# EBM Journal Club acupuncture induce abortion?

R2 王甜如

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陳星諭 醫師

### Outline

- Clinical Scenario
- Background
- A
- A
- A
- A
- A

必考題:AAAAA

PICO

## Clinical Scenario



## Background

- During pregnancy → pregnant women's health
   → the infant
- Over drug use → other treatments?
- Survey :
  - 575 women (Chinese medical care) → 17.4% received acupuncture for reproductive conditions.
  - acupuncture (North Carolina) → 19.5% of nurse midwives during pregnancy.

→ safety of acupuncture for pregnant women?

## Background

- Prospective survey on adverse events (AEs)
  - → acupuncture sessions : 0.01 per 10 000
  - → individual patients : 0.09 per 10 000

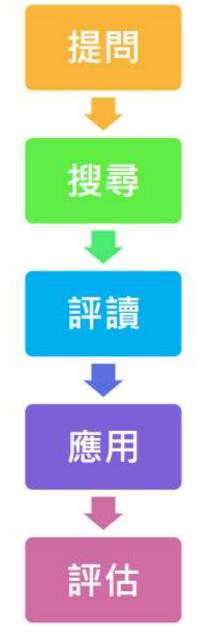
'very low'

- A systematic review (paediatric acupuncture)
  - → AEs were mild, and rare serious harms were identified.
  - → sporadic data during pregnancy
- general population : safe
- pregnant women: risk vs. benefit???

→ AEs associated with acupuncture + during pregnancy

### 執行實證醫學五大步驟

- 提出問題(Ask: PICO)
  - Formulate an answerable question
- 搜尋證據(Acquire)
  - Track down the best evidence
- 嚴格評讀(Appraisal: VIP)
  - Critically appraise the evidence
- 恰當應用(Apply: 3E)
  - Integrate with clinical expertise and patient values
- 評估結果(Audit)
  - Monitoring your performance

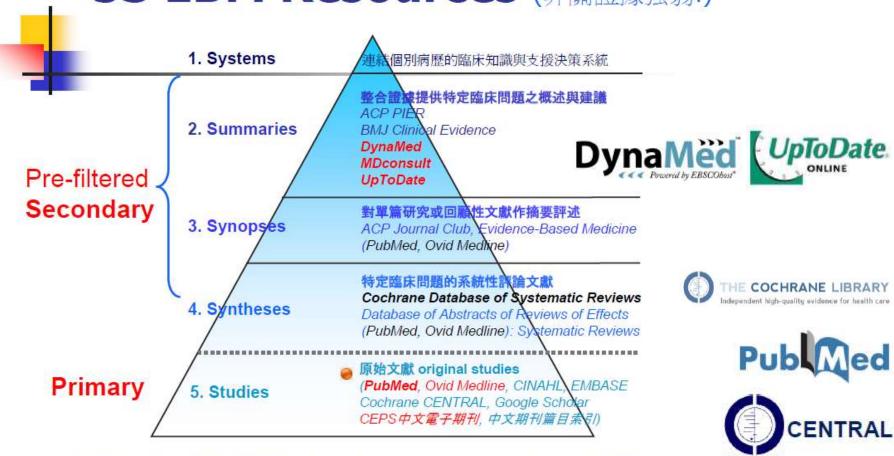


## Step 1: Asking

Problem 病人問題	Pregnancy
ntervention 介入處置	Acupuncture
Comparison 對照的處置	No acupuncture
Outcome 臨床結果	Abortion rate → side effect/adverse effect?

## Step 2: Acquire

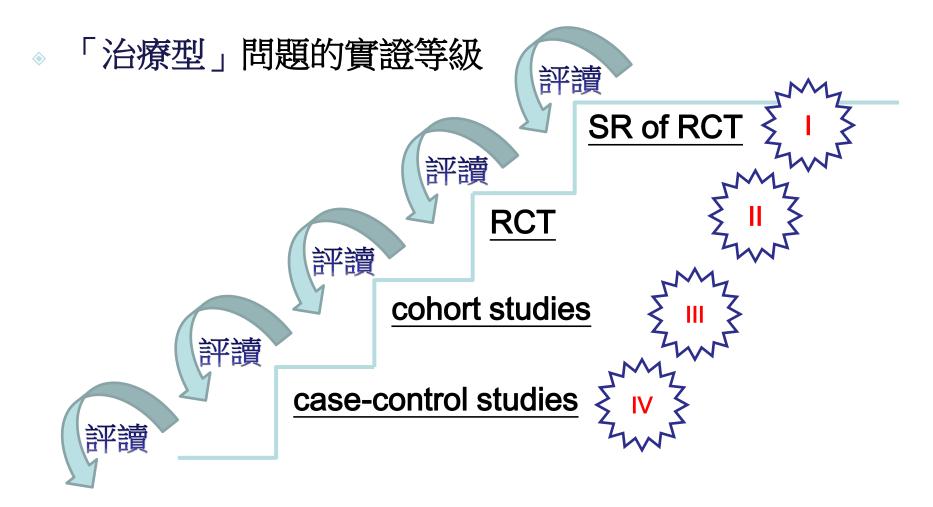
5S EBM Resources (非關證據強弱!)



