Using Forbidden Points in Pregnancy: Adverse Outcomes and Quality of Evidence in Randomized Controlled Trials—A Systematic Narrative Review

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ABSTRACT

Objective: Pregnancy is a complex physical and hormonal condition. Many women experience back and pelvic pain, reflux, and headaches during pregnancy. There has been a significant rise in the popularity of acupuncture for pain conditions in pregnancy, wherein nonpharmacologic options are important. Concerns have been raised by both traditional and medical acupuncturists about using “forbidden points” during pregnancy and the risk of preterm contractions (PTC), as this could limit women’s and practitioners’ willingness to continue treatment during pregnancy. There is also a risk of bias introduced into clinical trials when participants are highly selected or they drop out of studies due to adverse outcomes. This review examined randomized controlled trials (RCTs) of acupuncture using forbidden points prior to 37 weeks of pregnancy to treat pain conditions, with the primary outcome of PTC.

Methods: A database search identified RCTs, including trials of penetrating acupuncture that used forbidden points in their protocols to treat pregnancy-related pain conditions. STRICTA [*Standards for Reporting Interventions in Clinical Trials of Acupuncture*] and GRADE [*Grades of Recommendation, Assessment, Development, and Evaluation*] criteria were used to assess the quality of evidence. This review includes 8 RCTs reporting on 713 women.

Results: Only 2 studies reported on the primary outcome of PTC, and there were insufficient data to perform a primary analysis. In these 2 studies, 6 participants withdrew due to PTC. No study was at a low risk of bias for all GRADE domains, and 3 studies were at high or unclear risk of bias in all domains.

Conclusions: PTC is an important clinical outcome and should be reported routinely. The strength of evidence to date is insufficient to recommend using forbidden points prior to 37 weeks of pregnancy. Highly selected patient populations, risk of bias in study design, and participant withdrawal rates, suggest that high-quality trials are required.

Keywords: musculoskeletal pain, pain management, reproductive disorders, Traditional Chinese Medicine, trigger point

INTRODUCTION

PREGNANCY IS A COMPLEX physical and hormonal condition for women. Many women experience back, pelvic, and other pain conditions during pregnancy associated with the change in weight distribution that occurs, but also

due to the change in hormones to soften ligaments and tissue to accommodate the baby and prepare for birth.^{1,2} The most commonly experienced condition relates to back and pelvic pain. The Royal Australian College of General Practitioners describes lumbar pain as “pain experienced in the region between the last thoracic spinous process and first sacral

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spinous process, laterally bound by the lateral borders of the lumbar erector spine”³ The experience of back and pelvic pain is multifactorial and influenced by physiologic, psychologic, and social factors. It is one of the commonest conditions of pregnancy, with a prevalence estimated to be between 25% and 90%, with the majority of women reporting that this pain affects their daily routines and capacity to work.^{2,4,5}

Over the past decade, there has been a significant rise in the popularity of acupuncture for pain-related conditions, especially in pregnancy wherein nonpharmacologic options are important. Research in this area is reassuring, in that there are no reported increased rates of miscarriage or premature labor when treating pregnancy-related conditions with acupuncture.^{6,7}

However, concerns have been raised by both traditional and medical acupuncturists about the use of so-called “forbidden points” during pregnancy.^{8,9} This small group of points were historically used to treat difficult labor, and, while some of these have been indicated for use as labor-preparation points after 36 completed weeks of pregnancy, other points are only indicated when the onset of contractions is appropriate.¹⁰ With acupuncture on Large Intestine 4 (LI 4), Spleen 6 (SP 6), Bladder 32 (BL 32), and Bladder 67 (BL 67) being incorporated into medical-acupuncture research as part of point prescriptions for care, concerns about the possibility of these treatments stimulating preterm contractions (PTC) have been raised.^{11,12} PTC, even if they are self-resolving and do not result in preterm labor, are obviously very concerning to women. This has the potential to limit women’s willingness to continue with treatment and practitioners’ willingness to treat women during pregnancy.

The information on using these points is not straightforward, with some researchers recommending routine use at any time in a pregnancy, including the first trimester^{6,13} while others suggest caution and use indicated only post-36 completed weeks’ gestation as labor-preparation/induction.^{14,15} Additionally, there are researchers who suggest that these points are indicated or “warranted” for particular conditions within the framework of Traditional Chinese Medicine (TCM) theory, and when a woman’s personal constitution is considered.^{16,17} These differing approaches have the potential to create uncertainty among practitioners, despite an evidence base to recommend acupuncture for conditions such as pregnancy-related back and pelvic pain.¹⁸

Evidence suggests that the effectiveness of these points is significant and point-specific when used for strengthening contractions and for pain relief during labor and birth.^{19,20} While review evidence reports no increase in adverse events beyond the background population rate when used during pregnancy,^{7,21} reports of adverse events, such as premature contractions, which could result in women withdrawing from the research studies or discontinuing treatment,^{22,23} create potential for bias within research and are not reported.

Currently, practitioners in maternity care include a range of allied health practitioners, such as physiotherapists, acupuncturists, medical acupuncturists, and specialist educators. As dry needling or medical acupuncture becomes part of the toolbox of allied health practitioners, it is important to note the role that relevant Chinese Medicine theory and traditions play in informing frameworks for diagnosis and treatment. Medical acupuncture, also known as Western medical acupuncture, is a system wherein classical points that stimulate the nervous system (segmental and extrasegmental points) are chosen, but without reference to TCM theory.²⁴ The loss of the traditional frameworks is reflected in some of the current evidence in which segmental acupuncture points are common with no reference to the guiding treatment principles. Use of these forbidden points is standardized regardless of individual presenting patterns¹² and the quality of evidence has not been assessed using specific critical-assessment tools designed for acupuncture interventions.

