0 | 0 | 1 | 1 | U | U | Y | U | U | U | 3/88 | NR |
| Naeser et al. ¹⁷ | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | U | U | Y | N | U | U | 4/93 | Performed; successful |
| Park et al. ¹⁸ | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 1 | 1 | 1 | 1 | Y | Y | Y | Y | Y | Y | 2/75 | Performed; successful |
| Huang et al. ¹⁹ | 1 | 1 | 0 | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | U | U | Y | N | U | U | 3/55 | NR |
| Wayne et al. ²⁰ | 1 | 1 | 1 | 1 | 1 | 0 | 1 | 0 | 1 | 1 | 1 | Y | Y | Y | Y | Y | Y | 3/85 | Performed; successful |
| Schaechter et al. ²¹ | 1 | 1 | 0 | 0 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | U | U | Y | Y | Y | U | 0/- | Performed; successful |
| Fink et al. ²² | 1 | 1 | 0 | 1 | 1 | 0 | 1 | 0 | 0 | 1 | 1 | U | U | Y | N | N | U | 3/88 | Performed; successful |

Note: NR = not reported, PEDro = Physiotherapy Evidence Database.

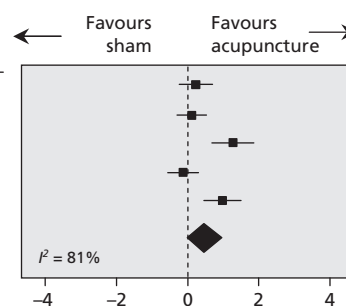
*PEDro Scale items: A = eligibility criteria specified, B = randomization, C = allocation concealment, D = groups similar at baseline, E = blinded subjects, F = blinded therapist, G = blinded assessors, H = adequacy of follow-up, I = ITT analysis, J = between-group comparison, K = point and variability measures; 1 = item positive, 0 = item negative or unknown.

†Cochrane risk of bias: L = Was the allocation sequence adequately generated?, M = Was allocation adequately concealed?, N = Was knowledge of the allocated intervention adequately prevented during the study?, O = Were incomplete outcome data adequately addressed?, P = Are reports of the study free of suggestion of selective outcome reporting?, Q = Was the study apparently free of other problems that could put it at a high risk of bias?; Yes (Y) = low risk of bias, No (N) = high risk of bias, Unclear (U) = uncertain risk of bias.

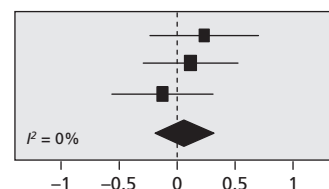
‡Acupuncture validity indicated by quality of acupuncture technique (0 = could not assess, 1 = completely different from previously described technique, 2 = different from previously described technique, 3 = similar to previously described technique, 4 = exactly or almost exactly the same as previously described technique) and degree of confidence, using 100-mm visual analogue scale, that acupuncture was applied in an appropriate manner (0% = complete absence of evidence that acupuncture was appropriate, 100% = total certainty that acupuncture was appropriate, - = could not assess).

A: Activities of daily living (Barthel Index) after intervention periods

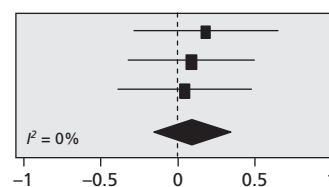
| Study | Acupuncture | | Sham acupuncture | | Standardized mean difference (95% CI) |
|-------------------------------|---------------|-------|------------------|-------|---------------------------------------|
| | Mean (SD) | Total | Mean (SD) | Total | |
| Gosman-Hedstrom ¹³ | 38.18 (24.77) | 37 | 32 (27.34) | 34 | 0.23 (-0.23 to 0.70) |
| Hopwood ¹⁵ | 5.8 (5.0) | 47 | 5.2 (5.15) | 45 | 0.12 (-0.29 to 0.53) |
| Huang ¹⁹ | 29.48 (17.25) | 40 | 8.36 (14.38) | 20 | 1.27 (0.69 to 1.86) |
| Schuler ¹⁴ | 13.6 (24.22) | 41 | 16.6 (23.24) | 40 | -0.13 (-0.56 to 0.31) |
| Xie ¹⁶ | 41.21 (22.08) | 32 | 21.62 (17.19) | 32 | 0.98 (0.46 to 1.50) |
| Overall | | 197 | | 171 | 0.47 (-0.02 to 0.96) |

