Efficacy and Safety of Needle Acupuncture for Treating Gynecologic and Obstetric Disorders: An Overview

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ABSTRACT

Background: Acupuncture is being used increasingly to treat gynecologic and obstetric disorders.

Objective: The aim of this review was to determine the efficacy and safety of acupuncture for treating pelvic and low-back pain during pregnancy, pain during labor, primary dysmenorrhea, and menopausal symptoms.

Design: This is an overview of systematic reviews (SRs) and randomized controlled trials (RCTs).

Search strategy: A literature search was conducted, in July 2010, in MEDLINE,[®] the Cochrane Database of Systematic Reviews, CENTRAL, the Database of Abstracts of Reviews of Effects, and Tripdatabase.

Selection criteria: Published SRs and RCTs found during the literature search were included as well as RCTs that were published after completion of the literature search.

Analysis: Data from SRs and RCTs that provided quantitative information were pooled.

Results: Eight SRs and nine RCTs were included. One SR and 4 RCTs showed that acupuncture reduced pelvic and low-back pain, compared to physiotherapy or usual prenatal care. Results were contradictory when interventions were compared with sham acupuncture. With respect to reduction of pain during labor, two SRs showed no differences between acupuncture and sham acupuncture. None of the three SRs included on primary dysmenorrhea produced conclusive results. Two SRs of studies on menopausal symptoms showed no differences between acupuncture and sham acupuncture. A meta-analysis of three additional RCTs identified a favorable effect of acupuncture for reducing frequency and intensity of hot flashes. Adverse effects were mild and infrequent.

Conclusions: Evidence for the efficacy of needle acupuncture for treating the disorders evaluated remains inconclusive. The intervention showed promising results for reducing pelvic and back pain during pregnancy and climacteric vasomotor symptoms, although well-designed studies are needed to make the results more precise and reliable.

Key Words: Acupuncture, Systematic Review, Obstetrics, Gynecology; Dysmenorrhea; Labor Pain, Pregnancy, Hot Flashes, Menopause

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INTRODUCTION

GYNECOLOGIC DISORDERS are very common health problems, accounting for more than 8% of consultations to acupuncturists.¹ Acupuncture may be a suitable alternative for treating pregnancy-related ailments given that, during pregnancy, the use of drugs must be limited and that acupuncture has a low rate of adverse events.²

Acupuncture is based on the principles of Traditional Chinese Medicine, according to which the functioning of the body is under the control of Qi, which flows through meridians. This theory posits that disease is an imbalance in the flow of Qi; acupuncture is used to correct this imbalance via insertion of needles that stimulate skin spots located along the meridians.³ There are other acupuncture-like techniques that do not involve using needles. Instead, stimulation is applied through pressure (acupressure), a laser, or by combustion of the root of *Tanacetum parthenium*, commonly known as feverfew (moxibustion).

Acupuncture is increasingly being recommended worldwide, especially for treating pain. Several hypotheses have been proposed to explain acupuncture's analgesic effect. Some researchers suggest that acupuncture activates A- δ fibers, which are involved in release of endorphins and are associated with an increase in levels of 5-hydroxytryptophan (a serotonin precursor) in the brain.⁴ It has been found that acupuncture points correspond to anatomical and physiologic characteristics, such as the areas of the body where peripheral nerves connect. An alternative mechanism is that needles may inactivate highly sensitive neuralgic areas in the muscles responsible for causing referred pain in a body area.

An increasing number of health care centers offer acupuncture for treating various ailments, including some gynecologic and obstetric disorders. Given the increasing use of this technique, it is essential to perform an objective and rigorous evaluation of its effectiveness and efficiency by conducting well-designed studies. In recent years, several clinical studies have been published on the use of acupuncture for treating obstetric and gynecologic disorders, such as pelvic and low-back pain during pregnancy, pain in labor, primary dysmenorrhea, and climacteric symptoms. However, these studies have produced inconclusive results. The objective of this overview was to determine the efficacy and safety of needle acupuncture for managing these disorders.

