

# The safety of acupuncture during pregnancy: a systematic review

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## Abstract

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### Objective

Although there is a growing interest in the use of acupuncture during pregnancy, the safety of acupuncture is yet to be rigorously investigated. The objective of this review is to identify adverse events (AEs) associated with acupuncture treatment during pregnancy.

### Methods

We searched Medline, Embase, Cochrane Central Register of Controlled Trials, Cumulative Index to Nursing and Allied Health Literature (CINAHL), Allied and Complementary Medicine Database (AMED) and five Korean databases up to February 2013. Reference lists of relevant articles were screened for additional reports. Studies were included regardless of their design if they reported original data and involved acupuncture needling and/or moxibustion treatment for any conditions in pregnant women. Studies of acupuncture for delivery, abortion, assisted reproduction or postpartum conditions were excluded. AE data were extracted and assessed in terms of severity and causality, and incidence was determined.

### Results

Of 105 included studies, detailed AEs were reported only in 25 studies represented by 27 articles (25.7%). AEs evaluated as certain, probable or possible in the causality assessment were all mild/moderate in severity, with needling pain being the most frequent. Severe AEs or deaths were few and all considered unlikely to have been caused by acupuncture. Total AE incidence was 1.9%, and the incidence of AEs evaluated as certainly, probably or possibly causally related to acupuncture was 1.3%.

### Conclusions

Acupuncture during pregnancy appears to be associated with few AEs when correctly applied.

**Keywords:** Acupuncture, Gynaecology, Obstetrics, Systematic Reviews

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## Introduction

During pregnancy, women may suffer from various conditions which could affect pregnant women's health as well as normal development and delivery of the infant. Concerns over drug use during pregnancy have helped increase the use of other non-pharmacological treatments. Among them, acupuncture is increasingly practised in pregnant women. In a recent survey of 575 women seeking Chinese medical care, 17.4% received acupuncture for reproductive conditions.<sup>1</sup> Another survey in North Carolina reported that acupuncture was used by 19.5% of nurse midwives during pregnancy.<sup>2</sup> Evidence of effectiveness of acupuncture during pregnancy is emerging for various conditions.<sup>3 4</sup> Recommending acupuncture as a treatment option then depends on its safety, so research on safety of acupuncture for pregnant women is needed urgently.

According to a recent prospective survey on adverse events (AEs) associated with acupuncture,<sup>5</sup> the risk of a serious AE with acupuncture is estimated to be 0.01 per 10 000 acupuncture sessions and 0.09 per 10 000 individual patients, which are regarded as 'very low'. A systematic review on the safety of paediatric acupuncture recently reported that a majority of AEs were mild, and rare serious harms were identified.<sup>6</sup> However, sporadic data on the safety of acupuncture during pregnancy are available. Although acupuncture is regarded as highly safe in the general population,<sup>5 7</sup> the risk–benefit profile in pregnant women may differ. This systematic review therefore aimed to summarise and critically evaluate all available reports on AEs associated with acupuncture treatment during pregnancy to safeguard against avoidable AEs.

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## Methods

### Search strategy

Electronic searches were conducted in the following databases from inception to February 2013: Ovid Medline, Cochrane Central Register of Controlled Trials, Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL) and the Allied and Complementary Medicine

Database (AMED). We also searched Korean databases including Korean Studies Information Service System (KISS), Korea Institute of Science and Technology Information (KISTI), DBPIA, Korea National Assembly Library and Korean Traditional Knowledge Portal (KTKP). Reference lists of reviews and relevant articles were screened for additional studies. For commentaries, letters, responses or editorials, the original articles were sought.

The following search terms were used: ‘acupunct\*’, ‘moxibustion’, ‘moxa’, and ‘pregnan\*’ in the title and abstract for Ovid Medline and modified terms and limits were used for other databases. As we were concerned that most articles poorly report AEs and are poorly indexed, we decided not to combine search terms for AEs at the cost of sensitivity. Trials published in English, Korean and Chinese were considered.

