Adverse event reporting in studies of penetrating acupuncture during pregnancy: a systematic review

Authors

Carl E. Clarkson,

Deborah O'mahony,

Diana E. Jones

Abstract

Background

Acupuncture within pregnancy has frequently been investigated, often finding this to be more effective than standard care. However, the adverse event severity, types and occurrence are unclear.

Objective

To investigate the quality of reporting adverse events and to attempt to identify occurrence, type and severity of adverse events in acupuncture and non-acupuncture groups.

Data sources

MEDLINE, CINAHL, Allied and Complementary Medicine Database, and Physiotherapy Evidence Database (PEDro) were searched for relevant studies between 2000 and 2014.

Study selection

Seventeen studies using penetrating acupuncture and making comment on adverse events experienced were included. Quality appraisal of the selected publications was performed using either the PEDro scale or the Downs and Black checklist. Quality of reporting was evaluated against STRICTA and CONSORT guidelines, with data on adverse events extracted in accordance with CONSORT and *Good Clinical Practice* adverse event guidelines.

Results

Overall quality of reporting of adverse events was poor, with information describing the adverse events often lacking in detail. A number of trends were noted: adverse events occurring within a treatment session was 3–17% in the acupuncture groups and 4–25% in the non-acupuncture groups. The percentage of women affected by an adverse event was between 14 and 17% in the acupuncture groups and between 15 and 19% in non-acupuncture groups.

Conclusions

Adverse event reporting within acupuncture trials is generally poor. The trends noted were that adverse events do occur, but would appear to be largely minor and comparable to non-acupuncture-related interventions.

Abbreviations

AMED - Allied and Complementary Medicine Database

CONSOR - Consolidated Standards of Reporting Trials

PEDro - Physiotherapy Evidence Database

PGP - pelvic girdle pain

RCT - randomized control trial

STRICTA - Standards for Reporting Interventions in Clinical Trials of Acupuncture

TCM - Traditional Chinese Medicine

Key Message

Quality of reporting adverse events, occurrence and severity is currently unknown for acupuncture during pregnancy. We have highlighted the paucity of reporting; however, on this basis adverse events appear minor and comparable with non-acupuncture interventions.

Introduction

The effectiveness of acupuncture for pregnancy-related ailments is an area of growing interest, with conditions such as pelvic girdle pain the subject of an increasing body of randomized controlled trial (RCT) evidence. A recent Cochrane review [1] reported moderate quality evidence in support of acupuncture for pelvic girdle pain and European guidelines recommend its use [2]. Favorable outcomes have been reported when acupuncture has been used for other pregnancy-related disorders such as low back pain [3], nausea and vomiting [4], dyspepsia [5], depression [6] and insomnia [7].

Best evidence on the types, severity and occurrence of adverse events as a result of receiving acupuncture during pregnancy is central to shared decision-making and informed consent. The range of adverse events that may be associated with acupuncture and moxibustion during pregnancy has recently been reviewed [8]; however, the definition of acupuncture was unclear, and no comparison was made between adverse events in acupuncture and non-acupuncture groups. Despite this recent review [8], the quality of reporting has yet to be established. In addition, the types, severity and occurrence of adverse events associated with a skin-penetrating needle compared with non-skin-penetrating interventions remains unclear.

Good Clinical Practice guidelines [9] suggest that authors should record any adverse event, categorize its severity and postulate if it is attributable to the intervention. An extension to the Consolidated Standards of Reporting Trials (CONSORT) statement [10] addressed the poor quality of reporting of adverse events in healthcare research, suggesting the use of the term “harms” and providing a series of recommendations on reporting. The Standards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA) guidelines [11], another extension of the CONSORT 2001 statement [12], were designed to improve the overall quality of reporting of acupuncture research trials. However, there has been little change in standards of reporting since their introduction [13].This systematic review will examine the quality of reporting of adverse events in studies of

acupuncture in pregnancy, using the CONSORT extension of harms [10] and STRICTA guidelines [11]. The types, severity and occurrence in women and fetuses/infants in both skin-penetrating needling and non-skin-penetrating treatment groups will also be assessed.

Material and methods

The following databases were searched between the years 2000 and 2014: MEDLINE; CINAHL; Allied and Complementary Medicine Database (AMED); and Physiotherapy Evidence Database (PEDro). English language restrictions were imposed. The keywords and truncations used in a combined search of MEDLINE, CINAHL and AMED using EBSCOhost Online Research Databases were ("acupuncture" OR "acupunct*" OR "acupuncture therap*" OR "segmental acupuncture" OR "Japanese acupuncture" OR "trigger point acupuncture" OR "auricular acupuncture" OR "ear acupuncture" OR "auricular acupuncture" OR "electroacupuncture" OR "electro-acupuncture" OR "electro acupuncture" AND "pregnant" OR "pregnan*" OR "pre-natal" OR "prenatal" NOT "fertility" OR "infertility". The search strategy was modified for PEDro. Hand searching of reference lists of retrieved articles was also carried out to identify further studies.

All types of research design using penetrating acupuncture in the treatment of pregnant women were considered for inclusion in this review. Studies focusing on women in labor were excluded. For the purpose of this review "acupuncture" was considered as any intervention that inserted needles into the skin, and is referred to as acupuncture throughout this article. If the authors used a skin-penetrating placebo acupuncture approach, this was termed, for reporting purposes of this study, as acupuncture. Studies that used non-penetrating sham acupuncture, and/or another non-acupuncture-related intervention were termed non-acupuncture and will be referred to as such throughout this article. No restrictions were placed on the dosage of the intervention administered.

The primary outcome of this review was to analyze the quality of reporting of adverse events in the included studies. The secondary outcomes were to report upon trends in: the occurrence of adverse events that were experienced following acupuncture and non-acupuncture; the severity and type of adverse events experienced; and the number of pregnant women affected by adverse events in acupuncture and non-acupuncture groups.