METHODS

Inclusion and Exclusion Criteria

The current authors included systematic reviews (SRs) of randomized controlled trials (RCTs) on the efficacy and safety of acupuncture with needles in women, age 16 or older, who were affected by the following gynecologic and obstetric disorders: (1) low-back and pelvic pain during

pregnancy; (2) pain during labor (excluding patients who assessed pain associated with interventions such as surgical repair of lacerations or episiotomy); (3) primary dysmenorrhea, and (4) climacteric symptoms. For the latter disorder, women with spontaneous or surgical menopause were included, but those with menopause caused by cancer treatment were excluded. To increase the comprehensiveness of this review, RCTs were also included that published after the date of completion of the literature search of the included reviews.

Studies that had the following controls were assessed: (1) sham acupuncture or placebo, which deviates from the theory of acupuncture in at least one of the aspects that is considered to be crucial, such as penetration of the skin or needle placement in the correct acupuncture points or (2) no acupuncture, defined as any standard treatment prescribed for the disorder of interest. Studies that used the experimental treatments as controls were excluded, as well as studies in which the control group received different care than the treatment group.⁵ Studies on electroacupuncture (EA) were excluded as well as studies or that assessed other methods of stimulation that did not involve insertion of needles (e.g. laser, transcutaneous electrical nerve stimulation, moxibustion, or acupressure). Also excluded were narrative reviews and SRs that did not specify a search strategy or that did not assess the risk of bias of included studies. RCTs that did not use an adequate method of randomization were also excluded.

The outcomes of interest were pain and menopausal symptoms. Studies that assessed pain should have used a measure of pain as the main outcome, preferably reported by patients using a visual analogue scale (VAS).⁵ Studies that evaluated menopausal symptoms should have used, preferably, changes in scores of menopausal symptoms (e.g., Kupperman Index, Menopause Rating Scale Score Nordin, or Mac Lennan Score).⁶ The frequency and intensity of vasomotor symptoms were also considered.

Literature Search

In July 2010, a literature search was conducted in MEDLINE,[®] the Cochrane Database of Systematic Reviews, CENTRAL, the Database of Abstracts of Reviews of Effects (DARE), and Tripdatabase. Health technology assessments were identified to detect additional RCTs and SRs, and references lists of included studies were also reviewed. Studies published in English, Spanish, French, Italian, Portuguese, and German were included. Two of the current authors reviewed the titles and abstracts independently of all retrieved references to select those that were potentially eligible for this review. Subsequently, the 2 authors evaluated the full-text publications of the selected studies to determine whether or not to include them. Disagreements were solved by consensus or by consulting with a third reviewer (a detailed search strategy is provided in Appendix 1; online only).⁷

FIG. 1. Identification of eligible studies for the overview. TENS, transcutaneous electrical nerve stimulation; RCT, randomized controlled trial; SR, systematic review.

Two reviewers assessed the risk of bias independently of the included studies. Any disagreement was solved by consensus or by consulting with a third reviewer. Risk of bias was assessed using the AMSTAR [A MeaSurement Tool to Assess systematic Reviews]⁸ instrument for SRs and the Jadad⁹ scale for RCTs (details on these instruments are provided in Appendix 2; online only).

Data were extracted from included studies in descriptive tables (see Appendix 3; online only) with information regarding risk of bias, interventions, characteristics of the participants, outcomes, and main study results. A collection was performed of effect estimates (and their 95% confidence intervals [CIs]) expressed as relative risk

(RR) for dichotomous outcomes and mean differences (MD) for continuous outcomes and for outcomes of interest from included SRs. The latter were standardized (standardized mean difference [SMD]) when the same outcome was measured using different scales.

Whenever possible, quantitative data were combined from new RCTs using meta-analyses. In accordance with the Cochrane Collaboration approach,⁷ a Mantel-Haenszel model was used, which applies a random-effects model, given the expected heterogeneity between the included studies. Heterogeneity was assessed using the I^2 statistic, with a threshold of 50%–70% as a sign of substantial heterogeneity.⁷ In these cases, data were not combined in