### **Study selection**

Studies were included if they (1) had original patient data; (2) involved pregnant women treated for any condition; (3) involved acupuncture treatment which includes needling and/or moxibustion as they are often used together; and (4) included reporting of AEs. Studies reporting that no AEs had occurred were also included. We also kept records of reports that did not mention harms. We excluded studies investigating the effect of acupuncture on delivery, abortion, assisted reproductive technology or postpartum conditions. There was no restriction to the type of studies — that is, we included randomised controlled trials (RCTs), non-randomised controlled clinical trials (CCTs), case series/reports or surveys if they contained unique data. We further sought original articles included or referenced in the reviews, editorials or commentaries for potentially relevant studies.

### **Data extraction**

Two authors (JP and YS) extracted data regarding author(s), publication year, country, study design, sample size, gestational week, condition/symptom for acupuncture treatment, details of acupuncture treatment based on the Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines,<sup>8</sup> control treatment if applicable, practitioner information and detailed information on AEs. AEs were classified into maternal and fetal outcomes because we deemed both to be clinically relevant and important. The original authors were

contacted when further information was needed. Extracted data were validated by another reviewer (HL).

### **Quality assessment of the included studies**

The quality assessment of AE data from RCTs and CCTs included in our review was performed on the following items, which were adopted and modified from previous suggestions.[9–12](#)

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2 Was the definition of AEs given?

3 Was the method used to monitor or collect AEs reported?

4 Were the type and frequency of AEs in each group reported in detail?

5 Was the severity of AEs assessed?

6 Was the causality between acupuncture and AEs assessed?

7 Were the participant withdrawals or drop-outs due to AEs described adequately?

Each item was given Y for yes, N for no and U for unclear reporting.

Disagreements were resolved by discussion.

### **Data analysis**

AE data from divergent sources such as different study designs and data collection methods may be better summarised in a qualitative manner than combining them using meta-analysis.[13](#) Hence, the results were presented descriptively by categorising the data according to the study design. AEs were analysed in terms of severity, causality and incidence.

Severity of the AEs was assessed by the two reviewers (JP and YS) based on the Common Terminology Criteria for AEs (CTCAEs) scale V.4.0.[14](#)

The following 5-point grading categories were applied: grade 1, mild (asymptomatic or mild symptoms; clinical or diagnostic observations only; intervention not indicated); grade 2, moderate (minimal, local, or non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living (ADL)); grade 3, severe or medically significant but not immediately life-threatening (hospitalisation or prolongation of hospitalisation indicated; disabling; limiting self-care ADL); grade 4, life-threatening consequences (urgent intervention indicated); grade 5, death ‘related to AE’.

Causality—that is, the strength of the relationship between AEs and acupuncture treatment—was assessed by two reviewers (JP, acupuncture specialist and YS, obstetrics/gynaecology specialist) in accordance with

the causality categories in the World Health Organisation-Uppsala Monitoring Centre system for standardised case causality assessment.<sup>15</sup> The causality categories used were certain, probable/likely, possible, unlikely, conditional/unclassified and unassessable/unclassifiable. The incidence of AEs was presented as the number of AEs per number of acupuncture sessions (%). As we expected that there would be few articles that clearly stated the number of treatment sessions, we adopted the following rules. First, we used the reported mean/median value when a range and the mean/median value were all available in the original study. Second, when the number of treatments varied across participants and only a range value was available, we took the midpoint value between the two extremes. Third, when participants withdrew or dropped out but the number of treatments that they had received was not reported, we considered they were treated once because we judged that the incidence of AEs should be calculated in a conservative manner. Finally, when the number of treatments was not reported at all, we put the number of participants as the denominator. Studies reporting that there were no AEs were included in our incidence analysis.

For sensitivity analysis we compared the incidence of AEs that were originally reported as such in the primary studies with the incidence calculated by including poor pregnancy outcomes which were not reported as AEs. Poor outcomes included perinatal outcomes (eg, miscarriage, stillbirth and neonatal death), congenital abnormalities, pregnancy complications (eg, pre-eclampsia and gestational diabetes) and fetal outcomes.<sup>16</sup>

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## Results

### Description of studies

A total of 2107 references were initially identified. Of these, 517 duplicates were removed and 1268 articles were excluded based on the title and abstract. After 217 of the 322 full-text articles were read and further excluded, 105 articles were included in this review: RCTs (n=42), CCTs (n=6), case series/reports (n=54) and surveys (n=3). [Figure 1](#) shows a flow diagram as recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA).<sup>17</sup> A complete list of

included and excluded articles is available by request from the corresponding author.