Therefore, to understand the potential effect of forbidden points during pregnancy the current authors examined published randomized controlled trials (RCTs) of acupuncture for lower-back, pelvic, and other pain conditions in pregnancy, with protocols that routinely include forbidden points. The primary outcome was incidence of PTC, and secondary outcomes included other adverse events, including preterm birth. To examine risk of bias and the quality of the current evidence for acupuncture for lower-back and pelvic pain, including study design, participant selection, generalizability of participant populations, and methods of analysis, the evidence was examined according to the STRICTA [*Standards for Reporting Interventions in Clinical trials of Acupuncture*] guidelines²⁵ and the GRADE [*Grades of Recommendation, Assessment, Development, and Evaluation*] criteria.²⁶

What Are the Forbidden Points?

A small group of acupuncture points were historically indicated for difficult labor. These were: SP 6, LI 4, GB 21, BL 60, BL 67, BL 32, and BL 33.²⁷ Of these points SP 6, BL 60, and BL 67 (with moxa) have been reported as being used prior to labor for labor preparation^{15,28} and during labor for pain relief and augmentation of labor.¹⁹ Observational midwifery feedback has reported that SP 6 promotes cervical ripening and that BL 60 and BL 67 aid optimal fetal positioning.¹⁵ This anecdotal reporting also included use of LI 4 and BL 32 for stimulating uterine contractions when appropriate and GB 21 to promote fetal descent during labor. The onset of contractions after acupuncture to BL 67 has also been reported.

Why This Is Important

Previous reviews on the safety of acupuncture in pregnancy—for conditions such as back, pelvic, and other pain

conditions—suggest that acupuncture during pregnancy does not increase the risk of adverse events, compared to noninvasive control groups. However, the potential bias introduced by participant selection, participant withdrawal, and lack of intention-to-treat analysis—due to adverse events such as PTC—is significant for evidence translation. Many of these studies do not follow the STRICTA guidelines for reporting on acupuncture studies, nor have they been evaluated using the GRADE tool; therefore, the quality and generalizability of the research has not been examined to make recommendations on use of these forbidden points in practice.

Aim, Objectives, and Outcome Measures:

The aim of this review was to examine RCTs of acupuncture for back, pelvic, and other pain conditions, when studies used forbidden points prior to 37 weeks of pregnancy, with the primary outcome of PTC and secondary outcomes of other adverse events, and to assess the quality of this evidence. [Standards for Reporting Interventions in Clinical trials of Acupuncture]

With this aim in mind, there were 4 objectives for this review:

- (1) To determine the incidence of PTC in RTCs of acupuncture using forbidden points prior to 37 weeks of pregnancy to treat lower-back, pelvic, and other pain conditions
- (2) To determine the incidence of other adverse outcomes in RTCs of acupuncture using forbidden points prior to 37 weeks of pregnancy for lower-back, pelvic, and other pain conditions
- (3) To assess generalizability of the study population and analysis of participants, using STRICTA criteria
- (4) To assess the quality of the research, using the GRADE criteria.

The main outcome measure was PTC. Secondary outcomes included other adverse outcomes and the results of assessments of the quality of evidence using the STRICTA criteria and the GRADE tool.

METHODS

A database search was conducted to identify peer-reviewed original research published from January 1 2000 to June 5 2019. The search included the following databases: Cumulative Index of Nursing and Allied Health Literature (CINAHL) PubMed, and Medline[®] via Ovid. The following search strategy was used within all search fields in CINAHL, Medline, and PubMed. MeSH [Medical Subject Headings] were used; terms included: acupuncture OR acup* OR acupuncture* OR needling OR dry needling OR needl* AND back pain OR pain OR hip pain OR pubic pain

OR pubic symphysis* OR symphysi* AND pregnancy OR preg* or gravi* AND randomised controlled trials OR RCT OR random*.

Manual searching was also conducted to ensure that known relevant articles were included in the review.

Selection Criteria

Articles were included if they reported peer-reviewed original research findings, used penetrating acupuncture to treat a pregnancy-related pain condition, and used forbidden points prior to 37 weeks of pregnancy as part of their treatment protocols. Articles were excluded if they were commentaries, editorials, systematic reviews, literature reviews, or non-randomized studies; did not use penetrating acupuncture; and did not use forbidden points in their protocols. Articles that were in languages other than English were translated when possible. The database search was supplemented by an internet search using the same search terms as above to identify any additional items, and bibliographic searching of included materials was also used to identify additional material. One author conducted the search and downloaded the results. Two authors independently examined the title and abstract of each result to identify relevant studies for inclusion. This review used a narrative approach.

RCTs of acupuncture were sought that compared verum acupuncture to placebo, sham, usual care, or other treatment methods to treat lower-back, pelvic, and other pain conditions during pregnancy, and routinely used any of the listed forbidden points in pregnancy.

The search yielded 52 studies with titles relevant to the selection criteria, which were assessed by two investigators independently (K.M.L. and D.B.). After duplicates were removed, 31 studies were screened; 15 of these were excluded, as they did not meet the inclusion criteria. The remaining 16, were reviewed for their full text, which resulted in 8 additional articles being excluded because the studies were not randomized (6 studies) or did not use forbidden points (2 studies). The remaining 8 articles were included in the analysis. Data were extracted by 2 study investigators independently (K.M.L. and K.L.S.). The CONSORT [Consolidated Standards of Reporting Trials] statement outlines these methods (Fig. 1).