COLLABORATION\*

Model from: Haynes, R. B. (2006). Of studies, syntheses, synopses, summaries, and systems: the "5S" evolution of information services for evidence-based health care decisions. ACP Journal Club, 145(3), A8.

## Search Strategy



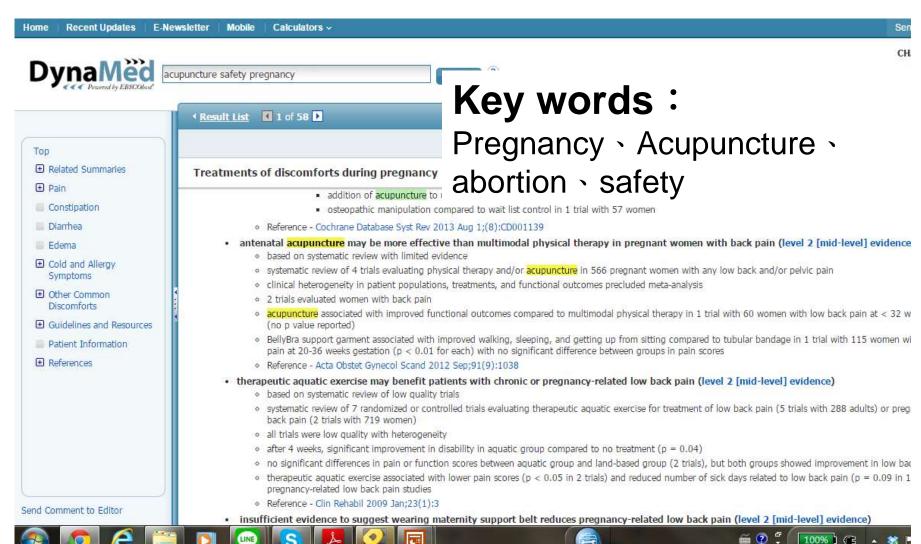


### **UptoDate**

acupuncture and pregr	nancy	→ All Topics	Contents
Search Results for "a	cupuncture and pregnancy"		
Click related term for All Topics	acupuncture: complementary and alternative and outcome of a	Ke	y words:
<ul><li>○ Adult</li><li>○ Pediatric</li><li>○ Patient</li></ul>	<ul> <li>Summary and recommendate</li> <li>Initial approach</li> <li>P6 acupressure point (Picture)</li> <li>Algorithm for treatment of na</li> </ul>	Pre abo	egnancy · Acupunctu ortion · safety
○ Graphics 👵	Musculoskeletal changes at	NEW STREET	gnancy and postpartum
	Induction of labor  Summary and recommendate	ions	
	Complementary and alterna  Specific therapies	tive therapies for a	Illergic rhinitis and conjunctivitis

Pregnancy is not an absolute contraindication, since acupuncture has been used and studied for gestational conditions such as breech presentation and pregnancy-associated nausea [95-100]. According to acupuncture theory, however, some points can induce labor, and the acupuncturist should be informed of the pregnancy [101,102]

## Dynamed



### **EBM ALL**



Key words:

Pregnancy safety · My Workspace OvidMD Search **Books** Multimedia Journals Acupuncture · abortion · ▼ Search History (8 searches) (close) side effect Searches acupuncture safety.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] **RESULT:** 2 pregnancy.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] Review(0) acupuncture side effect.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] ⇒ □ DISPLAY More ≫ abortion.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw] Advanced 4 ▶ 2543 → Display More ≫ 5 1 and 2 Advanced Delete Save 2 and 3 0 Advanced Delete E Save 7 3 and 4 0 Advanced ▶ 💢 Delete E Save 1 and 4 8 0 Advanced Delete Save Combine selections with: Save Search History