TABLE 1. CHARACTERISTICS OF INCLUDED SYSTEMATIC REVIEWS

<i>First author, year, reference, country & review type</i>	<i>Date of search</i>	<i>Objective</i>	<i>RCTs^b about needle acupuncture First author & year</i>	<i>Primary outcome</i>	<i>Secondary outcomes</i>	<i>Global quality^a</i>
Low-back and pelvic pain during pregnancy						
Pennick 2007 ¹⁰ Canada (Cochrane SR)	February 2006	To assess prevention and treatment of low-back & pelvic pain during pregnancy	Elden 2005, Kvornning 2004 & Wedenberg 2000	Pain measured by VAS	Days out of work, difficulty in performing ADLs & adverse effects	High YES: 10/11 NO: 1/11 (n. 10)
Pain during labor						
Smith 2006 ¹¹ Australia (Cochrane SR)	February 2006	To examine effects of alternative & complementary therapies for treating pain during labor in mothers & perinatal morbidity	Nesheim 2003, Ramnero 2002 & Skilnand 2002	Satisfaction of mothers with pain management & drug use for pain relief	Pain intensity (VAS), need to increase oxytocina administration, & labor duration, & Apgar punctuation	High YES: 10/11 NO 1/11 (n. 10)
Cho 2010 ¹² Korea	April 2009	To assess evidence for or against acupuncture for pain during labor	Borup 2009, Hantoushzadeh 2007, Martensson 2008, Nesheim 2003, Ramnerö 2002, Skilnand 2002 & Ziaei 2006	<i>Pain relief:</i> VAS or other numerical score. <i>Analgesia use:</i> meperidine, epidural analgesia, or other	Mother satisfaction, labor duration, need to intensify contractions, type of labor, Apgar score, child weight, pH of cord blood & adverse effects	High YES: 9/11 NO: 2/11 (n. 5 & 10)
Primary dysmenorrhea						
Yang 2008 ¹³ China	2008	To assess effects of therapies related to acupuncture for treating primary dysmenorrhea	Helms 1987, Wang 2005, Zhi 2007, Jiang 2007, Liu 1999 & Zhang 2003	Pain intensity (VAS) & pain relief	Analgesic use, MDQ & VAS (for anxiety)	Moderate YES: 7/1 NO: 4/11

(continued)

TABLE 1. (CONTINUED)

<i>First author, year, reference, country & review type</i>	<i>Date of search</i>	<i>Objective</i>	<i>RCTs^b about needle acupuncture First author & year</i>	<i>Primary outcome</i>	<i>Secondary outcomes</i>	<i>Global quality^a</i>
Cho 2010 ¹⁴ Korea	2008	To assess effectiveness of acupuncture for treating primary dysmenorrhea	Han 1998, Wang 2007, Helms 1987, Young 2008, Hu 2005, Zhang 2003, Jiang 2007, Zhi(a) 2007, Lee 2007, Zhi(b) 2007 & Li 1998, Zhou 2003, & Shi 1994	Pain relief & Symptoms reduction	Adverse effects	Moderate YES: 8/11 NO: 1/ 11 (N.5) Not applicable: (9 & 10)
Smith 2011 ¹⁵ Australia (Co-chrane SR)	2010	To determine effectiveness & safety of acupuncture for treating primary dysmenorrhea	Jiang 2007, Helms 1987, Smith 2010, Witt 2008 & Zhi 2007	Pain relief (VAS or other scales)	Symptoms reduction, use of drugs, limitation of ADLs, absence from work or school, HRQoL score & adverse effects	High YES: 10/11 Not applicable: 1/11 (n. 10)
Climacteric symptoms						
Lee 2009 ¹⁶ South Korea	October 2008	To assess effectiveness of acupuncture for treating climacteric hot flushes	Vincent 2007, Avis 2008, Kim 2007 & Nir 2007	Frequency or severity index of hot flushes (frequency × severity), compared with basal status	None	High YES: 9/11 NO: 2/11 (n. 5 & 10)
Cho 2009 ¹⁷ South Korea	July 2008	To assess if acupuncture treatment reduces vasomotor symptoms associated with menopause & its adverse effects	Nir 2007, Avis 2008, Kim 2007, Vincent 2007, Chen 2006, Liu 2007 & Zhang 2006	Frequency or severity of vasomotor symptoms	Sleep assessment, HRQoL score & adverse effects	Moderate YES: 8/11 NO: 1/11 (n. 5) Not applicable: 2/11 (n. 9 & 10)

^aAMSTAR [A Measurement Tool to Assess systematic Reviews] was used to assess the methodological quality of the systematic reviews. It contains 11 items that are assessed as “yes,” “no,” or “not applicable.” See ref. 8 and Appendix 2 (online only).

^bFor full references for these RCTs, consult the references in the first column of this table.