**B: Subanalysis for activities of daily living**

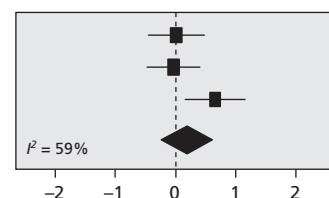
| Study | Acupuncture | | Sham acupuncture | | Standardized mean difference (95% CI) |
|-------------------------------|---------------|-------|------------------|-------|---------------------------------------|
| | Mean (SD) | Total | Mean (SD) | Total | |
| Gosman-Hedstrom ¹³ | 38.18 (24.77) | 37 | 32 (27.34) | 34 | 0.23 (-0.23 to 0.70) |
| Hopwood ¹⁵ | 5.8 (5.0) | 47 | 5.2 (5.15) | 45 | 0.12 (-0.29 to 0.53) |
| Schuler ¹⁴ | 13.6 (24.22) | 41 | 16.6 (23.24) | 40 | -0.13 (-0.56 to 0.31) |
| Overall | | 125 | | 119 | 0.07 (-0.18 to 0.32) |

**C: Activities of daily living (Barthel Index) after follow-up**

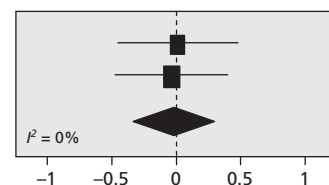
| Study | Acupuncture | | Sham acupuncture | | Standardized mean difference (95% CI) |
|-------------------------------|---------------|-------|------------------|-------|---------------------------------------|
| | Mean (SD) | Total | Mean (SD) | Total | |
| Gosman-Hedstrom ¹³ | 41.94 (25.78) | 37 | 37.17 (26.28) | 34 | 0.18 (-0.29 to 0.65) |
| Hopwood ¹⁵ | 9.4 (4.39) | 47 | 9 (4.64) | 45 | 0.09 (-0.32 to 0.50) |
| Schuler ¹⁴ | 14.5 (35.43) | 41 | 13 (29.78) | 40 | 0.05 (-0.39 to 0.48) |
| Overall | | 125 | | 119 | 0.10 (-0.15 to 0.35) |

**D: Global neurologic defect**

| Study | Acupuncture | | Sham acupuncture | | Standardized mean difference (95% CI) |
|-------------------------------|-------------|-------|------------------|-------|---------------------------------------|
| | Mean (SD) | Total | Mean (SD) | Total | |
| Gosman-Hedstrom ¹³ | 9.27 (9.23) | 37 | 9.17 (7.37) | 34 | 0.01 (-0.45 to 0.48) |
| Schuler ¹⁴ | 5 (19.56) | 41 | 5.7 (19.42) | 40 | -0.04 (-0.47 to 0.40) |
| Xie ¹⁶ | 6.45 (3.1) | 32 | 4.17 (3.72) | 32 | 0.66 (0.15 to 1.16) |
| Overall | | 110 | | 106 | 0.20 (-0.23 to 0.62) |

**E: Subanalysis for global neurologic defect**

| Study | Acupuncture | | Sham acupuncture | | Standardized mean difference (95% CI) |
|-------------------------------|-------------|-------|------------------|-------|---------------------------------------|
| | Mean (SD) | Total | Mean (SD) | Total | |
| Gosman-Hedstrom ¹³ | 9.27 (9.23) | 37 | 9.17 (7.37) | 34 | 0.01 (-0.45 to 0.48) |
| Schuler ¹⁴ | 5 (19.56) | 41 | 5.7 (19.42) | 40 | -0.04 (-0.47 to 0.40) |
| Overall | | 78 | | 74 | -0.01 (-0.33 to 0.30) |



Standardized mean difference (95% CI)

Figure 2: Meta-analyses of sham-controlled randomized clinical trials of the effectiveness of acupuncture for functional recovery after stroke. Trials included patients in the acute and subacute stages of stroke. The subgroup analyses (panels B and E) excluded trials with a high risk of bias. Standard mean differences greater than zero favour acupuncture. CI = confidence interval, SD = standard deviation.

95% CI -0.18 to 0.32; $I^2 = 0\%$ (Figure 2B). In the trial excluded from the meta-analysis because it reported medians and IQRs, the median Barthel Index score for activities of daily living at baseline was 6 (IQR 3.8–9) in the acupuncture group and 6 (IQR 4–9.3) in the sham acupuncture group. After two weeks of treatment, the median score was 11 (IQR 5–17) in the acupuncture group (difference 4, IQR 0–8), and the median score was 11 (IQR 7.3–15.8) in the sham acupuncture group (difference 3, IRQ 0–7).