Titles and abstracts of studies identified by both electronic and hand searches were collated and reviewed. Full texts of studies meeting the inclusion criteria were screened and publications were included if there was mention of adverse events in mother or fetus/infant in the text or tables. Due to the inclusion of a wide variety of study design, more than one quality assessment tool was required. Included RCTs were assessed for methodological quality using the PEDro checklist [14], to assess the internal validity and statistical interpretability. The Downs and Black checklist [15] was used to assess the quality of included cohort and case studies. Quality of reporting was evaluated against the STRICTA guidelines [11] and CONSORT extension on harms guidelines [10]. The term "harms" has not been used in this review as not all adverse events extracted would be deemed harmful and therefore its use could be misleading. In accordance with Good Clinical Practice guidelines [9], the severity and description of events that were considered as adverse was extracted in line with the study authors' interpretation, not the interpretation of the authors of this review.

Methodological quality scores were calculated for each included study for the PEDro [14] and Downs and Black [15] checklists with higher scores indicating greater internal validity and statistical interpretability. Each study's quality of reporting against CONSORT [10] and STRICTA [11] guidelines was collated in tabular format.

For each included study the number of adverse events that occurred in both the acupuncture and non-acupuncture groups (if applicable), and the percentage in relation to the number of treatment sessions administered, were calculated. A range was calculated if the number of treatments received was variable, if the exact amount of adverse events was unclear or if the number of treatments received by drop outs (included in this analysis) was unclear. The number and percentage of women in acupuncture and non-acupuncture groups who experienced an adverse event was also calculated. An aggregate figure was calculated for percentage of adverse events experienced and percentage of women experiencing an adverse event.

Data on the severity of adverse events were analyzed in relation to an adverse event tree [9] where the judgment of the chief investigator in the primary study determined the event as serious or not; attributable to the study or not; and if attributable to the study, whether it was a serious adverse event, a serious related event or a serious adverse reaction. Data were not separated into ailments treated, as the acupuncture intervention would be very similar and there were too few studies to enable appropriate subgroup analysis.

Results

Study description

After removing duplicates, a total of 252 studies were identified, which were screened by title and abstract to determine their eligibility; 227 articles were excluded because they did not meet the selection criteria. Of the remaining 25 studies, eight [16-23] were excluded because they did not mention whether adverse events were found or not. A Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) diagram [24] (Figure 1) identifies the different stages of the selection process. Seventeen studies [3-7, 25-36] were included (Table 1) and systematically reviewed.

Ten studies investigated acupuncture's effect on pain [3, 26, 27, 29-33, 35, 36]; three studies investigated nausea and/or vomiting [4, 25, 34]; one investigated depression [6]; one emotional complaints [28] one dyspepsia [5] and another insomnia [7]. Thirteen studies used an RCT design [3-7, 25, 27-30, 32, 34, 36]; three employed a case study design [26, 31, 33], and another used a retrospective cohort design [35]. Five studies included women within the first trimester [4, 6, 25, 26, 34]. One author (da Silva) was the first named on four studies [5, 7, 27, 28], and two authors were first named on two articles, Elden [29, 30] and Ternov, who was also cited as Kvorning [32, 35]. Nine included studies were published in acupuncture-related journals [5, 7, 26-28, 30, 31, 33, 34] and six in journals directly related to women's health [3, 4, 6, 29, 32, 36]. Twelve studies compared acupuncture to a non-acupuncture group (Table 2) [3-7, 27-30, 32, 34, 36].

Methodological quality and quality of acupuncture-specific reporting

Table 2 relates key STRICTA guideline [11] domains to each included study. Table 2 also includes the PEDro scale [14] score for each RCT and the Downs and Black checklist [15] overall score for study quality for other study designs. Two-thirds of the included RCTs (n = 8) scored 5/10 or lower [5, 7, 25, 27-29, 32, 36] on the PEDro scale [14]. Higher methodological quality scores did not necessarily mean that the quality of acupuncture-specific reporting related to the STRICTA guidelines [11] was of a similarly higher standard. For example, of the five RCTs [3, 4, 6, 30, 34] scoring 6/10 or higher on the PEDro scale [14] only one study [6] reported on all criteria as for the STRICTA guidelines. Likewise, a lower methodological score did not necessarily indicate poorer compliance to STRICTA

guidelines [11]. Seven studies specified details of the practitioner's background [5-7, 25, 27, 28, 33]. Twelve studies described the type of acupuncture used, categorized into TCM or Western acupuncture [3-7, 25, 27, 28, 31, 33, 34, 36].

The reporting of needling approach (depth, number of needles and retention time) varied. Five studies did not give any description of the depth of needling [3, 31, 32, 35, 36]. The 12 studies that described the depth of needling used differing levels of detail. Five studies gave vague depths: “classical acupuncture depth” [5, 28], “traditional depth” [7, 27] and “standard depth” [6]. Six studies described the depth needled in either centimeters or millimeters and gave it as a range [4, 25, 26, 29, 30, 34].

Eight studies gave an incomplete description of the number and dimensions of the needles used [3, 25, 26, 29, 30, 32, 33, 35], and only one study did not report information on needle retention time [32].

Quality of adverse event reporting

Table 3 details the supporting information provided by included studies in relation to adverse events’ recording as recommended by the CONSORT extension on reporting of harms in RCTs [10]. Only five studies mentioned harms either within their title or abstract [29, 32, 34-36]. Eleven studies included infant health as part of their results [3, 5, 7, 27-29, 31, 32, 34-36], all of which stated that there were no adverse events attributable to acupuncture or non-acupuncture interventions. Three studies did not explain clearly whether adverse events were attributable to the intervention [4, 27, 35], and seven studies indicated that at least one adverse event experienced was attributable to the intervention [5-7, 26, 28, 29, 36]. The two studies that had adverse event reporting as a primary aim included the most supporting information [29, 34]. Eight studies [3-7, 30, 34, 36] failed to provide detailed information for all drop outs. The most common form of reporting of adverse event method appears to be patient self reporting (n = 7), though the method of reporting was unclear in seven studies [3, 25, 31-34, 36]. Four studies indicated measurement of adverse events to the medium term [3, 29, 31, 34], with no studies finding lasting health impacts to either mother of fetus/child.