### **EBM ALL**

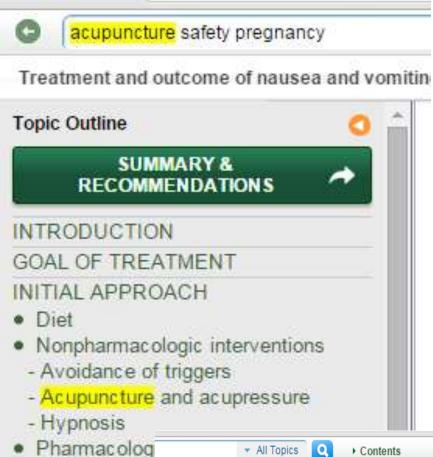


Hea	lth			<b>Kev</b>	wor	ds:		
	1	acupuncture.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	•		nancy			
	2	complication.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	•	•	ounctui ounctui		•	\
	3	pregnant.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	•	- Abor		ic side	S GIIG	;()
	4	abortion.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	•	RES	SULT	•		
	5	adverse event.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	•	¯ Revi	ew(0)		More ≫	
	6	1 and 3	•	149	Advanced	• Display	More ≫	
	7	5 and 6	•	9	Advanced	Display	More ≫	
	8	1 and 2 and 3	•	15	Advanced	Display	More ≫	
	9	1 and 3 and 5	•	9	Advanced	Display	More ≫	
	10	acupuncture during pregnancy.mp. [mp=ti, ot, ab, tx, kw, ct, sh, hw]	٠	13	Advanced	Display	More »	

Institution	Perinatal Center, Department of Obstetrics and Gynecology, Institute for Clinical Sciences, Sahlgrenska Academy, Sahlgrenska University Hospital/East, Gothenburg University, Gothenburg, SE-416 85, Sweden. helen.elden@vgregion.se
Title	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.
Source	BMC complementary and alternative medicine. Vol.8, pp.34, 2008.
Abstract	BACKGROUND: Previous publications indicate that acupuncture is efficient for the treatment of pelvic girdle pain, PGP, in pregnant women. However, the use of acupuncture for PGP is rare due to insufficient documentation of adverse effects of this treatment in this specific condition. The aim of the present work was to assess adverse effects of acupuncture on the pregnancy, mother, delivery and the fetus/neonate is comparison with women that received stabilising exercises as adjunct to standard treatment or standard treatment alone.  METHODS: In all, 386 women with PGP entered this controlled, single-blind trial. They were randomly assigned to standard treatment plus acupuncture (n = 125), standard treatment plus specific stabilising exercises (n = 131) or to standard treatment alone (n = 130) for 6 weeks. Acupuncture that may be considered strong was used and treatment was started as early as in the second trimester of pregnancy. Adverse effects were recorded during treatment and throughout the pregnancy. Influence on the fetus was measured with cardiotocography (CTG) before-during and after 43 acupuncture sessions in 43 women. A standardised computerized method to analyze the CTG reading numerically (Oxford 8000, Oxford, England) was used. After treatment, the women rated their overall experience of the treatment and listed adverse events if any in a questionnaire. Data of analgesia and oxytocin augmentation during labour, duration of labour, frequency of preterm birth, operative delivery, Apgar score, cord-blood gas/acid base balance and birth weight were also recorded.
	RESULTS: There were no serious adverse events after any of the treatments. Minor adverse events were common in the acupuncture group but women rated acupuncture favourably even despite this. The computerized or visually assessed CTG analyses of antenatal recordings in connection with acupuncture were all normal.
	CONCLUSION: This study shows that acupuncture administered with a stimulation that may be considered strong led to minor adverse complaints from the mothers but had no observable severe adverse influences the pregnancy, mother, delivery or the fetus/neonate.
Publication Type	Journal Article, Randomized Controlled Trial, Research Support, Non-U.S. Gov't

Elden H, Ostgaard HC, Fagevik-Olsen M, Ladfors L, Hagberg H

Author





#### Key words:

Acupuncture during pregnancy
Acupuncture safety pregnancy

g of pregnancy

Patient Info | acupuncture 3個,共9個 ▲

g of pregnancy

acupuncture Find Patient Print

vitamins before bed with a snack, instead of in the morning or on an empty stomach, may also be helpful [13].