RCT, randomized controlled trials; SR, systematic review; VAS, Visual analogue scale; ADLs, activities of daily living; MDQ, menstrual discomfort questionnaire; HRQoL, Health-Related Quality of Life.

meta-analyses, and results were presented in narrative form. All statistical calculations were conducted using RevMan 5.0.

RESULTS

The literature search yielded 728 references, of which 614 were excluded based on the information contained in their titles and abstracts. The full texts of the remaining 114 articles were assessed, of which 17 were included. These were eight SRs^{10–17} and nine RCTs^{18–27} (Fig. 1). Excluded studies and reasons for exclusion are listed in Appendix 4 (online only).

Of the eight SRs included, five were of high methodological quality (AMSTAR scores 9–10).^{10–12,15,16} Three Cochrane reviews^{10,11,15} showed the highest quality. The remaining SRs did not provide lists of excluded studies and did not assess publication bias.^{13,14,16} The characteristics of the included SRs are shown in Table 1.

The assessment of the risk of bias of the nine RCTs included are in Table 2. The main source of bias among these RCTs was the lack of blinding of interventions. Only three studies blinded participants and evaluators,^{19,20,23} the rest were open studies.^{18,21,22,24–27}

Low-Back and Pelvic Pain During Pregnancy

For this outcome, a Cochrane review¹⁰ of high quality was identified; it included three RCTs (a total of 356 women). Four more RCTs^{18–21} were added that had been published after the literature search was conducted for this review.

Two of the RCTs included in the Cochrane review compared acupuncture with usual care.^{28,29} One study showed that women treated with acupuncture had less pelvic pain in the morning than those who only exercised.²⁸ Mean differences with respect to baseline were 12 mm on a 100-mm VAS (95% CI: 5.9–17.3; $p < 0.001$) and 9 mm (95% CI: 1.7–12.8; $p = 0.031$) for both groups, respectively. When assessing pain intensity in the afternoon, the results also favored acupuncture. There was a follow-up to this study published after the SR, which showed a 99% decrease in pain at 12 weeks after birth, regardless of treatment group.¹⁸ The other study included in the Cochrane review²⁹ showed results that favored acupuncture, with a decrease in pain in 60% of women treated with acupuncture, compared to 14% of those who received usual prenatal care. This study, however, did not report treatment duration.

The third study included in the SR, compared acupuncture versus physiotherapy and found a greater reduction in pain intensity both during the day and at night in an acupuncture-treated group.³⁰

With respect to the four RCTs published after the literature review, three compared verum acupuncture versus sham acupuncture. One of the RCTs included 70 women

and compared classical acupuncture (with deep stimulation) to acupuncture with surface stimulation.²¹ Pain intensity decreased in the classical acupuncture group, but the small size of the groups did not justify a conclusion that there were any differences between the two kinds of treatment. Another study that included 115 women did not find differences in pain reduction between the groups treated with verum acupuncture and sham acupuncture.¹⁹ The last study ($N = 159$) compared verum auricular acupuncture with sham auricular acupuncture and self-care.²⁰ After 1 week of treatment, 80% of the participants treated with verum acupuncture had a significant reduction in pain, compared with 56% of the subjects in the sham acupuncture group ($p = 0.001$) and 36% of the self-care group ($p < 0.001$). There was no difference in pain reduction between the sham acupuncture group and the self-care group ($p = 0.46$). More women in the verum acupuncture group had a reduction of pain that could be considered clinically significant (a 30% reduction) than in the sham acupuncture and the self-care groups (81% versus 59% versus 47%; $p = 0.015$).

The results of two RCTs^{19,28} were pooled for the proportion of women with pelvic pain when rolling over in bed (Fig. 2). Data were included from 370 women, and the results favored acupuncture ($RR = 0.85$, 95% CI: 0.74–0.98). Two other RCTs^{18,29} provided data on pain reduction reported by pregnant women, but these data could not be combined because of the presence of statistical heterogeneity, possibly caused by differences in time of evaluation. Data from two RCTs^{19,30} were also pooled for the proportion of women that assessed the treatment as good or excellent. This analysis included 161 women and did not yield differences between the groups ($RR = 1.12$, 95% CI: 0.92–1.35).

Pain During Labor

Two SRs^{11,12} were included that included, globally, seven RCTs on acupuncture with needles. The main comparisons were acupuncture versus standard analgesic treatment, no treatment, and sham acupuncture.