Of the four publications that reported zero adverse events (Table 4) [25, 31, 33, 34], three [25, 31, 33] provided minimal information in relation to CONSORT guidelines on reporting harms [11].

Categories and types of adverse events

A number of trends were noted. Thirty-one non-serious adverse events were categorized as being potentially attributable to receiving acupuncture (Figure 2). One serious adverse event, premature labor, was attributed to being potentially acupuncture related and categorized as an unexpected serious related event. The investigators discontinued acupuncture from this point, and reported that the event ceased and had no lasting impact on mother/infant, delivering uneventfully at 42 weeks [35]. In the non-acupuncture groups, 19 non-serious adverse events were reported, all potentially attributable to the intervention (Figure 3). No serious adverse events were recorded as being potentially attributable to the intervention.

Altered taste, tiredness, treatment discomfort, uterine contractions, being placed on bed rest, treatment discomfort (noted as needle pain in acupuncture group) were all reported in both acupuncture and non-acupuncture groups. The details of the need for bed rest occurring in the acupuncture and non-acupuncture groups were not disclosed [3]. The serious events that were not attributable to acupuncture or non-acupuncture interventions were all noted in two studies [6, 34].

Occurrence of adverse events and numbers of women experiencing adverse events

Although all studies reported the total number of women, details on where dropouts occurred were not always clear. It was assumed for this review that if dropouts had suffered an adverse event, this would have been included in the overall reporting. In six studies the precise number of treatment sessions administered was difficult to ascertain [5-7, 27, 28, 35]. Of the 12 studies that included a non-acupuncture group [3-7, 27-30, 32, 34, 36], four did not articulate how many sessions the non-acupuncture groups received [5, 7, 27, 28], and one did not provide specific detail [6]. Where data were available, the acupuncture groups all received more sessions than the non-acupuncture groups.

Eight studies gave enough detail to calculate the precise number of treatment sessions that produced an adverse event [3, 4, 25, 26, 30, 31, 33, 34], four of them being zero [25, 31, 33, 34]. Two of the studies including women within the first trimester reported that zero adverse events occurred [25, 34]. For the nine remaining studies that did not give precise data [5-7, 27-29, 32, 35, 36], a range was calculated. Out of the 12 studies that compared penetrating acupuncture to a non-penetrating treatment, five studies [5, 7, 27, 28, 32] did not state whether adverse events were noted in the non-acupuncture groups, two studies suggested more adverse events occurred in the acupuncture group compared with the non-acupuncture groups [3, 4], one study suggested more adverse events in the non-acupuncture group [30], and in three studies it was unclear whether the acupuncture or non-acupuncture group experienced more adverse events [6, 29, 36]. One study found no difference between the groups [34]. The aggregate average percentage range of adverse events occurring within a treatment session was 3–17% in the acupuncture groups and 4–25% in the non-acupuncture groups.

An exact figure of how many women were affected by adverse events was clear in 12 studies [5, 7, 25-28, 30-34, 36]. When acupuncture was compared with non-acupuncture, the number of women affected by an adverse event was reported as: more in the non-acupuncture group in one study [36]; no difference in one study [34]; more in the acupuncture group in two studies [3, 30]; five did not state how many women were affected in the non-acupuncture groups [5, 7, 27, 28, 32]; and in three it was unclear [4, 6, 29].

The majority of types of adverse events experienced were transient and non-serious, with the one serious adverse event equating to 1 per 1193 women, or once per 7375–7941 sessions. On average, the percentage of women affected by an adverse event ranged between 14 and 17% in the acupuncture groups, and between 15 and 19% in the non-acupuncture groups. It was not possible to ascertain whether adverse events or the number of women affected by them, were more or less prevalent in the acupuncture compared with the non-acupuncture groups.

Discussion

This systematic review examined the quality of reporting of adverse events in studies of acupuncture in pregnancy, with trends noted in their type, occurrence and severity, in both acupuncture and non-acupuncture groups.

Overall the quality and clarity of reporting of adverse events was found to be poor. Only 17 studies out of a possible 25 reported on adverse events and of these 17 studies, only two studies provided adequate data [29, 34]. However, 11 studies did give some explanation as to whether at least one adverse event was attributable to the intervention received. This said, within these 11 studies the

reporting of attribution was not provided for all adverse events and a lack of clarity prevented exact data reporting for either adverse event occurrence or women affected. As a result, we cannot say whether the adverse events reported upon were considered to be as a result of the intervention the person received every time they occurred.

The wide range of what might be considered to be an adverse event in itself affects the level of reporting. For example, one study [29] recorded deqi as an adverse event, despite it being sought when inserting needles. For most clinicians, deqi is a desired response from acupuncture [37]. The CONSORT extension on harms statement [10] proposes the use of the term “side effect” for anything that may or may not be expected as a result of an intervention. An adverse event or harm should be reported separate from a side effect. Given the lack of consensus in the literature in relation to the reporting of adverse events, harms and side effects, the term “harm” was not adopted because it would have inadequately reflected the type of data that were extracted from included studies.

Explanations for the poor reporting could include researchers not collecting data on adverse events; authors being unaware or publishing before the creation of the CONSORT extension on harms statement in 2004 [10]; translation into English; or word limits in journals. However, it is important to report upon the trends that were noted on data extraction to help aid clinicians and patients on informed consent. Transient and non-serious adverse events were the norm in the included studies, and no adverse events were recorded as having an effect on the fetus, which supports a previous review [8]. The non-serious events were very similar in both acupuncture and non-acupuncture groups, which tentatively suggests that their occurrence is neither more nor less when receiving a skin-penetrating needle compared with another intervention. The one serious adverse event had no long lasting effect on mother or baby, and it was questionable as to whether it was attributable to inserting a needle. The data presented also suggest that some women experienced more than one adverse event.