The same findings applied to activities of daily living after more than six months of follow-up measured with the Barthel Index ($n = 244$; standard mean difference 0.10, 95% CI -0.15 to 0.35; $I^2 = 0\%$) (Figure 2C). For global neurologic deficits, none of the three trials included in the meta-analysis showed a significant difference in favour of acupuncture ($n = 216$; standard mean difference 0.20, 95% CI -0.23 to 0.62; $I^2 = 59\%$) (Figure 2D). A subgroup analysis that excluded the trial from China with a high risk of bias¹⁶ showed no significant effect of acupuncture ($n = 152$; standard mean difference -0.01, 95% CI -0.33 to 0.30; $I^2 = 0\%$) (Figure 2E).

Of the three trials that involved patients in the chronic stage of stroke,^{20–22} one was excluded from the meta-analysis because it did not report numerical data.²¹ A meta-analysis of the data from the other two studies did not show favourable effects of acupuncture on function according to the Modified Ashworth Scale ($n = 58$; mean difference 0.01, 95% CI -0.65 to 0.67; $I^2 = 0\%$) (see Appendix 5, at www.cmaj.ca/cgi/content/full/cmaj.091113/DC1).^{20,22}

The low number of trials prevented assessment of publication bias.

Adverse events

Four trials reported on the occurrence of adverse events: one reported a case of seizure in the acupuncture group,¹⁸ another noted five cases of hematoma around the acupuncture points,¹⁴ a third trial recorded two cases of dizziness (without group information),¹⁹ and the fourth trial reported no adverse events.¹⁵

Interpretation

Few randomized sham-controlled trials have tested the effectiveness of acupuncture during stroke rehabilitation. Only 2 of the 10 studies included in our study reported that acupuncture was effective.^{16,19} However, poor reporting and high risks of bias rendered both studies less than reliable. Our meta-analyses did not show positive effects of acupuncture.

There are several possible explanations for these findings. Acupuncture might indeed be ineffective; existing studies may have been inadequately designed; or the treatment may not have been optimally administered. For instance, three trials included patients more than six months after stroke,^{20–22} which may be too late to achieve significant improvements. In addition, the number of treatment sessions or the degree of stimulation may have been insufficient to generate a significant effect; the treatment may have been suboptimal; or the protocol applied in the acupuncture group may not have been suitable for treating stroke symptoms. Alternatively, sham acupuncture may not be inert; thus, no intergroup differences

can possibly emerge. Sham penetrating acupuncture, with needles inserted at nonacupuncture points, may cause physiologic effects.²³

Previous systematic reviews included some but not all Asian studies.^{8,24–28} Smith and colleagues²⁵ did not include all relevant trials. Sze and colleagues²⁶ evaluated the effects of acupuncture on motor recovery after stroke but included studies only from the Chinese literature; they concluded that acupuncture did not have additional effects on motor recovery after stroke but had a small positive effect on disability. Three Cochrane reviews compared the effects of acupuncture with sham acupuncture and no treatment on recovery after acute stroke,⁸ stroke rehabilitation²⁷ and dysphagia in acute stroke.²⁸ All concluded that there was insufficient evidence. We made an effort to identify all relevant trials, including those in China, Japan and Korea, where acupuncture is widely practised and found more studies than the previous reviews.

Limitations

Our review has several limitations. Although great efforts were made to retrieve all trials on the subject, we cannot be certain that we succeeded. The paucity and often suboptimal quality of the primary data are further drawbacks.

Conclusion

Our meta-analyses of data from rigorous randomized sham-controlled trials did not show a positive effect of acupuncture as a treatment for functional recovery after stroke.

This article has been peer reviewed.

Competing interests: None declared.

Contributors: Jae Cheol Kong, Myeong Soo Lee and Byung-Cheul Shin designed the review, appraised and selected the trials, contributed to the analysis and interpretation of the data and drafted the manuscript. Jae Cheol Kong and Byung-Cheul Shin performed the literature searches, extracted data and contacted authors for additional data. Yung-Sun Song and Edzard Ernst contributed to the design of the review and the analysis and interpretation of the data and critically revised the manuscript for important intellectual content. All of the authors approved the version submitted for publication.

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