One SR was a Cochrane review that included three RCTs.¹¹ Two of these compared acupuncture with no treatment ($N = 288$), which were combined in a meta-analysis that showed greater use of analgesics in the untreated group ($RR = 0.70$, 95% CI: 0.49–1.00). The other RCT compared acupuncture with sham acupuncture. Use of analgesics was lower in the acupuncture group ($RR = 0.72$, 95% CI: 0.58–0.88).

The other SR¹² included seven RCTs (a total of 1483 women), three of which had also been included in the Cochrane review.¹¹ The researchers conducted a meta-analysis of three of the seven RCTs, and found no differences in mean pain between a verum acupuncture group and a sham acupuncture group at 30 minutes (MD: -10.79 mm using a VAS of 100 mm, 95% CI: -35.16 to -13.58), 60 minutes (MD: -8.02 mm, 95% CI: -1.88 to -5.84), or 120 minutes

TABLE 2. CHARACTERISTICS OF INCLUDED RCTS

<i>First author, year, reference & country</i>	<i>Participants</i>	<i>Intervention</i>	<i>Control</i>	<i>Follow-up</i>	<i>Primary outcome</i>	<i>Quality assessment^a</i>
Low back and pelvic pain during pregnancy						
Elden 2008 ¹⁸ Sweden	N = 386; women with gestational age of 21–31 weeks with pelvic-girdle pain; mean age: 30 years	Acupuncture with needles and usual care (n = 125)	1—usual care (n = 130) 2—usual care and exercises (n = 131) Sham acupuncture & usual care (n = 57)	12 weeks	Movement related pain measured by VAS	1-1-0-0-1
Elden 2008 ¹⁹ Sweden	N = 115; women with gestational age of 12–29 weeks with pelvic-girdle pain at night; mean age: 30.5 years	Acupuncture with needles and usual care (n = 58)	Sham acupuncture & usual care (n = 57)	1 week	Pain intensity during movements and at night	1-1-1-1-1
Wang 2009 ²⁰ United States	N = 159; women with gestational age of 25–38 weeks with back and/or pelvic pain; mean age: 32 years	Auricular acupuncture in three points (n = 58)	1—Sham acupuncture in 3 auricular nonacupuncture points (n = 54) 2—Self-care (n = 32)	2 weeks	Pain measured by VAS	1-1-1-1-1
Lund 2006 ²¹ Sweden	N = 70. Women with gestational age of 22–36 weeks, with pelvic or low-back pain; mean age: 29 years	Deep-needle acupuncture with manual stimulation; intramuscular needles (n = 35)	Superficial needle acupuncture; subcutaneous needles (n = 35)	45 days	Pain intensity measured by VAS during rest & during three different activities	1-1-0-1-1
Climacteric symptoms						
Huang 2006 ²² United States	N = 29; women from ages 45–65 without menstrual periods in the last 6 months; mean age N/A	Acupuncture with needles in 5–7 therapeutic active points (n = 12)	Sham acupuncture in 4–5 nonacupuncture points with placebo needles (n = 17)	3 weeks	Measures of nocturnal hot flashes & sleep	1-1-0-1-1
Cohen 2003 ²³ United States	N = 17; menopausal women with nocturnal hot flashes; mean age: 47.3 years	Acupuncture with needles in body points related to menopause symptoms (n = 7)	Treatment designated as a general tonic specifically designed to benefit the flow of Qi (n = 9)	3 weeks	Hot flashes severity, mood changes & sleep disturbances	1-1-1-1-1
Borud 2009 ²⁴ Norway	N = 267; postmenopausal women with ≥ 7 hot flushes per 24 hours during 7 consecutive days; mean age: 53.5 years	Acupuncture with needles and self-care (n = 134)	Self-care (n = 133)	12 months	Change in mean hot flush frequency	1-1-0-0-1
Kim 2010 ²⁶ South Korea	N = 175; peri- or postmenopausal women, age range 45–65, who had average daily hot flush scores ≥ 10 for 1 week before screening visit	Acupuncture with needles with manual stimulation for 4 weeks (n = 116)	Usual care during 4 weeks; optional acupuncture treatment after this period (n = 9)	1 month	Mean reduction in 24-hour hot flushes score	1-1-0-0-1
Venzke 2010 ²⁷ United States	N = 56; women without menstrual period in the last 6 months & who have vasomotor symptoms; mean age N/A	Acupuncture with needles (n = 28)	Sham acupuncture using nonpenetrating needles in 6 nonacupuncture points (n = 28)	12 weeks	Scores in Greene Climacteric Scale, Beck Depression Inventory, Beck Anxiety Scale & TCM anxiety diagnosis	1-0-0-1-1