In this review we noted no trends between adverse events and any of the following: the ailment being investigated, the trimester acupuncture was initiated, the mean age of participants, the type of acupuncture administered, country of publication, or the detail provided within the STRICTA [11] and CONSORT [10] guidelines.

The authors of this review took the decision to define acupuncture as a needle penetrating the skin, meaning where a penetrating placebo approach was adopted it was categorized as acupuncture, although it is acknowledged that a penetrating placebo approach would not necessarily be considered as acupuncture in clinical practice. Making the distinction between penetrating and non-penetrating interventions provides a clear comparison and can help with identifying whether needle penetration leads to greater or lesser risk of experiencing an adverse event.

This review used the best practice frameworks of STRICTA [11], CONSORT extension on harms [10] and Good Clinical Practice [9] adverse event reporting as the structure within which to present findings. As recommended, adverse event types have been reported upon based on the included studies’ authors’ interpretation. Given the generally poor reporting quality of the included studies, the provision of a range percentage in this review provides more insight into adverse event occurrence rate than the more common single figure, but cannot be interpreted with a great deal of confidence because of the paucity of information provided within individual studies. Although the clinical experience of author CEC, coupled with safety acupuncture research within the general population [38-40], would suggest that the real incidence lies closer to the more conservative percentages, the poor detail and clarity of reporting make this impossible to confirm.

As this was a systematic review looking at adverse events, it was necessary to use tools to assess study quality as well as reporting quality. Using different assessment tools for different studies hinders the uniformity of assessment from the review. Although the CONSORT extension of harms [10] is not a validated tool for assessing quality of reporting of adverse events, it is a guideline for authors to follow when publishing, and therefore its use in this review as a benchmark highlights the poor depth of reporting. Adverse events included did not necessarily arise as a result of acupuncture treatment, as demonstrated by the same types of adverse events being recorded in both acupuncture and non-acupuncture groups (Figures 2 and 3), and the reporting of adverse events was more often than not open to interpretation or had missing data. It is therefore beyond the scope of this review to suggest whether these adverse events occurred as a direct result of the intervention administered or was due to other factors. Based on our findings, the trend suggests that a penetrating needle appears to be as safe as non-acupuncture interventions; however, the amount of women included in the selected studies are unlikely to be enough to be representative of the population of pregnant women globally. Finally, studies that were not published in English were excluded from this analysis, and so a more accurate picture of types, severity and occurrence could potentially be gained from including non-English published studies.

The CONSORT statement [10] recommends that all trials publishing data on effectiveness should also publish any safety issues to help guide the reader in terms of the safety risk–benefit of the intervention under study. Authors should follow STRICTA [11], the CONSORT extension on harms [10] and Good Clinical Practice guidelines [9] when reporting results of acupuncture studies regardless of study design. They should clearly state whether they thought the adverse events/side effects observed were caused by the intervention, and if drop outs were as a result of experiencing an adverse event. We would also suggest that the CONSORT statement of harms [10] is extended to include details on the exact occurrence and amount of women affected. Due to editorial constraints and accompanying word limits, publishers could consider using adherence to the CONSORT statement as part of their consideration when receiving a manuscript. A uniform approach for the use of the terms “harms” and “side effects” would ensure that differentiation is made between desirable/undesirable effects and highlight those effects that were deemed potentially harmful. Enhanced reporting, including that of zero adverse events and of adverse events in all groups under study, would ensure that the severity, type and occurrence of adverse events were made transparent. Future investigation into the safety aspects of acupuncture in pregnancy should be extended into audit of adverse events in clinical settings. In addition, the characteristics of the individual women investigated could be researched to determine if there are particular attributes that predispose a woman to experience one or several adverse events.

Conclusion

This review has highlighted the poor quality of adverse event reporting and trends in severity, types and occurrence reported in the English language published literature on acupuncture in pregnancy. Adverse events do occur in the pregnant population, but would appear to be largely minor and transient and comparable to other non-acupuncture-related interventions. In the context of shared decision-making, pregnant women should be made aware of the severity, occurrence and type of potential adverse events associated with acupuncture before consenting to acupuncture treatment.

Funding

CEC and DEJ acknowledge institutional support.

References

1. Pennick V, Liddle SD. Interventions for preventing and treating pelvic and back pain in pregnancy. Cochrane Database Syst Rev. 2013;8:CD001139.

2. Vermani E, Mittal R, Weeks A. Pelvic girdle pain and low back pain in pregnancy: a review. Pain Pract. 2009;10:60–71.

3. Wang S-M, Dezinno P, Lin EC, Lin H, Yue JJ, Berman MR, et al. Auricular acupuncture as a treatment for pregnant women who have low back and posterior pelvic pain: a pilot study. Am J Obstet Gynecol 2009;201:271.e1–9.

4. Knight B, Mudge C, Openshaw S, White A, Hart A. Effect of acupuncture on nausea of pregnancy: a randomized, controlled trial. Obstet Gynecol. 2001;97:184–8.

5. da Silva JBG, Nakamura MU, Cordeiro JA, Kulay JL, Saidah R. Acupuncture for dyspepsia in pregnancy: a prospective, randomised, controlled study. Acupunct Med. 2009;27:50–3.

6. Manber R, Schnyer RN, Lyell D, Chambers AS, Caughey AB, Druzin M, et al. Acupuncture for depression during pregnancy: a randomized controlled trial. Obstet Gynecol. 2010;115:511–20.

7. da Silva JBG, Nakamura MU, Cordeiro JA, Kulay LJ. Acupuncture for insomnia in pregnancy – a prospective, quasi-randomised, controlled study. Acupunct Med. 2005;23:47–51.