Critical Appraisal Analysis Tools and Assessment of Bias

Critical appraisal tools assist assessment of bias that might be present in studies, due to their designs or other features, and lead to incorrect findings even if the bias was unintended. Bias refers to features of a study that can systematically affect or alter observations within the study and conclusions about the study, which might not reflect the underlying truth(s) of the study.²⁹ Study findings could then over- or underestimate the true effect(s) of the study. When

FIG 1. CONSORT [*Consolidated Standards of Reporting Trials*] flow chart of acupuncture safety review. RCTs, randomized controlled trials.

assessing risks of bias, then, one considers the chance that the features of the study design, or conduct of the study, will yield misleading results. Sources of bias can result from study design, participant selections, and analysis and reporting methods (see Table 1). Ultimately, when findings are translated into guidelines and practice, the introduction of bias could lead to a waste of resources, loss of effective interventions, and even harm(s) for consumers.³⁰

The *Cochrane Handbook for Systematic Reviews of Interventions*³¹ reported several sources of bias; these are included in Table 1.

Two main sources of bias are attrition bias and selection bias; these are discussed in the sections below.

Assessing Attrition Bias

Assessing outcomes—both anticipated and adverse—with as little bias as possible, is at the heart of RCT designs. When there is loss of participants following randomization, this is referred to as attrition and can introduce bias known as *attrition bias*. Attrition bias is an important aspect of any trial and, as a general rule, losses to follow-up of <5% of

TABLE 1. RISK OF BIAS: THE COCHRANE HANDBOOK FOR SYSTEMATIC REVIEWS OF INTERVENTIONS³¹

Type of bias	Description of bias
Selection bias	Refers to systematic differences between baseline characteristics of the groups that are compared or the systematic difference in recruited populations, compared to the general population
Performance bias	Refers to systematic differences between the groups in the care that is provided or in exposure to factors other than the interventions of interest
Detection bias	Refers to systematic differences between groups in how outcomes are determined
Attrition bias	Refers to systematic differences between groups in withdrawals from a study
Reporting bias	Refers to systematic differences between reported and unreported findings

participants is considered to pose a low threat to study validity, while losses >20% pose a serious risk to study validity.³² When there are differential or excessive rates of losses between groups, the characteristics of the groups change, and there is a loss of information about the acceptability and tolerability of the treatment, as well as its true effectiveness.³³

Assessing Selection Bias

When recruiting participants for research, there is an often reported difference in the participant population than the general population of interest. The randomization of participants, in theory, will balance these differences between the intervention and control groups. However, *selection bias* can arise because participants differ from the general population in ways other than what is being investigated in the study or intervention.³³ Research participants tend to be healthier and more compliant in general. It is therefore important to consider if the research population reflects the actual patients that one plans to apply the evidence to, if the treatment effect is exaggerated, or that the real patient population will be less tolerant of the treatment itself.

The inclusion of highly selected participant populations might limit generalizability of a study's results to the population of interest, and potentially contribute to selection bias due to confounding.³³ Additionally, real patients could experience more-significant adverse events due to their differing background health statuses.³⁴

Critical Appraisal Tools

This review used two critical appraisal tools. These were:

- (1) Revised STRICTA items for reporting acupuncture studies.³⁵ The aim of the STRICTA guidelines is to increase transparency in reporting trials, enable critical appraisal and interpretation of results, and provide sufficient detail for replication of studies. The STRICTA guidelines are designed to replace Item 5 in the CONSORT statement.³⁶
- (2) The GRADE tool is a transparent framework for developing and presenting summaries of evidence and provides a systematic approach for making clinical practice recommendations.²⁶ The Centre for Evidence Based Medicine, on its Catalogue of Bias website, describes the GRADE tool as a “systematic approach for assessing and communicating the certainty of evidence and going from evidence to recommendations or decisions.”³³

RESULTS

This review included 8 randomized controlled trials, randomizing 856 women and reporting on 713 women.

Trials were published between 2000 and 2012, and included between 40 and 386 participants each. All studies used a randomized controlled trial design and included the use of ‘forbidden points’ in their treatment protocols. Three studies included investigation into low back and pelvic pain, three studies investigated pelvic pain only, two studies investigated low-back pain only, one study each examined dyspepsia and tension-type headaches in pregnancy.

The studies were 2- and 3-armed trials. There were seven 2-armed trials, with two comparing two alternative acupuncture interventions, one using acupuncture at different gestational ages (20 and 26 weeks; Ekdahl and Petersson, 2010²²), and one using acupuncture at different depths (superficial versus deep needling; Lund et al., 2006³⁷). The 5 other controlled trials compared acupuncture to usual care (3 trials, Kvorning et al., 2004,³⁸; and Guerreiro da Silva et al., 2012,³⁹ 2009⁴⁰), sham acupuncture (1 trial, Elden et al., 2008),⁴¹ and an active control group of physiotherapy (1 trial, Wedenberg et al., 2000⁴²). One 3-armed trial compared acupuncture with usual care and an active control group of stability exercises (Elden et al, 2005⁴³).

Primary Outcome Measure—PTC

Most studies did not report on the primary outcome of this review, PTC (see Table 2), and there was insufficient data to perform a primary analysis of this outcome, so this outcome is reported narratively in this article.