Acupuncture and acupressure — P6 acupressure wristbands (picture 1) do not require a prescription and have become a popular self-administered intervention [14]. A 2014 systematic review of randomized trials did not find P6 acupuncture or acupressure wristbands significantly more effective than placebo [15]. One reason may be that a strong placebo effect has been observed in patients who receive sham therapy [16-19]. Self-administered nerve stimulation therapy over the volar aspect of the wrist at the P6 acupressure point using a commercial device also showed some promise in a randomized, controlled trial [20]. P6 acupuncture or acupressure has not been associated with any adverse effects on pregnancy outcome.

**Hypnosis** — Hypnosis has been reported to be helpful in some patients [21]. Psychotherapy can also be a useful adjunctive therapy, particularly if psychological sources of anxiety are identified and can be ameliorated [22,23].

Pharmacologic treatment — Historically, pregnant women have been excluded from most clinical drug trials. Thus, there are limited data from pregnant women to support the safety and efficacy of agents used to treat nausea and vomiting. A number of reports have demonstrated that antiemetic drug therapy is more effective than placebo and does not increase the incidence of congenital anomalies [24]. However, there is little evidence from well-designed comparative trials upon which to base a

### Pubmed

#### **PubMed Clinical Queries**

Results of searches on this page are limited to specific clinical research areas. For comprehensive searches, use PubMed directly.

acupuncture abortion			⊗ Search	
Clinical Study Categories  Category: Therapy  Scope: Broad  ▼		Systematic Reviews	Medical Genetics Topic: All	
Res [And Key words: acuj war Pregnancy	on].	Results: 3 of 3  The safety of acupuncture during pregnancy: a systematic review.  Park J, Sohn Y, White AR, Lee H.	Results: 0 of 0  This column displays citations p	
Acupuncture Abortion Acupuncture	lisation	Acupunct Med. 2014 Jun; 32(3):257-66. Epub 2014 Feb 19.  Effects of acupuncture on the outcomes of in vitro fertilization: a systematic review and meta-analysis.  Qu F, Zhou J, Ren RX.  J Altern Complement Med. 2012 May; 18(5):429-39. Epub 2012 Apr 27.		
Side effect safety  [Ob: gyn: War Hu.) Zhoi RESULT:	luring	'Forbidden points' in pregnancy: do they exist? da Silva AV, Nakamura MU, da Silva JB. Acupunct Med. 2011 Jun; 29(2):135-6. Epub 2011 Mar 20. See all (3)		
Acu Review(2)	going d trial.	This column displays citations for systematic reviews, meta-		

### Pubmed

#### Results: 3

- The safety of acupuncture during pregnancy: a systematic review.
- Park J, Sohn Y, White AR, Lee H.

Acupunct Med. 2014 Jun;32(3):257-66. doi: 10.1136/acupmed-2013-010480. Epub 2014 Feb 19.

PMID: 24554789 [PubMed - in process] Free PMC Article

Related citations

- Effects of acupuncture on the outcomes of in vitro fertilization: a systematic review and meta-
- analysis.

Qu F, Zhou J, Ren RX.

J Altern Complement Med. 2012 May; 18(5):429-39. doi: 10.1089/acm.2011.0158. Epub 2012 Apr 27. Review.

PMID: 22540969 [PubMed - indexed for MEDLINE]

Related citations

- 'Forbidden points' in pregnancy: do they exist?
- da Silva AV, Nakamura MU, da Silva JB.

Acupunct Med. 2011 Jun;29(2):135-6. doi: 10.1136/aim.2010.003699. Epub 2011 Mar 20.

PMID: 21422007 [PubMed - indexed for MEDLINE]

Related citations

Original paper



## The safety of acupuncture during pregnancy: a systematic review

Jimin Park,<sup>1</sup> Youngjoo Sohn,<sup>2</sup> Adrian R White,<sup>3</sup> Hyangsook Lee<sup>4</sup>

#### Debate

#### 'Forbidden points' in pregnancy: do they exist?

André V Guerreiro da Silva,<sup>1</sup> Mary Uchiyama Nakamura,<sup>1</sup> João Bosco Guerreiro da Silva<sup>2</sup>

Emperor's Book of Acupuncture, The Systematic Classic of Acupuncture and Moxibustion and The Classic of Difficult Issues, 20-22 modern authors state that many points are related to be danger-

### Levels of Evidence

### Level 1 (likely reliable) Evidence:

randomized trials with at least 80% follow up, inception cohort studies for prognostic information, <u>systematic review</u> of Level 1 evidence reports.