8. Park J, Sohn Y, White AR, Lee H. The safety of acupuncture during pregnancy: a systematic review. Acupunct Med. 2014;32:257–66.

9. National Institute for Health Research (NIHR) Clinical Research Network. Introduction to Good Clinical Practice (GCP) A practical guide to ethical and scientific quality standards in clinical research. Leeds: NIHR Clinical Research Network, 2012.

10. Ioannidis JP1, Evans SJ, Gøtzsche PC, O'Neill RT, Altman DG, Schulz K, et al. Better reporting of harms in randomized trials: an extension of the CONSORT statement. Ann Intern Med. 2004;141:781–8.

11. Macpherson H, Altman DG, Hammerschlag R, Youping L, Taixiang W, White A, et al. Revised STandards for Reporting Interventions in Clinical Trials of Acupuncture (STRICTA): extending the CONSORT statement. PLoS Med. 2010;7:100–6.

12. Moher D, Schulz KF, Altman DG. The CONSORT statement: revised recommendations for improving the quality of reports of parallel-group randomised trials. Lancet. 2001;357:1191–4.

13. Prady SL, Richmond SJ, Morton VM, MacPherson H. A systematic evaluation of the impact of STRICTA and CONSORT recommendations on quality of reporting for acupuncture trials. PLoS Med. 2008;3:157–77.

14. Sherrington C, Herbert RD, Maher CG, Moseley AM. PEDro: a database of randomised trials and systematic reviews in physiotherapy. Manual Ther. 2000;5:223–6.

15. Downs SH, Black N. The feasibility of creating a checklist for the assessment of the methodological quality both of randomised and non-randomised studies of health care interventions. J Epidemiol Community Health. 1998;52:377–84.

16. Ekdahl L, Petersson K. Acupuncture treatment of pregnant women with low back and pelvic pain – an intervention study. Scand J Caring Sci. 2010;24:175–82.

17. Gear J. Acupuncture for nausea in early pregnancy: a discussion and case. J Chinese Med. 2008;86:18–23.

18. Harper T, Coeytaux R, Chen W, Campbell K, Kaufman JS, Moise KJ, et al. A randomized controlled trial of acupuncture for initiation of labor in nulliparous women. J Matern Fetal Neonatal Med. 2006;19:465–70.

19. Lund I, Lundeberg T, Lonnberg L, Svensson E. Decrease of pregnant women's pelvic pain after acupuncture: a randomized controlled single-blind study. Acta Obstet Gynecol Scand. 2006;85:12–19.

20. Oomman S, Liu D, Cummings M. Acupuncture for acute postoperative pain relief in a patient with pregnancy-induced thrombocytopenia – a case report. Acupunct Med. 2005;23:83–5.

21. Schnyer RN. Acupuncture treatment for depression during pregnancy: conceptual framework and two case reports. Complementary Health Practice Rev. 2003;8:40–52.

22. Thomas CT, Napolitano MPG. Use of acupuncture for managing chronic pelvic pain in pregnancy – a case report. J Reprod Med. 2000;45:944–8.

23. Manber R, Schnyer RN, Allen JJB, Rush AJ, Blasey CM. Acupuncture: a promising treatment for depression during pregnancy. J Affect Disord. 2004;83:89–92.

24. Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. PLoS Med. 2009;6:e1000097.

25. Carlsson CP, Axemo P, Bodin A, Carstensen H, Ehrenroth B, Madegård-Lind I, et al. Manual acupuncture reduces hyperemesis gravidarum. J Pain Symptom Manage. 2000;20:273–9.

26. Cummings M. Acupuncture for low back pain in pregnancy. Acupunct Med. 2003;21:42–6.

27. da Silva JB, Nakamura MU, Coredeiro JA, Kulay JL. Acupuncture for low back pain in pregnancy – a prospective, quasi-randomised, controlled study. Acupunct Med. 2004;22:60–7.

28. da Silva J. Acupuncture for mild to moderate emotional complaints in pregnancy – a prospective, quasi-randomised, controlled study. Acupunct Med. 2007;25:65–71.

29. Elden H, Fagevik-Olsen M, Ostgaard HC, Stener-Victorin E, Hagberg H. Acupuncture as an adjunct to standard treatment for pelvic girdle pain in pregnant women: randomised double-blinded controlled trial comparing acupuncture with non-penetrating sham acupuncture. BJOG. 2008;115:1655–68.

30. Elden H, Ostgaard H, Fagevik-Olsen M, Ladfors L, Hagberg H. Treatments of pelvic girdle pain in pregnant women: adverse effects of standard treatment, acupuncture and stabilising exercises on the pregnancy, mother, delivery and the fetus/neonate. BMC Complement Altern Med. 2008;8:34.

31. Forrester M. Low back pain in pregnancy. Acupunct Med. 2003;21:36–41.

32. Kvorning N, Holmberg C, Grennert L, Åberg A, Åkeson J. Acupuncture relieves pelvic and low-back pain in late pregnancy. Acta Obstet Gynecol Scand. 2004;83:246–50.

33. Rouse S. The use of acupuncture in the physiotherapy treatment of pelvic pain in pregnancy. J Acupuncture Assoc Chartered Physiother. 2008;1:67–72.

34. Smith C, Crowther C, Beilby J. Acupuncture to treat nausea and vomiting in early pregnancy: a randomized controlled trial. Birth. 2002;29:1–9.

35. Ternov NK, Grennert L, Åberg A, Algotsson L, Åkeson J. Acupuncture for lower back and pelvic pain in late pregnancy: a retrospective report on 167 consecutive cases. Pain Med. 2001;2:204–7.

36. Wedenberg K, Moen B, Norling A. A prospective randomized study comparing acupuncture with physiotherapy for low-back and pelvic pain in pregnancy. Acta Obstet Gynecol Scand. 2000;79:331–5.