PTC were reported in 2 studies.^{22,42} The study by Ekdahl et al. (2010)²² compared early ($n=20$) and late ($n=20$) acupuncture at 20 weeks and 26 weeks of gestation for low-back and pelvic pain. Overall, there were 8 withdrawals from the study, with 3 women experiencing PTC, 1 from the early acupuncture group and 2 from the late acupuncture group. These participants' outcomes were not included in the final analysis, that is, there was no intention-to-treat (ITT) analysis. The study by Wedenberg et al. (2000),⁴² compared acupuncture ($n=30$) with physiotherapy ($n=30$) for low-back and pelvic pain. This study reported 2 exclusions from the acupuncture arm, due to crossover of treatment, and 12 withdrawals from the physiotherapy arm, 3 were due to PTC and 1 woman gave birth during the study period. There was no ITT analysis for this study and post-randomization withdrawals constituted a 23% dropout rate.

The other 6 studies did not report on PTC as an outcome.

Other Adverse Events, Withdrawals and Attrition Bias

There were withdrawals due to adverse events or loss to follow-up from all studies except 1,³⁹ with only one study stating that they followed an ITT analysis.⁴¹ The other six studies, in which no ITT analysis was reported and dropouts were noted, accounted for the randomization of 698 women and reported on 563 women, constituting a dropout rate of 19.4%.

TABLE 2. TRIAL DETAILS AND OUTCOME MEASURES OF RTCs

<i>1st author, year, ref. & condition</i>	<i>N acup/controls</i>	<i>Clinical indications</i>	<i>Inclusion/exclusion criteria</i>	<i>Primary outcome (secondary) PTC</i>	<i>2nd & 3rd trimesters</i>	<i>TCM labor-preparation points</i>	<i>PTC reported in study withdrawals or as adverse events</i>
Ekdahl, 2010 ²² Back & pelvic pain	N = 40 Acup 1 = 20 Acup 2 = 20 Analysis 16/16	Low-back & pelvic pain	<i>Inclusion:</i> Healthy pregnant women presenting with low-back & pelvic pain at maternity health care centers in Southern Sweden <i>Exclusion:</i> Treatment with cortisones, anticoagulants or immunosuppressive drugs; heart disease, diabetes, pacemakers, epilepsy, hepatitis, HIV/AIDS, acute infection, psychiatric disease, hematologic disorders, & renal disease; premature contractions; & needle phobia	<i>Primary:</i> Pain scores—emotional dimensions of pain (POMS-VAS)	Group 1 at 20/40 Group 2 at 26/40 for 6 weeks	Choice of points; protocols used from previous studies might have included LI 4, SP 6, BL 60, & local <i>Ah Shi</i> Back points (BL 32 & BL 33).	8 women withdrew overall; 3 women withdrew due to experiencing PTC (1 from group 1 & 2 from group 2); adverse events not reported Withdrawal rate: 10%
Elden, 2008 ⁴¹ Pelvic-girdle pain	N = 115 Acup = 58 Sham = 57 Analysis (ITT) 54/53	Pelvic-girdle pain	<i>Inclusion:</i> Healthy acupuncture-naïve pregnant women with singleton fetuses at 12–29 weeks of gestation; experiencing evening pain >50 mm on a 100-mm VAS. <i>Exclusion:</i> Other pain conditions; history of orthopedic disease or surgery in the spine or pelvic girdle; systemic disorders; coagulation disturbances; or increased risk of infection	<i>Primary:</i> Intensity of pelvic-girdle pain on 100-point VAS <i>Secondary:</i> Credibility of intervention/sham; Composite Disability rating (DRI) HRQoL	12–29 weeks for 8 weeks	Choice of points; all women received L14, BL 60, (BL 32, BL33 & <i>Ah Shi</i> points if tender)	Adverse reported in terms of fainting, bleeding, needle pain, De Qi sensation, & sleepiness; early delivery × 2 acup group; discontinued intervention (2 from acup & 5 from sham); withdrawal after allocation (2 from acup & 5 from sham) Withdrawal rate 7%
Lund et al 2006	N = 70 Superficial = 35 Deep = 35 Analysis 22/25	Pelvic pain	<i>Inclusion:</i> gestational age of 22–36/40; pain more than 2 weeks; pain intensity ≥60/100 on VAS; increased pelvic pain on movement/provocation <i>Exclusion:</i> Not naïve to acup; fear of needles; urogenital infections; symptoms of pelvic pain from previous pregnancy	<i>Primary:</i> Pain intensity at 3 timepoints during day	18–36 weeks for 5 weeks	SP 6 & LI 4, (BL 31 & BL 32 as <i>Ah Shi</i> points if tender)	Withdrawal reported due to increased pain, fainting, & allergic reaction to nickel; PTC not reported; 1 withdrawal due to premature labor Withdrawal rate: 33%

(continued)

TABLE 2. (CONTINUED)