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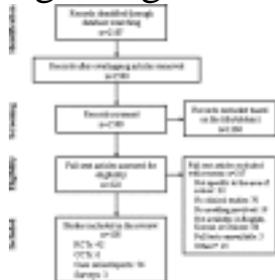


Figure 1

caption a4

Flow diagram of studies included in the systematic review.

\*Includes 23 commentaries/summary articles, one retracted article and one article with a healthy pregnant woman. CCT, controlled clinical trial; RCT, randomised controlled trial.

### Study characteristics

Of the 105 included articles, detailed AEs were extracted from 27 reports (25.7%; 25 studies and 2 additional reports<sup>18 19</sup> of the included studies<sup>20 21</sup>). Of these, the most frequent design was case reports/series (51.4%) followed by RCTs (40.0%), CCTs (5.7%) and surveys (2.9%). A complete list of the other studies which did not mention AEs or reported that no AEs had occurred is provided in online supplementary table S1. Among them, 55 studies did not mention AEs, 22 studies reported there were no AEs and one study<sup>22</sup> reported that fewer AEs had occurred in the acupuncture group without a detailed description of AEs. Details of AEs are summarised in online supplementary tables S2 and S3 based on the severity of AEs (mild/moderate AEs in online supplementary table S2 and severe AEs/death in online supplementary table S3); 18 were RCTs,<sup>4 18–21 23–36</sup> 2 were CCTs<sup>37 38</sup> and 5 were case series/reports.<sup>39–43</sup>

Studies were conducted across several countries: five each in Sweden and Brazil, four in the UK, three in China, two each in the USA and Italy and one each in Australia, Spain, Switzerland and Korea.

The most frequent condition treated with acupuncture was low back pain and/or pelvic pain (n=9) followed by fetal malposition (n=7). The others included nausea and vomiting, tension-type headache, depression, dyspepsia, insomnia, emotional complaints, lateral epicondylitis and back

pain, sciatica, rib flare and symphysis pubis dysfunction.

Details of acupuncture interventions are summarised in online supplementary table S4 based on the revised STRICTA.<sup>8</sup> Regarding the style of acupuncture, manual acupuncture was most commonly used (n=14), followed by moxibustion to treat fetal malposition (n=7); manual acupuncture plus electroacupuncture, auricular acupuncture alone or auricular acupuncture with or without manual acupuncture were tested in three studies of low back and/or pelvic pain, respectively; one study used manual acupuncture plus bee venom pharmacopuncture for lateral epicondylitis.

The number of acupuncture sessions ranged from 2 to 40 over 5 days to 8 weeks; 12 used fixed treatment, 10 used partially individualised treatment, two used individualised treatments and one did not report detailed information.

Twelve studies used 12 meridian points only, two studies used 12 meridian points, extra meridian points and trigger/tender points, three studies used 12 meridian points and local tender points, three studies used standardised points (12 meridian points and extra meridian points) plus additional points (but the additional points were not clearly reported), two studies used auricular acupuncture with or without local tender points, one study used 12 meridian points and extra meridian points, one used tender or trigger points only and one did not report the acupuncture points used. In 17 trials involving acupuncture treatment only, the acupuncture treatment was given by acupuncturists in 10 trials, by midwives in three studies and in four studies the practitioner was not stated. In seven moxibustion trials, pregnant women with or without her partner/helper performed moxibustion treatment in three trials, a family member alone provided moxibustion treatment in one study and three trials did not report the relevant information. One study that tested acupuncture plus bee venom pharmacopuncture did not report the relevant information but it was assumed that a doctor gave the treatment.

### **Severity and causality of AEs associated with acupuncture**

We identified a total of 429 AEs in the 27 reports (online supplementary tables S2 and S3). From approximately 22 283 sessions of acupuncture in 2460 pregnant women, 322 AEs were regarded as mild, 6 as moderate, 99 as severe, 2 as death related to AE and 2 were not assessable due to a lack

of information. With regard to causality, the AEs were evaluated as certain (n=144), probable (n=15), possible (n=132), unlikely (n=124) or unassessable (n=14). AEs evaluated as certain, probable and possible in the causality assessment were all evaluated as mild or moderate in severity. Severe AEs or death related to AEs were all considered unlikely to have been caused by acupuncture treatment.