37. Hopwood V. Acupuncture in physiotherapy. Oxford: Butterworth Heinemann, 2004.

38. White A, Hayhoe S, Hart A, Ernst E. Adverse events following acupuncture: prospective survey of 32,000 consultations with doctors and physiotherapists. BMJ. 2001;323:485–6.

39. Macpherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34,000 treatments by traditional acupuncturists. BMJ. 2001;323:486–7.

40. Witt CM, Pach D, Brinkhaus B, Wruck K, Tag B, Mank S, et al. Safety of acupuncture: results of a prospective observational study with 229,230 patients and introduction of a medical information and consent form. Forsch Komplementmed. 2009;16:91–7.

Figure 1: Flow chart of articles identified through the review process (PRISMA)

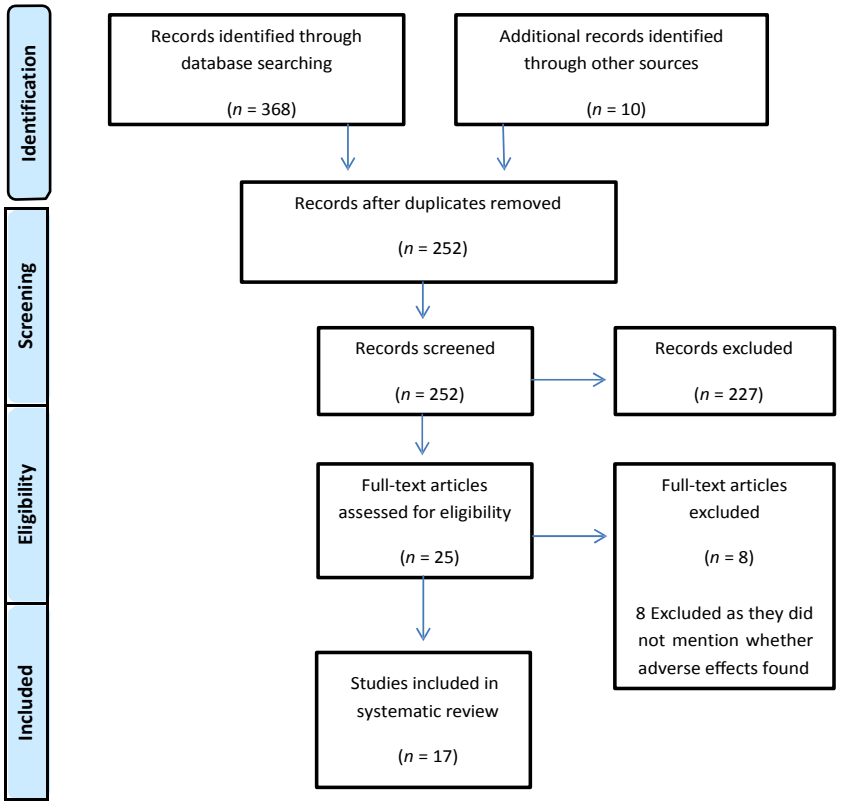

Table 1: Characteristics of included studies

Study/location	Study design	Trimester intervention introduced[a]	Ailment researched	Overall findings – Acupuncture effective?	Publishing journal
Carlsson et al. (25) Sweden	RCT	1–2	Nausea and vomiting	Yes	Journal of Pain and Symptom Management
Cummings (26) UK	Case study	1	LBP	Yes	Acupuncture in Medicine
da Silva et al. (27) Brazil	RCT	2–3	LBP	Yes	Acupuncture in Medicine
da Silva et al. (7) Brazil	RCT	2–3	Insomnia	Yes	Acupuncture in Medicine
da Silva (28) Brazil	RCT	2–3	Emotional complaints	Yes	Acupuncture in Medicine
da Silva et al. (5) Brazil	RCT	2–3	Dyspepsia	Yes	Acupuncture in Medicine
Elden et al. (29) Sweden	RCT	2–3	PGP	Yes	BJOG
Elden et al. (30) Sweden	RCT	2–3	PGP	ND	BMC Complementary and Alternative Medicine
Forrester (31) UK	Case study	2	LBP	Yes	Acupuncture in Medicine
Knight et al. (4) UK	RCT	1	Nausea	ND	Obstetrics and Gynecology
Kvorning et al. (32) Sweden	RCT	2–3	LBP and PGP	Yes	Acta Obstetricia et Gynecologica Scandinavica
Manber et al. (6) USA	RCT	1–3	Depression	Yes	Obstetrics and Gynecology
Rouse (33) UK	Case study	3	PGP	Yes	Journal of the Acupuncture Association of Chartered Physiotherapists
Smith et al. (34) Australia	RCT	1–2	Nausea and vomiting	Yes	Complementary Therapies in Medicine
Ternov et al. (35) Sweden	Case studies[b]	2–3	LBP and PGP	Yes	Pain Medicine
Wang et al. (3) USA	Pilot RCT	3	LBP and PGP	Yes	American Journal of Obstetrics and Gynecology
Wedenberg et al. (36) Sweden	RCT	2–3	LBP and PGP	Yes	Acta Obstetricia et Gynecologica Scandinavica

LBP, low back pain; ND, no difference; PGP, pelvic girdle pain; RCT, randomized control trial.

[a]1–11 weeks considered first trimester, 12–24 weeks considered second trimester, 25+ weeks considered third trimester.

[b]Retrospective cohort.