<i>1st author, year, ref. & condition</i>	<i>N acup/ controls</i>	<i>Clinical indications</i>	<i>Inclusion/exclusion criteria</i>	<i>Primary outcome (secondary) PTC</i>	<i>2nd & 3rd trimesters</i>	<i>TCM labor-preparation points</i>	<i>PTC reported in study withdrawals or as adverse events</i>
Elden et al 2005	N = 386 SC = 130 Acup = 125 Stabilizing exercises = 131 Analysis SC = 108 Acup = 110 Stabilizing exercises = 112	Pelvic-girdle pain	<i>Inclusion:</i> Healthy women at 12–31 completed gestational weeks; well-integrated in the Swedish language; with singleton fetuses & defined pregnancy-related pelvic-girdle pain <i>Exclusion:</i> Other pain conditions; systemic disorders; or contraindications to treatment	<i>Primary:</i> Pain intensity related to motion 100-points on VAS morning and evening <i>Secondary:</i> Independent examiner blinded & assessed recovery from symptoms	12–31 weeks for 6 weeks	Choice of points; all women received LI 4 & BL 60 (BL 32 & BL 33 as <i>Ah Shi</i> points if tender)	Includes self-reporting of minor adverse events; acup group informed of potential for bleeding or bruising, pain on needling, drowsiness, & aggravation of symptoms; no PTC reported; 19 preterm labors reported within the 3 intervention groups (5 from acup, 7 from stabilizing exercises, & 7 from standard treatment); declined treatment (10 from acup & 9 from stabilizing exercises)
Kvornig, 2004 ³⁸ Pelvic & low-back pain	N = 100 Acup = 50 SC = 50 Analysis 37/35	Low-back & pelvic pain	<i>Inclusion:</i> Ages 15–39, 24–37 weeks pregnant; reporting girdle or low-back pain (including mixed pat-terns) <i>Exclusion:</i> Not described	<i>Primary:</i> Severity of pain out of 10 (on VAS) <i>Secondary:</i> Dosage of medication (1 dose = 500 mg of paracetamol); self-rated functional capacity score out of 10	24–37 weeks for minimum of 3 weeks	BL 60	Withdrawal rate: 14.5% Needle pain, sweating, tiredness, hematoma, nausea & weakness reported; no serious adverse events; 3 women delivered during study (acup group); gestation not reported
Wedenberg, 2000 ⁴² Pelvic & low-back pain	N = 60 Acup = 30 Physiologic = 30 Analysis 28/18	Low-back & pelvic pain	<i>Inclusion:</i> Pregnant women living in area, with low-back pain; gestational age <32 weeks <i>Exclusion:</i> Not described	<i>Primary:</i> Morning & evening pain on VAS <i>Secondary:</i> DRI	20–32 weeks for 4 weeks	BL 60	Withdrawal rate: 12% No serious adverse events; 12 withdrew from physiologic arm (3 due to PTC); 1 birth during study Withdrawal rate: 23%

(continued)

TABLE 2. (CONTINUED)

<i>1st author, year, ref. & condition</i>	<i>N acup/controls</i>	<i>Clinical indications</i>	<i>Inclusion/exclusion criteria</i>	<i>Primary outcome (secondary) PTC</i>	<i>2nd & 3rd trimesters</i>	<i>TCM labor-preparation points</i>	<i>PTC reported in study withdrawals or as adverse events</i>
Guerreiro da Silva, 2012 ³⁹ Tension-type headache	N=43 Acup=20 SC=23 Analysis 20/23	Tension-type headache	<i>Inclusion:</i> Pregnant women ages 15–39 years, 15–30 weeks of pregnancy & tension-type headache (minimum of 4/10). <i>Exclusion:</i> High-risk pregnancy (defined by obstetricians); underlying diseases that were potential causes of the symptoms; similar symptoms prior to pregnancy; & acupuncture treatment in past year	<i>Primary:</i> Mean difference between first & last interview after 8 weeks of treatment. <i>Secondary:</i> Changes over time on NRS assessments of pain intensity disturbances in mood, sleep & work, use of medications (paracetamol, self-reported). A 500-mg tablet was considered 1 dose	15–30 weeks for 8 weeks	LI 4 & GB 21	“No important adverse events were reported” Withdrawal rate: 0%
Guerreiro da Silva, 2009 ⁴⁰ Dyspepsia	N=42 Acup=21 SC=21 Analysis 20/16	Dyspepsia	<i>Inclusion:</i> Ages 15–39, 15–30 weeks pregnant, with dyspepsia symptoms; no underlying diseases as possible causes of symptoms, nor history of similar symptoms prior to pregnancy <i>Exclusion:</i> High-risk pregnancy group or treated by acupuncture in past year	<i>Primary:</i> Self-reported severity & frequency of dyspepsia (NRS 0–10) <i>Secondary:</i> Efficacy variables such as antacid consumption (a 600-mg tablet = 1 dose); effect on sleeping & eating (NRS)	15–30 weeks for 8 weeks	LI 4	“No important adverse events were reported” Withdrawal rate: 14%

RTC, randomized controlled trial; acup, acupuncture; PTC, preterm contractions; TCM, traditional Chinese Medicine; HIV, human immunodeficiency virus; AIDS, acquired immunodeficiency syndrome; POMS, Profile of Mood States; VAS, visual analogue scale; DRI, Disability Rated Index; HRQoL, health-related quality of life; SC, standard care; NRS, numeric rating scale.

Two studies reported on preterm birth as an adverse event.^{41,43} The Elden et al., 2005 study⁴³ compared acupuncture with stabilizing exercises and usual care. In this study, there were 19 preterm births, 5 in the acupuncture group, 7 in the stabilizing exercise group, and 7 in the usual-care group. These withdrawals were included in the final ITT analysis. In the Elden et al., 2008⁴¹ study, 2 women were reported to have had preterm births, both in the acupuncture group. They were not included in the final analysis. One study³⁸ reported that 3 women gave birth during the minimal study period, but their gestational ages were not reported and they were not included in the final analysis.

In the Lund et al., study,³⁷ the researchers reported 23 dropouts (13 from the superficial-needle group (including 1 who gave birth during the study period) and 10 from the deep-needle group). These losses constituted a 33% dropout rate, and their data were not included in the final analysis.

In 2 studies,^{39,40} the researchers reported that “no important adverse events occurred”; however there were 5 withdrawals from the 2009 study⁴⁰ (1 from the acupuncture group, 4 from the usual-care group), and outcomes were not included in the final analysis.