### **Mild/moderate AEs**

Among the 322 mild AEs, 302 involved maternal complications: needle or unspecified pain (n=48), local bleeding (n=40), haematoma, tiredness, headache and/or drowsiness (n=21 for each), worsened symptom/condition (n=19), dizziness, discomfort at needling points (n=15 for each), ecchymosis/bruise, uterine contractions with or without abdominal pain, and unpleasant odour with or without nausea and throat problems (n=14 for each), heat or sweating (n=10), nausea (n=9), unpleasantness with treatment (n=5), feeling faint (n=4), sleep disturbance and excessive fatigue (n=3 for each), irritability/agitation, heaviness of arms, rash at needling points, feeling energised, local anaesthesia, itching and unspecified problems (n=2 for each), weakness, altered taste, pressure in nose, transient ear tenderness, bed rest, thirst, sadness, oedema, tattooing of the skin at needling points, shooting sensation with intense paraesthesia down the leg to the foot by needling, breech engagement, and threatened preterm labour which spontaneously disappeared completely within a day followed by a normal delivery in the 42nd week (n=1 for each). Cardini *et al*<sup>35</sup> reported a sense of tenderness and pressure in the epigastric region and epigastric crushing but they did not state the number of AEs nor the group that experienced the AEs.

Of the mild AEs, fetal adverse outcomes occurred in 20: small for date (n=13) and multiple twists of the umbilical cord around the neck (n=4) or shoulder (n=3).

Six AEs were evaluated as moderate: fainting (n=5) and transient fall in blood pressure (n=1).

### **Severe AEs**

Ninety-nine severe AEs were all considered unlikely to have been caused by acupuncture treatment. In severe AEs, maternal complications were 86:

hypertension and/or pre-eclampsia (n=37), preterm delivery between 20 and 37 weeks of pregnancy (n=19), miscarriage (n=15), premature rupture of the membranes (n=5), antepartum haemorrhage/abruption or placenta praevia (n=6), pregnancy termination due to unspecified reasons (n=2), caesarean delivery (n=1), and tachycardia and atrial sinus arrhythmia (n=1). The 15 miscarriages were all reported from one study<sup>19 21</sup> in which the participants received five sessions of acupuncture over a month for nausea and vomiting in early pregnancy. The reported miscarriage rate of 5% (15/293 in the acupuncture in addition to usual care group, 6/147 in the sham acupuncture in addition to usual care group and 9/143 in the usual care only group) was lower than the population risk estimate of 11% in Australia, suggesting that acupuncture was not associated with a higher risk of miscarriage.

Fetal complications were congenital defects (n=12) and admission to neonatal intensive care unit due to preterm delivery (n=1).

#### **Death related to AE**

Two deaths were reported: one stillbirth and one neonatal death. Manber *et al*<sup>28</sup> reported premature delivery of twins with one unexpected neonatal death which was classified as unrelated to acupuncture by the study investigators and the Data Safety and Monitoring Board. We also evaluated them as unlikely in the causality assessment. The lack of acupuncture-related maternal mortality is worthy of note.

#### **Incidence of AEs**

The incidence of AEs based on study design is shown in online supplementary table S5. The total incidence of AEs in the acupuncture group was 1.9% (429 AEs in 22 283 sessions), and limiting the calculation to AEs evaluated as certain, probable and possible in the causality assessment resulted in an incidence of 1.3% (291 AEs in 22 283 sessions). In other words, the incidence of AEs amounted to 193 and 131 AEs per 10 000 acupuncture sessions, respectively. The risk of mild or moderate AEs was 1.5%, estimated to be 147 per 10 000 treatments. There were no serious AEs or deaths probably causally related to acupuncture in 10 000 treatments.