Table 2: Quality of reporting of included studies in relation to STRICTA (11) checklist

Study	Methodology quality score	Practitioner background specified?	Style of acupuncture stated?	Non-acupuncture group intervention reported?	Frequency of acupuncture reported fully?	Depth of needling reported?	Number of points needled and needle dimensions reported fully?	Needle retention time stated?
Carlsson et al. (25)	4/10	Yes	TCM	NA	Yes	Yes	No	Yes
Cummings (26)	10/15, 67%	No	U	NA	No	Yes	No	Yes
da Silva et al. (27)	3/10	Yes	TCM	Yes	Yes	Yes	Yes	Yes
da Silva et al. (7)	2/10	Yes	TCM	Yes	Yes	Yes	Yes	Yes
da Silva (28)	3/10	Yes	TCM	Yes	Yes	Yes	Yes	Yes
da Silva et al. (5)	4/10	Yes	TCM	Yes	Yes	Yes	Yes	Yes
Elden et al. (29)	4/10	No	U	Yes	Yes	Yes	No	Yes
Elden et al. (30)	9/10	No	U	Yes	Yes	Yes	No	Yes
Forrester (31)	9/15, 60%	No	Western	NA	Yes	No	Yes	Yes
Knight et al. (4)	7/10	No	TCM	Yes	Yes	Yes	Yes	Yes
Kvorning et al. (32)	4/10	No	U	Yes	Yes	No	No	No
Manber et al. (6)	6/10	Yes	TCM	Yes	Yes	Yes	Yes	Yes
Rouse (33)	9/15, 60%	Yes	Western and TCM	NA	Yes	Yes	No	Yes
Smith et al. (34)	8/10	No	TCM	Yes	Yes	Yes	Yes	Yes
Ternov et al. (35)	17/26, 65%	No	U	NA	No	No	No	Yes
Wang et al. (3)	6/10	No	Western	Yes	Yes	No	No	Yes
Wedenberg et al. (36)	4/10	No	Western	Yes	Yes	No	Yes	Yes

NA, not applicable; STRICTA, Standards for Reporting Interventions in Clinical Trials of Acupuncture; TCM, traditional Chinese medicine; U, unclear; Western, Western style acupuncture.

Table 3: Qulaity of reporting of included studies in relation to CONSORT Better Reporting of Harms in Randomised Trials (10) checklist

Study	AE reporting in title/ abstract?	AE reporting a specified aim of study?	Discussion of benefits/ harms in article?	Validated scale to assess harms?	AE expected?	AE reporting method	Full drop out information provided?[a]	Intervention attributable to at least one AE?	Medium to long-term effects measured?	Infant health measured?
Carlsson et al. (25)	No	No	No	U	U	U	Yes	NA	NA	U
Cummings (26)	No	No	Yes	U	U	PSR	Yes	Yes	No	No
da Silva et al. (27)	No	No	No	U	U	PSR	Yes	U	No	Yes
da Silva et al. (7)	No	No	No	U	U	PSR	No	Yes	No	Yes
da Silva (28)	No	No	No	U	Yes	PSR	Yes	Yes	No	Yes
da Silva et al. (5)	No	No	No	U	U	PSR	No	Yes	No	Yes
Elden et al. (29)	Yes	Yes	Yes	U	Yes	IQ	Yes	Yes	Yes	Yes
Elden et al. (30)	No	No	No	U	U	PSR	No	No	No	No
Forrester (31)	No	No	Yes	U	U	U	Yes	NA	Yes	Yes
Knight et al. (4)	No	No	No	U	U	PSR	No	U	No	No
Kvorning et al. (32)	Yes	No	Yes	U	Yes	U	Yes	No	No	Yes
Manber et al. (6)	No	No	Yes	U	U	IQ	No	Yes	U	No
Rouse (33)	No	No	Yes	U	U	U	Yes	NA	No	No
Smith et al. (34)	Yes	Yes	Yes	Yes	Yes	IQ	No	No	Yes	Yes
Ternov et al. (35)	Yes	No	Yes	U	U	U	Yes	U	No	Yes
Wang et al. (3)	No	No	No	U	U	U	No	Partially	Yes	Yes
Wedenberg et al. (36)	Yes	No	No	U	U	U	No	Yes	No	Yes

AE, adverse event; IQ, investigator questioning; NA, not applicable; PSR, participant self-reporting; U, unclear.

[a]How many drop outs from each group and whether the drop out was as a result of the intervention received.

Table 4: Percentage adverse event occurrence and percentage affected in acupuncture vs non-acupuncture groups

Study	Total sample size (women who received acupuncture)	Number of sessions: acupuncture/ nonacupuncture[a]	% of times that adverse events occurred: acupuncture/ nonacupuncture[a]	% of women who experienced an adverse event: acupuncture/ nonacupuncture[a]
Carlsson et al. (25)	37	416/NA	0/NA	0/NA
Cummings (26)	1	20/NA	10/NA	100/NA
da Silva et al. (27)	61 (27)	216–324/NA	2–28/U	22/U
da Silva et al. (7)	22 (12)	96–144/NA	1–13/U	8/U
da Silva (28)	44 (25)	200–300/NA	1–24/U	16/U
da Silva et al. (5)	36 (20)	160–240/NA	1–8/U	5/U
Elden et al. (29)	108(56)	672/624	8–100/5–100	96–100/65–100
Elden et al. (30)	386 (124)	1414/261	5/11	35/11
Forrester (31)	1	7/NA	0/NA	0/NA
Knight et al. (4)	55 (28)	103/100	11/8	4-39/4-30
Kvorning et al. (32)	72 (37)	222/105	3–38/U	38/U
Manber et al. (6)	150 (101)	863–1093/466–566	2–31/1–11	2–22/10
Rouse (33)	1	9/NA	0/NA	0/NA
Smith et al. (34)	552 (414)	2070/138	0/0	0/0
Ternov et al. (35)	167	495[b]/NA	6[b]/NA	17–22/NA
Wang et al. (3)	159 (112)	112/47	5/2	4–5/2
Wedenberg et al. (36)	60 (30)	300/270	1–7/2	7/19
Total	1919 (1193)	7375–7941/2011–2111	3–17/4–25[c]	14–17/15–19[c]

NA, not applicable; U, unclear.

[a]A range was calculated if the number of treatments received, occurrence or amount of women effected by adverse events were open to interpretation, variable or if the number of treatments received by drop outs was unclear.