Most minor adverse events reported included bleeding, bruising, needle pain, drowsiness, nausea, fainting, allergy to nickel, or aggravation of symptoms (Elden et al., 2008⁴¹; Lund et al, 2006³⁷; Elden et al., 2005,⁴³; Kvorning et al., 2004⁴²). Other studies did not report on adverse events (Ekdahl and Petersson, 2010²²; Guerreiro da Silva et al., 2012³⁹ and 2009⁴⁰). See Table 2.

Inclusion and Exclusion: Participant Selection Criteria, Selection Bias, and Generalizability

Most studies reported small sample sizes and participant selection criteria included only women in the second and third trimesters of pregnancy (See Table 2). Six of the studies included only healthy women with low-risk pregnancies, no risk factors contraindicating acupuncture, no other prior medical conditions, and having signs of low-back or pelvic-girdle pain (Ekdahl and Petersson, 2010²²; Elden et al., 2008⁴¹; Lund et al, 2006³⁷; Elden et al. 2005⁴³), tension headaches (Guerreiro da Silva et al., 2012³⁹), or dyspepsia (Guerreiro da Silva, et al., 2009⁴⁰). Only 2 studies reported including all women presenting with the condition in the inclusion criteria.^{38,42}

Other demographic information about the participants who were included in the studies was not reported in all but 1 study,³⁹ making assessment of participant differences at baseline not possible.

STRICTA Reporting Guidelines

The studies were evaluated according to the STRICTA guidelines for reporting of acupuncture trials³⁵ (see Table 3), and addressed each of the six items.

Item 1. Acupuncture rationale included reporting on style of acupuncture, reasoning for treatment approach, and the extent to which treatment varied between participants. For style of acupuncture and treatment theory, 2 studies^{41,43} used segmental acupuncture, 1 study reported using superficial verses deep acupuncture³⁷ but no theoretical framework was described. Kvorning et al. reported acupuncture with stimulation verses no acupuncture³⁸ but no theoretical framework was provided. Two studies^{39,40} reported using TCM theory according to the classics and TCM theory and trigger-point locations.

Treatment variation was according to site of pain in 3 studies^{37,38,43} and, in 1 study the emotional response to needling.³⁸ Minimal or no variation was reported for 4 studies,^{22,39,41} or was not described.⁴²

Item 2. Number of needles, location, depth, response sought, stimulation type, retention time and needle type were generally well reported, with only 1 study providing insufficient details for replication.²²

Item 3. Treatment regimens were well described in all studies.

Item 4. Other components of treatment were not reported in any study except the Wedenburg trial, in which details of the physiotherapy intervention (control group) were described.⁴²

Item 5. This item describes practitioners' backgrounds, including qualifications, affiliations, and information provided to participants. In the 2 studies by Guerreiro da Silva et al.,^{39,40} the practitioner received 600 postgraduate hours of training in acupuncture; however, no qualifications were provided. Two studies^{22,38} reported that the practitioners were midwives trained in acupuncture, and 1 study had a physiotherapist trained in acupuncture.³⁷ However, no further details or information about qualifications were provided. Three studies did not report on this item at all.^{41,43,45}

Item 6. This item concerns reports on control or comparator interventions, including the rationale for the comparator and a detailed description of what the intervention includes. The rationale and description of the control group were well-reported in three studies,^{22,41,43} and Lund et al., provided details of the comparison treatment but not the rationale.³⁷ These were minimally described or not described at all in the four remaining studies.^{38–40,42} See Table 3

Risk of Bias

Using the GRADE risk of bias assessment tool,²⁹ the areas of potential bias were examined, including, selection bias, performance bias, detection bias, attrition bias, and reporting bias (see Table 1). No study was at a low risk of

TABLE 3. STRICTA REPORTING GUIDELINES FOR RCTs

1st author, year, ref., & condition	Item 1: Acup rationale	Item 2: Details of needling	Item 3: Treatment regimen	Item 4: Other components of treatment	Item 5: Practitioners background & description of participating acupuncturists	Item 6: Control of comparator interventions	Reporting of adverse events CONSORT
	a. Style of acup b. Reasoning for Rx provided (theoretical) c. Extent of variation of Rx	a. Number of needles per subject per session (mean & range) b. Names/location of points (uni/bi) c. Depth of insertion d. Response sought e. Needle stimulation (MA, EA) f. Needle retention time g. Needle type	a. # of Rx sessions b. Fx & duration of sessions	a. Details of other interventions (e.g., moxa, herbs, cupping)	a. 20 wk vs. 26 wk b. Described		
Ekdahl, 2010 ²² Back & pelvic pain	a. Not reported b. Not reported c. No variation	a. 5 needles first session, 10 thereafter b. Not reported c. Not reported d. De Qi f. 20–30 min g. Not reported	a. 8–12 treatments b. Over 6 weeks (2× per week for first 2 weeks, 1× per week thereafter)	Not reported	Midwife trained in acupuncture	a. Standard treatment and stabilizing exercises b. Described	Group 1: 20/40 (n=20), 2 withdrew (1 PTC, 1 no reason) Group 2: 26/40 (n=20), 4 withdrew (2 PTC, 1 symptom reduction, 1 illness); other adverse events not reported
Elden, 2005 ⁴³ Pelvic-girdle pain	a. Segmental acup b. Not reported c. 10 classical acup points in same segments as pelvic-girdle pain; 2 points on medial leg & foot	a. 10 segmental +7 extrasegmental points b. Yes (in a table) c. 15–70 mm d. De Qi f. 30 min & manually stimulated every 10 min g. Stainless steel 0.30.	a. 12 treatments b. 2× weekly for 6 weeks	None	Not reported	a. Standard treatment and stabilizing exercises b. Described	Loss to follow-up Standard: n=7 (3 early births, 3 declined visit, 1 moved) Acup: n=6 (5 early births, 1 declined visit) Stabilizing exercise: n=9 (4 early births; 5 declined visit)
Elden, 2008 ⁴¹ Pelvic-girdle pain	a. Segmental b. Not reported c. No variation	a. 10 segmental +7 extrasegmental points b. Yes (in table) c. 15–70 mm d. De Qi f. 30 min & manually stimulated every 10 min g. Stainless steel 0.30mm	a. 12 treatments b. 2× weekly for 6 weeks	None	Not reported	a. Standard treatment b. Described	Includes self-reporting of minor adverse events: bleeding or bruising; pain on needling; drowsiness; & aggravation of symptoms; no PTC reported; 19 preterm labors reported within the 3 intervention groups (5 in acup group, 7 in stabilizing exercise group; & 7 in standard treatment group)
Lund, 2006 ³⁷ Pelvic-girdle pain	a. Not reported beyond superficial vs. deep b. Not reported c. Varied by site of pain	a. 10 classical acup points chosen depending on site of pain, including BL 32. Combine peripheral points SP 6, LV 2, LI 4 b. Yes provided c. Superficial/deep, depth not reported d. Deep—De Qi stim f. 30 min g. length/0.20-mm diameter (Seirin®) and 30 mm length/0.30-mm diameter (Marco Polo distributor)	a. 10 treatments b. 30 min, 2× week for 5 weeks	a. Only needling details given	a. Physiotherapist “experienced” in acupuncture (no qualification provided)	a. Not provided b. Deep needling vs. superficial needling	Withdrawal reported due to increased pain, fainting, & allergic reaction to nickel; PTC not reported on; 1 withdrawal due to premature labor; no difference seen in outcomes for superficial vs. deep needling; both groups had reductions in pain