^aFor quality assessment, the Jadad scale is used to assess five items: (1) Was the study described as randomized?; (2) Was the method of randomization described in the article, and was that method was appropriate?; (3) Was the study described as double-blinded?; (4) Was the the method of blinding described, and was it appropriate?; (5) Was there a description of withdrawals and dropouts? See Appendix 2 (online only)

VAS, visual analogue scale; N/A, not available; TCM, Traditional Chinese Medicine.

FIG. 2. Low-back and pelvic pain while turning in bed. CI, confidence interval; Mantel-Haenszel model.

(MD: -10.15 mm, 95% CI -23.18 to -2.87). Another study compared acupuncture with no treatment, finding no difference in pain reduction at 60 minutes (MD: 2.60 mm, 95% CI -6.29 to -11.49) and 120 minutes (MD: 5.50 mm, 95% CI -3.34 to -14.34). There was also a meta-analysis of the remaining studies, which compared acupuncture and conventional analgesia, and this analysis showed a lower requirement for meperidine in women treated with acupuncture ($RR=0.20$, 95% CI: 0.12 to -0.33) but there were no differences between groups regarding epidural analgesia ($RR=0.68$, 95% CI: 0.46 to -1.00).

Primary Dysmenorrhea

This outcome was assessed in three SRs that included a total of 16 RCTs.^{13–15} Four studies compared acupuncture against standard therapy (nonsteroidal anti-inflammatory drugs [NSAIDs] and/or oral contraceptives) found that acupuncture contributed to a reduction of symptoms measured with different pain scales (SMD: 0.92 [95% CI: 0.20 – 1.65], SMD: 0.69 [95% CI: 0.31 – 1.07], SMD: 0.73 [95% CI: 0.36 – 1.10], and SMD: 0.59 [95% CI: 0.22 – 0.96]).^{14,15} With respect to the percentage of women experiencing pain relief as a dichotomous outcome, five comparisons found that acupuncture was better than pharmacologic therapy, but another five comparisons did not find any differences.^{13–15}

Two studies evaluated the use of acupuncture applying heat. One of the studies found that acupuncture was superior to treatment with NSAIDs ($RR=1.39$, 95% CI: 1.09 – 1.76), but the other did not find any differences.¹⁴

Four studies compared verum acupuncture to sham acupuncture, and all reported a reduction in pain in both study groups. One study with 48 women included in the three SRs,^{13–15} found that acupuncture was associated with greater pain reduction (90.9% versus 36.4%; $p<0.05$). In contrast, the remaining three studies found no differences between the groups.^{14,15}

Quality of life was assessed in two trials.¹⁵ One identified an improvement among women treated with acupuncture, compared with usual care in the areas of body pain, mental health, vitality, social function, and emotions. The other study found no differences in these parameters, compared to sham acupuncture.

Climacteric Symptoms

Two SRs were included: one covered four RCTs¹⁶ and the other covered seven RCTs.¹⁷ In addition, five more RCTs^{22–27} were included; these were published after the literature search for these SRs. The outcomes measured in most studies were vasomotor symptoms.

Of the seven studies included in the one of the SRs,¹⁷ two used hormone therapy as a control group, whereas another used oryzanol, an antioxidant found in rice bran oil. The remaining four trials, also included in the other SR,¹⁶ used sham acupuncture. In three of these studies, there was no difference between verum acupuncture and sham acupuncture regarding frequency, severity, or rate of hot flashes. However, the results of a pilot study of 29 women that also compared verum acupuncture with sham acupuncture suggested favorable effects of verum acupuncture on the severity of hot flashes.

Three of the five RCTs published after the aforementioned SRs compared verum acupuncture and sham acupuncture.^{22,23,27} One of the RCTs²² found that the severity of nocturnal hot flashes decreased significantly in a verum acupuncture group (27.84 ± 6.26 versus $30.67\% \pm 18.49\%$; $p=0.017$), although there was no statistically significant difference in the frequency of hot flashes ($23.72 \pm 45.68\%$; $p=0.170$). Another trial²³ found that a verum acupuncture group had a reduction in severity of hot flashes from baseline to the second ($p=0.05$), third ($p=0.005$), and fourth ($p=0.019$) months, while a sham acupuncture group had no change. The third study²⁷ found no difference between groups in any of the parameters measured, although both groups improved significantly after 2 weeks of treatment.