[b]Upper limit unable to be calculated.

[c]Aggregate average percentage, rounded up if 0.5 or above.

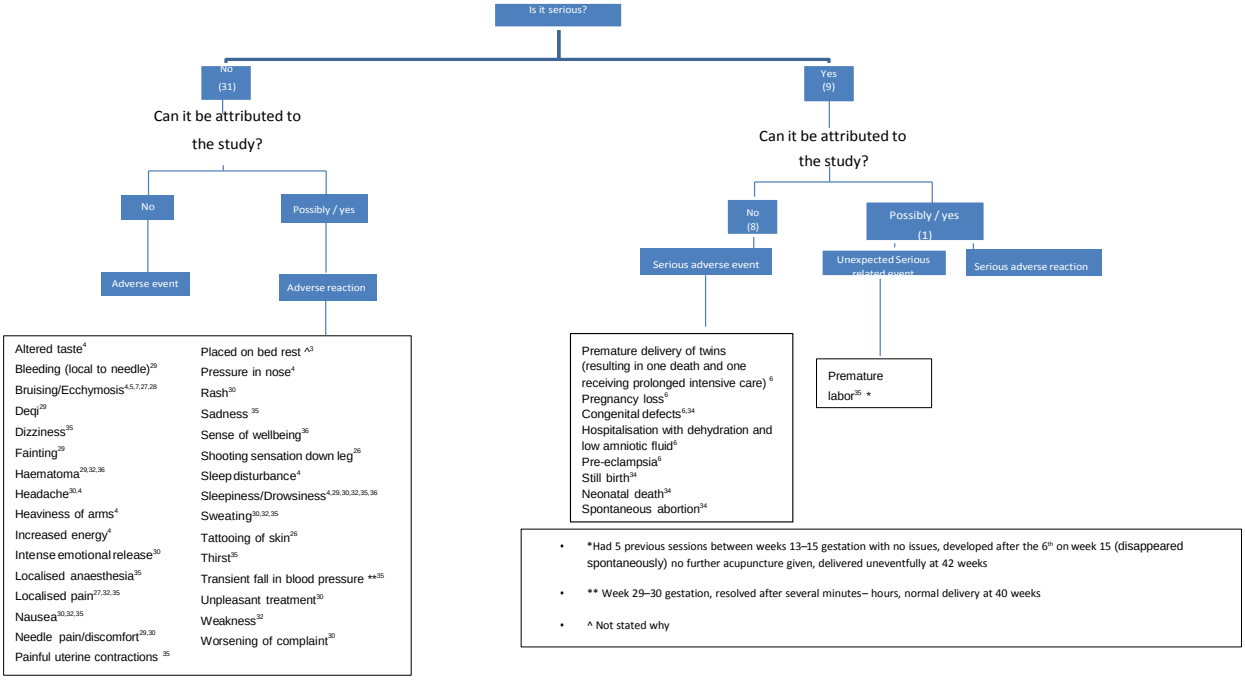

Figure 2. Adverse events reported in acupuncture groups.

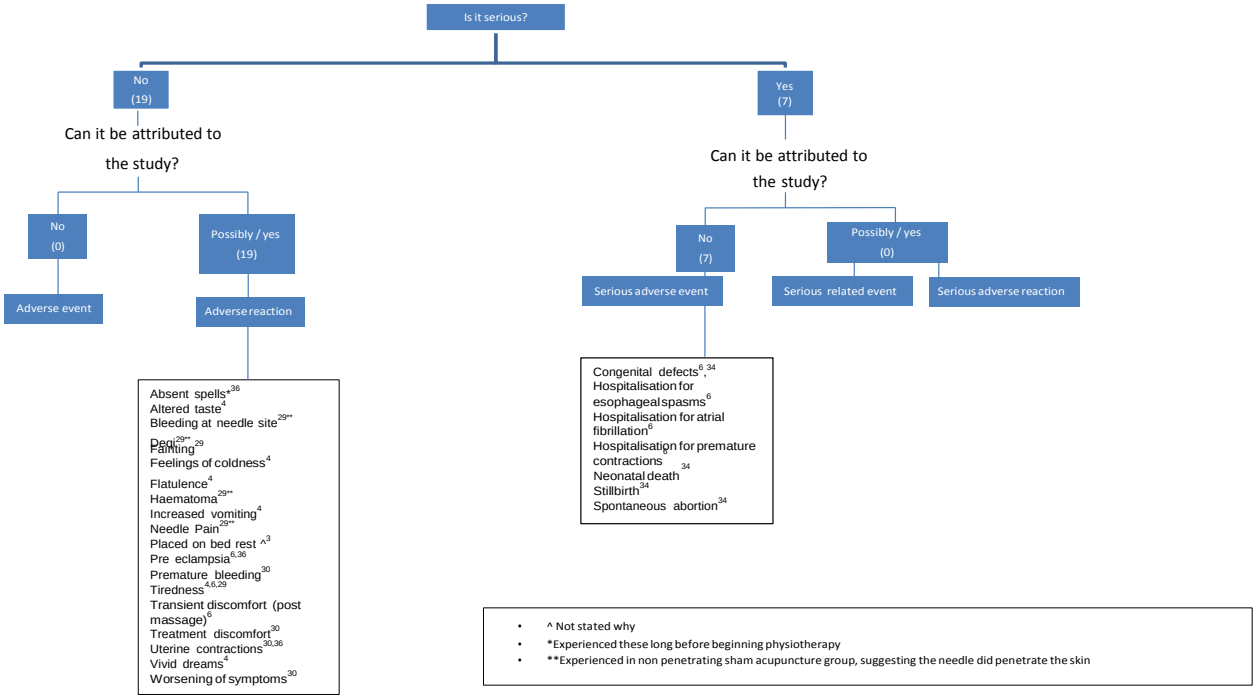

Figure 3. Adverse events in non-acupuncture groups.