(continued)

TABLE 3. (CONTINUED)

	Item 1: Acup rationale		Item 2: Details of needling		Item 3: Treatment regimen		Item 4: Other components of treatment interventions		5. Practitioners background & description of participating acupuncturists		Item 6: Control of comparator interventions		Reporting of adverse events CONSORT			
	a. Style of acup	b. Reasoning for Rx provided (theoretical)	a. Number of needles per subject per session (mean & range)	b. Names/location of points (uni/bi)	c. Depth of insertion	d. Response sought	e. Needle stimulation (MA, EA)	f. Needle retention time	g. Needle type	a. # of Rx sessions	b. Fx & duration of sessions	a. Details of other interventions (e.g., moxa, herbs, cupping)		a. Rationale for control/comparator (lit)	b. Precise description of the control or comparator	
Kvornig, 2004 ³⁸ Pelvic & low-back pain	a. Not reported beyond acupuncture with stim vs no acup	b. Not reported	a. Not reported	b. Some acupoints reported, but others described by muscular or tendon location, or trigger points	c. Not reported	d. De Qi	e. MA	f. At least 10min	g. Not reported	a. 2×week for 2 weeks, then 1×week thereafter	b. At least 3 weeks	a. Not reported	b. “Controls given no sham stimulation”	a. Not reported	Needle pain, sweating tiredness, hematoma, nausea & weakness reported; no serious adverse events; 3 women in acup group gave birth during study; gestation not reported; average gestational age was 30+4/40; forbidden point was BL 60	
Wedenberg, 2000 ⁴² Pelvic & low-back pain	a. Not reported	b. Not reported	a. 2–10 needles per session	b. Most commonly used: BL 26–BL 30; BL 60; CW 2; local points	c. 1 cm	d. De Qi	e. MA	f. Not reported	g. Not reported	a. 3×week for 2 weeks, then 2 x week for 2 weeks=10 Rx 1 mo	a. Not reported	a. Yes	b. Described	a. Not reported	No serious adverse events reported; tiredness & sleepiness reported as routine part of Rx; 3 women (in physiotherapy group) complained of premature uterine contractions	
Guerreiro da Silva, 2012 ³⁹ Tension-type headache	a. TCM & trigger point	b. TCM	a. Average 15 needles	b. LV 3, LI 4, LU 7, GB 21, GB 41, Yintang, GV 20 + up to 6 trigger points (bi)	c. Not reported	d. De Qi	e. MA	f. Not reported	g. Stainless steel 0.2×40mm	a. 1–2×wk for 8 wk	b. Max 12 sessions, 25 min each	a. Not reported	a. Conventional treatment (qualifications not reported)	a. Acupuncturists: 600hr postgraduate training (qualifications not reported)	a. Conventional treatment further	“No important adverse events were reported”
Guerreiro da Silva, 2009 ⁴⁰ Dyspepsia	a. Traditional acup	b. TCM according to classics	a. Average 12 needles	b. Commonest: LI 4; PC 6; ST 44; CV 12; St 21; LV 13; ST 36; & SP 4	c. Not reported	d. De Qi	e. MA	f. 25 min	g. Stainless steel 1.2×40-mm	a. 1–2×week	b. Max 12 sessions	a. Not reported	a. Conventional Rx – not described	a. Acupuncturists: 600hr postgraduate training (qualifications not reported)	a. Conventional treatment further	“No important adverse events were reported”

STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture RCT, randomized controlled trial; acup, acupuncture; Rx, prescription; uni, unilateral; bi, bilateral; MA, manual acupuncture; EA, electroacupuncture; Fx, effects; moxa, moxibustion; lit, literature; CONSORT, Consolidated Standards of Reporting Trials; min, minute(s); wk, week(s); PTC, preterm contractions; mo, month(s) stim, stimulation; TCM, Traditional Chinese Medicine; max, maximum; hr, hour(s).

bias in all domains. However, the study by Elden et al. (2008)⁴¹ was at the lowest risk of bias overall and 3 studies,^{22,39,42} were equally at the highest risk of bias overall.