The remaining RCTs compared acupuncture with self-care or usual care.^{24–26} One of the RCTs²⁶ found that, after 4 weeks of treatment, the reduction in score for hot flashes at 24 hours was higher in an acupuncture group than in a control group (-16.57 versus -6.93 ; $p<0.0001$). The frequency and severity of hot flashes was also lower in the acupuncture group. The other trial^{24,25} noted that the frequency of hot flashes decreased by 5.8% and 3.7% in 24 hours in an acupuncture group and a control group after 12 weeks of treatment, respectively ($p<0.001$), although the differences did not remain at 6 and 12 months ($p=0.3$ and 0.2 , respectively).

Only three studies of those published after the literature search of the SRs could be pooled for assessing frequency and

FIG. 3. Frequency (A) and intensity (B) of daily hot flashes. CI, confidence interval; Std., standard; SD, standard deviation, IV, inverse variance method.

intensity of hot flashes.^{22,24–26} For the former outcome, data from 452 women were combined, showing favorable results of acupuncture (SMD = -0.59 ; 95% CI: -0.79 to -0.39 ; Fig. 3A). For the latter, data from 422 women were combined, also showing favorable results of acupuncture (SMD = -0.56 ; 95% CI: -0.76 to -0.36 ; Fig. 3B). Two studies^{26,27} reported the outcome “hot flush score,” but their results could not be combined because of heterogeneity of the studies.

Adverse Effects

Few studies provided data on adverse effects (AEs). AEs were uncommon in these studies, and, when these effects did occur, they were mild and transient. Data from only two studies could be pooled.^{18,22} Data from two RCTs (144 women) showed no difference between verum acupuncture and sham acupuncture in proportion of women that com-

plained of pain when needles were being inserted ($RR = 0.94$, 95% CI: 0.48 – 1.63 ; Fig. 4A). For insomnia (2 RCTs, 144 women), no differences were observed between the groups ($RR = 1.45$, 95% CI: 0.41 – 5.12 ; Fig. 4B).

DISCUSSION

This overview was performed to examine the effectiveness and safety of acupuncture for treating some common gynecologic and obstetric disorders. The results of this review showed that acupuncture seems to alleviate pelvic and low-back pain during pregnancy, compared to usual prenatal care or physiotherapy. However, when verum acupuncture was compared with sham acupuncture, the results were conflicting. The results of the two SRs on acupuncture for pain relief during labor showed no differences when

FIG. 4. Adverse effects. (A) Pain in needle-insertion point. (B) Insomnia. M-H, Mantel-Haenszel model; CI, confidence interval.

comparing verum acupuncture versus sham acupuncture.^{12,13} However, verum acupuncture was associated with a lower use of analgesics. None of the three SRs that evaluated the use of acupuncture for treating primary dysmenorrhea could reach conclusions about acupuncture's effectiveness. With respect to the effect of acupuncture on climacteric symptoms, none of the reviews found any differences between verum acupuncture and sham acupuncture in severity and frequency of hot flashes. Data from three newer RCTs (one of which was published in 2009 and had follow-up results published in 2010)^{22,24-26} were combined in a meta-analysis, which showed a favorable effect of acupuncture for reducing frequency and intensity of hot flashes. However, the outcome assessment was blinded only in one of the included trials.²²

Overall, it appears that acupuncture's main benefit involves reducing pelvic and low-back pain during pregnancy and primary dysmenorrhea, compared with usual care or no treatment. However, when verum acupuncture was compared with sham acupuncture or a proven treatment (such as NSAIDs in the case of the primary dysmenorrhea), the results were contradictory.