#### **Sensitivity analysis**

When poor outcomes that were not reported as AEs in the original articles

were counted as AEs, the total AE incidence in the acupuncture group was 4.8% (1067 AEs in 22 283 sessions) and limiting this to AEs evaluated as certain, probable and possible in the causality assessment resulted in 1.9% (418 AEs in 22 283 sessions). This is more than twice that of our original analysis (total AE incidence 1.9%) which included reported AEs only. Nevertheless, these values are comparable to or lower than those investigated in the general population receiving acupuncture treatment (table 1).

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Author (year)	Country	Design	Condition	No. of patients	AE incidence (per 100 sessions)	Most frequent AEs	A
Yamashita (2000) <sup>14</sup>	Japan	Prospective survey	NR1	331	0.43	Tiredness, drowsiness, symptom aggravation, minor bleeding on needle withdrawal	12 10 10 10
White (2011) <sup>15</sup>		Prospective	NR1	NR	0.71	Bleeding or hematoma	12

[Table 1](#)  
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### Quality assessment of AE data from RCTs and CCTs

We assessed the quality of AE data from RCTs and CCTs based on six predetermined items (table 2). The quality of data reporting was mostly poor. Only one study (5.0%)<sup>19 21</sup> provided a definition of AEs. Eight out of 20 studies (40.0%) reported the method used to collect AEs: three studies used direct questioning,<sup>1,8 20 26 3,4</sup> two used patient diaries,<sup>28 33</sup> one used a questionnaire,<sup>36</sup> Vas *et al*<sup>4</sup> used patient case notes, direct questioning and a questionnaire and Smith *et al*<sup>19 21</sup> used direct questioning and patient case notes. Ninety percent of studies reported the type and frequency of AEs in each group but none stated the severity; only Elden *et al*<sup>18 20</sup> assessed the severity of some but not all of the reported AEs. Two studies<sup>4 35</sup> did not state in which group the AEs had occurred. Only one of the included studies assessed the causality between

acupuncture treatment and reported AEs.<sup>28</sup> Seventeen of the 20 trials adequately described the participant withdrawals and drop-outs due to AEs. In two studies it was impracticable to extract data on withdrawals and drop-outs relevant to AEs; one study<sup>29</sup> did not report the reason for withdrawals and another<sup>32</sup> did not mention the withdrawals and drop-outs at all. Cardini *et al*<sup>31</sup> stated the reason for withdrawals but it was not sufficiently clear.

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**Table 2**  
Assessment of the quality of AE data from RCTs and CCTs included in the review

Author (year)	Was the definition of AEs given?	Was the method used to monitor or collect AEs reported?	Were the type and frequency of AEs in each group reported in detail?	Was the severity of AEs assessed?	Was the causality between acupuncture and AEs assessed?
<b>RCTs/quasi-RCTs</b>					
Yin (2011) <sup>6</sup>	N	Y	N	N	N
Guerrero da Silva (2012) <sup>11</sup>	N	N	Y	N	N

Assessment of the quality of AE data from RCTs and CCTs included in the review [Go to:](#)  
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## Discussion

### Main findings

This systematic review has found that the majority of AEs associated with acupuncture during pregnancy are mild and transient, and serious AEs are very rare. Needling or unspecified pain was the most commonly reported mild AE, followed by bleeding. AEs were largely mild in severity. We found acupuncture treatment during pregnancy was associated with few serious AEs and all of them were evaluated as unlikely to have been caused by acupuncture treatment. The estimated incidence of AEs associated with acupuncture in pregnant women was 193 per 10 000 acupuncture sessions. Limiting the calculation to AEs evaluated as certain, probable or possible in the causality assessment resulted in an incidence of 131 per 10 000 treatments. These values are comparable to or less serious than those investigated in the general population receiving acupuncture treatment ([table 1](#)).

### Interpretation of review findings

There are some specific issues worth mentioning in this review. Rare AEs associated with treatment are difficult to study and are usually published as case reports. The incidence of AEs is best estimated in large prospective surveys and, in acupuncture research, there are some large surveys from the general population.<sup>5 45 47</sup> In general, commonly reported mild AEs associated with acupuncture include bleeding or haematoma, pain and tiredness or drowsiness.<sup>5 44</sup> Pneumothorax, infection and nerve lesions have been reported as serious AEs, although they are rare.<sup>5 48</sup> In our review, needling pain and bleeding were the most common mild AEs and the incidence was similar to those from previous studies. Severe AEs (primarily hypertension and/or pre-eclampsia in the mother and congenital defects in the baby) were all evaluated as unlikely to have been caused by acupuncture treatment. While the incidence of serious AEs is higher than those from other trials,<sup>7 45 49</sup> this may be attributable to special characteristics of pregnant women. Deaths related to AEs were all stillbirths or neonatal deaths which were unlikely to have been due to acupuncture. What should be noted here is that AEs did occur in pregnant women but most of them were mild and transient, and severe AEs such as pneumothorax and nerve lesions were not recorded at all.