Random-Sequence Generation

Three studies reported methods of randomization, using random-sequence generation and were at low risk of selection bias.^{38,41,43} However, the risk of bias was unclear in 3 studies due to inadequate description of randomization-sequence generation,^{22,37,42} and there was a high risk in 2 studies, as no descriptions were provided.^{39,40}

Allocation Concealment

Four studies were at a low risk of selection bias for this outcome^{37,38,41,43} and, in 4 studies, the risk was unclear, as there were inadequate descriptions of allocation concealment.^{22,39,40,42}

Blinding of Participants and Personnel

Two studies were at either a low⁴³ or unclear³⁷ risk of performance bias. The remaining 6 studies were at a high risk of bias due to lack of blinding for the participants as well as the personnel conducting the study.

Blinding of Outcome Assessment

Only 2 studies^{38,43} were at a low risk of detection bias due to blinding of the outcome assessor. One study was at an unclear risk due to inadequate description.⁴¹ The remaining 5 studies were all at a high risk of bias due to the lack of blinding of outcome assessors.

Incomplete Outcome Data

Three studies were at a low risk of attrition bias,^{40,41,43} and 2 were at an uncertain risk due to inadequate reporting of outcomes.^{38,39} The remaining 3 studies^{22,37,42} were at a high risk of bias due to high, unaccounted for, withdrawals from the studies.

Selective Reporting Bias

As there were no clear protocols referenced in any of the studies, it remains unclear whether studies reported were reported selectively or not. All studies were rated as being at an unclear risk of bias.

Other Bias—Selection Bias

Studies reported selected patient groups, with most including only low-risk healthy women, with no predisposing factors or complications of pregnancy, therefore they were at an unclear risk of selection bias. Only 2 studies reported including all women presenting with the condition in the inclusion criteria.^{37,42} See Figure 2.

DISCUSSION

This review examined RCT trials of penetrating acupuncture that used forbidden points prior to 37 weeks of pregnancy to treat pregnancy-related pain conditions as part of the studies' treatment protocols. The primary outcome of this review was incidence of PTC. Overall, few trials reported on the primary outcome of PTC, with 2 studies reporting 6 women who withdrew from trials due to PTC. Overall, there were 35 reported births during the study periods, wherein 32 were preterm, and, for 3, the gestation was not reported.

Ongoing concerns are raised by both traditional and medical acupuncturists about the use of forbidden points during pregnancy and the risk of PTC. The research literature suggests that they are not seen as severe adverse events in terms of miscarriages or premature births, however; these contractions are distressing to women and have the potential to limit practice.

The evidence suggests that segmental acupuncture points, including forbidden points, are common in research protocols, as was seen in this review. However there was little evidence of reference to the guiding treatment principles of TCM. This

FIG. 2. GRADE [Grades of Recommendation, Assessment, Development, and Evaluation]. Risk of bias in included studies. N/A, not applicable.

suggests that medical acupuncturists are using acupuncture from a different framework and might have dismissed forbidden points as not being relevant. Yet in the literature, there are reports of PTC. While the incidence of PTC remains uncertain according to this examination of the current evidence, highly selected patient populations, rates of dropouts, and lack of ITT analyses, as well as underreporting of this outcome, might have introduced significant biases into the studies, limiting their validity and the generalizability of their findings. Other research demonstrated their use of forbidden points for augmenting labor,¹⁹ and the points have been reported to stimulate uterine contractions and study withdrawal when used for cephalic versions of breech-presenting babies.⁴⁴

While forbidden points were selected in these medical acupuncture research protocols, within a TCM framework, these points are not considered to be essential for clinical practice and women have reported clinically meaningful reduction of their lower-back pain/pelvic pain without the use of these points.¹¹ Within a TCM framework, the use of these points is performed with knowledge and philosophical understanding to guide the treatment.¹⁶

When considering risk factors in patient populations, it could also be relevant that these points are used with an appropriate rationale after 36 weeks. This may be particularly relevant for women presenting with histories of an incompetent cervix, previous preterm deliveries, previous precipitate labor, twin pregnancies, or medical complications, such as polyhydramnios for which medical management is required at the onset of labor. Consideration of the presenting problem and TCM pattern of the person is essential when applying acupuncture protocols.

Generally, studies included in this review did not report adequately on outcomes, such as adverse events, reasons for dropping out of the studies, and losses to follow-up, as well as not describing these in sufficient detail to determine the level of evidence for the safety of acupuncture at points that are generally contraindicated during pregnancy. Additionally, the population included in the studies, wherein inclusion and exclusion criteria apply—and from which the study inferences were made—do not necessarily reflect the general population of women who experience back, pelvic, or other pain during pregnancy, with other factors that may increase risk of PTC.

In view of the reported incidences of PTC and the quality of evidence in studies to date when used, the routine use of forbidden points to treat pregnancy related pain conditions before 37 weeks of pregnancy is questionable.

CONCLUSIONS

PTC is an important clinical outcome and should be reported routinely as it has a significant impact on clinical practice. The strength of evidence to date is insufficient to recommend using forbidden points prior to 37 weeks of pregnancy. Highly selected patient populations, risk of bias

in study designs, and participant withdrawal rates suggest that high-quality trials are required.

AUTHOR DISCLOSURE STATEMENT

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