Similarly, a recent published study that performed an individual patient data meta-analysis of RCTs of acupuncture for chronic pain also found a greater effect of acupuncture when it was compared with a nonacupuncture control than when verum acupuncture was compared with sham acupuncture. Although the researchers found that verum acupuncture was superior to sham acupuncture, these differences were relatively modest and much lower than differences from comparison of acupuncture with a nonacupuncture control.³¹ Other SRs that assessed the use of acupuncture for treating different conditions also found an acupuncture effect when acupuncture was compared with usual treatment, but there were no significant differences when verum acupuncture was compared with sham acupuncture.³²⁻³⁴

The results of three more-recently published SRs on gynecologic and obstetric disorders³⁵⁻³⁷ drew similar conclusions to this overview. One³⁵ evaluated the use of acupuncture and acupressure in pain management during labor, and another SR³⁶ evaluated the use of acupuncture for treating common reproductive health disorders, including primary dysmenorrhea and climacteric symptoms. Both reviews concluded that there was insufficient evidence to make recommendations for or against using acupuncture to treat these conditions. The third SR was a comprehensive review that included 16 SRs³⁷ on the effectiveness of acupuncture and EA for treating various gynecologic disorders. With respect to primary dysmenorrhea and climacteric symptoms, this review included the same SRs identified in the current overview,^{13,14,16,17} and the researchers of the third SR concluded that there was insufficient evidence for the effectiveness of acupuncture for treating primary dysmenorrhea and vasomotor symptoms.

Few studies included in the current overview reported on the safety of acupuncture adequately. However, acupuncture

can be considered a safe procedure with a low incidence of AEs; those AEs that did occur were mild.

It is noteworthy to mention the short follow-up of participants in the included RCTs, precluding any conclusion about the long-term benefit of acupuncture for these conditions. Even some studies on low-back and pelvic pain during pregnancy followed-up patients just for 1 week. For studies on primary dysmenorrhea and climacteric symptoms, which are two conditions that can linger over time, most studies followed up patients for less than 3 months, and only three of the studies had long-term follow-ups (12 months).

Although the methodological quality of the included reviews was high or very high, the RCTs included had important methodological limitations. With respect to the newer RCTs included, there were adequate concealment of randomization sequence, handling of dropouts, and reporting of results, although two studies did not describe the method of randomization.

The design and implementation of RCTs on acupuncture is challenging, especially with respect to blinding these trials. This is particularly important when assessing subjective outcomes such as pain. In the case of acupuncture, it is impossible to blind the acupuncturist, and therefore it is essential that both patients and staff responsible for assessing outcomes be unaware of the intervention allocation.

Another issue related to RCTs on acupuncture is the choice of a comparison group. Ideally, sham acupuncture must be used to demonstrate the effectiveness of the intervention (verum acupuncture). This has been proposed to offset the potential "placebo effect" of acupuncture,³⁸ although some researchers suggest that sham acupuncture can stimulate production of opioids in the body in a manner similar to conventional acupuncture, and therefore have an analgesic effect.³⁹ Consequently, the best design to evaluate the efficacy of acupuncture would be a three-armed RCT that compared groups treated with verum acupuncture, sham acupuncture, and no treatment. However, blinding of the patients in such a study would not be possible.

One of the main strengths of this overview is that a comprehensive literature search was conducted. In addition, to increase its comprehensiveness, RCTs were also included even if they were published after the date of completion of the literature search of the included SRs. Whenever possible data were extracted and combined from primary studies to provide new results. Studies conducted in various countries and published in different languages were included, although, this was not the case for Eastern languages. However, some of the SRs did include RCTs conducted in Eastern countries, which ruled out the impact of geographic or linguistic bias.

CONCLUSIONS

The available evidence on the effectiveness of acupuncture for treating gynecologic and obstetric disorders remains

inconclusive and, therefore, does not yield conclusions about acupuncture's benefits. It may have some effect for reducing pelvic and low-back pain during pregnancy and also may reduce frequency and intensity of hot flashes during menopause. However, the small sizes of the studies included in this review and the difficulties related to masking the outcome assessment prevented the current authors from drawing any firm conclusions.

ACKNOWLEDGMENTS

The authors thank Hector Pardo for the editing support.

This project was funded by the Instituto de Salud Carlos III (record number PI09/90578), in Spain.

X.B.C., M.J.M.Z., and Z.S. conceived the study. I.S. performed the search. Z.S. and A.S.O. selected the included articles and extracted data. M.J.M.Z., Z.S., and A.S.O. analyzed data. A.S.O. S.M.U., and I.S. updated the SR. A.S.O. wrote the first draft of this article. All of the authors reviewed this article critically for important intellectual content and gave final approval of the version to be published.

DISCLOSURE STATEMENT

No competing financial interest exists.

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