The safety of acupuncture during pregnancy: a systematic review

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CRD summary
This review assessed the safety of acupuncture treatment during pregnancy, concluding that adverse events were generally mild, and that serious adverse events were rare. Given the generally poor quality of reporting in the included studies and the somewhat limited data and evidence synthesis, the authors’ conclusions should not be considered reliable, particularly when not presented alongside acupuncture effectiveness data.

Authors’ objectives
To assess the safety of acupuncture treatment during pregnancy.

Searching
Ten databases (including MEDLINE and the Cochrane Central Register of Controlled Trials CENTRAL) were searched up to February 2013 for articles published in English, Korean or Chinese. Search terms were reported. In addition, reference lists of relevant articles were manually screened.

Study selection
Studies were eligible for inclusion if they assessed the safety of acupuncture needling and/or moxibustion treatment for any condition in pregnant women. Studies were excluded if they assessed acupuncture for delivery, abortion, assisted reproduction, or postpartum conditions.

Included studies were published from 1998 to 2013; they were conducted in Brazil, USA, Europe (including four UK studies), China, Korea, and Australia. The most frequently treated condition was low back pain and/or pelvic pain, followed by foetal malposition. Other conditions treated included nausea and vomiting, insomnia (for example). Acupuncture regimens varied across studies; the number of sessions ranged from two to 40 over five days to eight weeks. Some acupuncture regimens were administered in conjunction with other interventions, such as bee venom pharmacopuncture. Control groups received sham acupuncture, usual care, or no treatment. Most studies stated that acupuncture was administered by an acupuncturist (where reported). Adverse events were reported mostly by participants, but were reported by health care practitioners in some studies.

Two reviewers screened studies for inclusion.

Assessment of study quality
Previously published quality assessment criteria were modified to assess the quality of randomised controlled trials (RCTs) and controlled clinical trials (CCTs). Each of the six criterion were assessed as yes, no, or unclear reporting.

At least two reviewers performed the quality assessment, with discrepancies resolved through discussion.

Data extraction
The incidence (number of adverse events per number of acupuncture sessions as %) of maternal and foetal adverse events were extracted by two reviewers and validated by another reviewer. Mean/median values were preferentially extracted where available. Otherwise, the midpoint value between minimum and maximum range values was extracted.

Study authors were contacted where necessary. Where participants dropped out, but the number of treatments they received was not reported, the participants were considered to have been treated once. Where the number of treatments was not reported at all, the number of participants acted as the denominator.

Methods of synthesis
The incidence of adverse events was reported as a narrative synthesis according to study design, and also severity (based on the Common Terminology Criteria for Adverse Events scale) and causality of adverse events (defined as certain, probable, possible, unlikely caused by the acupuncture, or could not be assessed).
Sensitivity analysis was undertaken to compare studies that reported adverse events versus studies that calculated adverse events by including poor pregnancy outcomes (perinatal outcomes, congenital abnormalities, pregnancy complications, and foetal outcomes).

**Results of the review**

One hundred and five articles were included in the review, comprising 42 RCTs, six CCTs, 54 case series/reports, and three surveys. The quality of data from RCTs and CCTs was mostly poor (findings were fully reported in the review).

Fifty five studies did not mention adverse events, 22 studies reported there were no adverse events, and one study reported that fewer adverse events occurred in the acupuncture group, but with no further details. Twenty five studies (27 articles) reported details on 429 adverse events. The total incidence of adverse events in the acupuncture group was 1.9% (429 events in 22,283 sessions). The risk of mild/moderate adverse events was 1.5%.

**Mild adverse events** (322 events): Mild adverse events (302) involved maternal complications, mostly needle or unspecified pain or local bleeding, but also including events such as rash or sleep disturbance and excessive fatigue. Mild foetal adverse events (20) included small for date and multiple twists of the umbilical cord or shoulder.

**Moderate adverse events** (6 events): Moderate adverse events included fainting and transient fall in blood pressure.

**Severe adverse events** (99 events): Severe maternal complications (86) mainly included events such as hypertension and/or pre-eclampsia, but also included preterm delivery (<37 weeks), tachycardia and atrial sinus arrhythmia. Severe adverse events were considered unlikely to have been caused by acupuncture treatment. Foetal complications included congenital defects and admission to neonatal intensive care units due to preterm delivery. There were two infant deaths considered unlikely to be caused by acupuncture and no maternal deaths.

Sensitivity analysis reported that the total incidence of adverse events in the acupuncture groups was 4.8%.

Further results were reported in the review.

**Authors’ conclusions**

Adverse events associated with acupuncture during pregnancy were generally mild and transient, and serious adverse events were rare.

**CRD commentary**

The review question and supporting inclusion criteria were broadly stated. The literature search was comprehensive but, as the search was limited by language, relevant articles may have been missed. The authors acknowledged the potential for publication bias. Each stage of the review process was performed in duplicate, thereby minimising the potential for reviewer error and bias.

The quality of RCTs and CCTs was assessed; most studies were considered to be poorly reported. A large body of evidence was identified, but approximately half the studies did not mention adverse events. The total number of pregnant women included in the review was unclear. The narrative synthesis was somewhat limited and it would have been useful to present incidence rates for control groups to allow comparisons to be made between the two treatment groups. There was variability across studies in acupuncture regimens and who administered treatment. Most adverse events were self-reported, which may have introduced some form of bias. The authors acknowledged that there was a lack of appropriate information on obstetric complications and the possibility that the adverse event incidence may have been underestimated in the review.

Given the poor quality of reporting in the included studies and the limitations of the evidence, the authors’ conclusions should not be considered reliable, particularly when not presented alongside data on the effectiveness of acupuncture.

**Implications of the review for practice and research**

**Practice:** The authors stated that pregnant women should be informed of the findings, together with the effectiveness data, to enable them to make an informed decision.

**Research:** The authors stated that further evidence was required on the safety of acupuncture in pregnant women.
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