### **Strengths and limitations of this review**

The assessment of the benefit–harm profile should also be considered in the context of the nature of the condition for which the intervention is applied.<sup>13</sup> This review looks at the important population of pregnant women who may be different from the general population in several respects. As pregnant women have relatively limited treatment options for pregnancy-specific and/or general health problems because of the fear of miscarriage, premature delivery or teratogenicity, solid evidence on the safety of acupuncture is all the more needed. To our knowledge, this is the first systematic review dealing with this topic.

Some limitations of this review should be noted. There is a lack of appropriate information regarding obstetric complications, particularly in the case of the most serious complications such as maternal and perinatal mortality. It may be difficult to make any meaningful conclusions about these important AEs. Hemminki *et al*<sup>50</sup> found that unpublished trials gave more information on AEs than published trials. We may have missed relevant articles or unpublished data. Due to limited resources, we only

included trials published in English, Korean and Chinese. However, as the AE results did not significantly differ across countries,<sup>5 7 45</sup> the excluded studies may not have significantly reversed the overall picture.

Although every medical intervention carries some risk of AEs, the research focus has been on the benefit of the intervention and information on harm has been neglected. Inadequate reporting of harms has been ubiquitous in conventional medicine as well as in complementary and alternative medicine.<sup>51 52</sup> The absence of reported AEs thus does not mean that there are not any. In our review, AEs were reported from only 25.7% of the included studies, the most frequent design being case reports/series followed by RCTs, CCTs and surveys. Each of the different designs has pros and cons: observational studies are useful to identify AEs which have long latent periods or are unusual, but these reports do not provide information on the incidence due to a lack of denominator data. Clinical trials are useful in determining the incidence but are unsuitable for new, rare or long-term AEs and may only provide limited information on AEs due to exclusion of patients at high risk because of comorbidity. Surveys also have limitations such as recall bias which occurs intentionally or unintentionally in the recollection and reporting process. The overall incidence of AEs associated with acupuncture for pregnant women in this review therefore may be just an approximation of the true value. All but one<sup>19 21</sup> of the included RCTs and CCTs did not predefine potential AEs, and the definition of AEs may have been different across studies. Methods of monitoring or collecting AE data were not clear in 60% of studies. Evidence from our review therefore may be incomplete and susceptible to reporting and publication bias.

While most included trials satisfactorily reported the type and frequency of AEs and the withdrawals or drop-outs due to AEs in each group, the definition and severity of AEs, causality between the intervention and AEs and the collecting and monitoring methods of AEs were generally poorly reported. Only 25.7% provided safety information and 52.4% did not mention AEs at all. For studies reporting that there were no AEs (21%) it is assumed that they were not ascertained or recorded.<sup>13</sup> Thus we may not be entirely free from risk of having underestimated the AE incidence.

**Clinical implications of this review**

Controversies about so-called ‘forbidden points in pregnancy’ exist.<sup>53</sup> Some experimental studies suggest no evidence on harm by needling LI4, SP6 or sacral points<sup>54 55</sup> while others argue that the classic literature should be taken into consideration on the basis of the potential physiological mechanisms whereby acupuncture may adversely affect pregnancy.<sup>56</sup> However, the suggested mechanisms have been refuted,<sup>53</sup> and a recent literature review failed to find any plausible explanation for repeatedly or differently mentioned forbidden points across books.<sup>57</sup> In this context, this systematic review found that AEs associated with acupuncture during pregnancy are generally mild, and serious AEs are rare. The present findings should be given to pregnant women together with effectiveness data so that they can make an informed decision. In addition, future large prospective studies would give us better information and a more accurate estimate of AEs associated with acupuncture in pregnant women.

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