#### Level 2 (mid-level) Evidence:

randomized trials with less than 80% follow up, non-randomized comparison studies, and diagnostic studies without adequate reference standards.

### Level 3 (lacking direct) Evidence:

case series, case reports, expert opinion and conclusions extrapolated indirectly form scientific studies.

Grade	US Preventive Task Force	NHS F	NHS R&D Center for EBM		
А	This is good evidence to support	1a	SR of RCT		
	the Recommendation		(with narrow confidence interval)		
		1b	individual RCT		
			(with narrow confidence interval)		
		1c	All-or-none studies		
В	There is fair evidence to support	2a	SR of cohort studies		
	the Recommendation		( with homogeneity )		
	Studies included in the review: n=105		individual cohort study or low-quality RCT(<80%		
			follow up)		
	RCTs: 42 CCTs: 6	2c	outcome research ; Ecological studies		
	Case series/reports: 54	3a	SR of case-control study		
L	Surveys: 3	3b	individual case-control study		
С	There is insufficient evidence for	Case	series and poor quality cohort/case-control		
	or	Studie	es		
	against, but recommendation may be made on other grounds				
D	There is fair evidence to exclude		t opinion without explicit critical appraisal, or		
	the Recommendation		on bench research		
Е	There is good evidence to exclude	le the recommendation			

## Step 3: Appraisal



- Critical appraisal sheet of CEBM, university of Oxford
  - Are the results of the review valid?
  - What were the result?

#### SYSTEMATIC REVIEW: Are the results of the review valid?

What is best?	Where do I find the information?	
The main question being addressed should be clearly stated. The exposure, such as a therapy or diagnostic test, and the outcome(s) of interest will often be expressed in terms of a simple relationship.	The <i>Title</i> , <i>Abstract</i> or final paragraph of the <i>Introduction</i> should clearly state the question. If you still cannot ascertain what the focused question is after reading these sections, search for another paper!	
This paper: Yes No 🗆 Unclear 🗆 Comment:	•	

Title

Original paper

## The safety of acupuncture during pregnancy: a systematic review

Abstract

#### ABSTRACT

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.

#### SYSTEMATIC REVIEW: Are the results of the review valid?

What question (PICO) did the systema	tic review address?		
What is best?	Where do I find the information?		
The main question being addressed should be clearly stated. The exposure, such as a therapy or diagnostic test, and the outcome(s) of interest will often be expressed in terms of a simple relationship.	The Title, Abstract or final paragraph of the Introduction should clearly state the question. If you still cannot ascertain what the focused question is after reading these sections, search for another paper!		
This paper: Yes No 🗆 Unclear 🗆  Comment:			

### Last paragraph of introduction

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.

F - Is it unlikely that important, relevo	ant studies were missed?
What is best?	Where do I find the information?
The starting point for comprehensive search for all relevant studies is the major bibliographic databases (e.g., Medline, Cochrane, EMBASE, etc) but should also include a search of reference lists from relevant studies, and contact with experts, particularly to inquire about unpublished studies. The search should not be limited to English language only. The search strategy should include both MESH terms and text words.	The <b>Methods</b> section should describe the search strategy, including the terms used, in some detail. The <b>Results</b> section will outline the number of titles and abstracts reviewed, the number of full-text studies retrieved, and the number of studies excluded together with the reasons for exclusion. This information may be presented in a figure or flow chart.
This paper: Yes No 🗆 Unclear 🗆 Comment:	

#### 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.

F - Is it unlikely that important, releva	ant studies were missed?
What is best?	Where do I find the information?
The starting point for comprehensive search for all relevant studies is the major bibliographic databases (e.g., Medline, Cochrane, EMBASE, etc) but should also include a search of reference lists from relevant studies, and contact with experts, particularly to inquire about unpublished studies. The search should not be limited to English language only. The search strategy should include both MESH terms and text words.	The <b>Methods</b> section should describe the search strategy, including the terms used, in some detail. The <b>Results</b> section will outline the number of titles and abstracts reviewed, the number of full-text studies retrieved, and the number of studies excluded together with the reasons for exclusion. This information may be presented in a figure or flow chart.
This paper: Yes 🗆 No 🗆 Unclear 🗸	
Comment:	

#### Methods

### Search strategy

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.



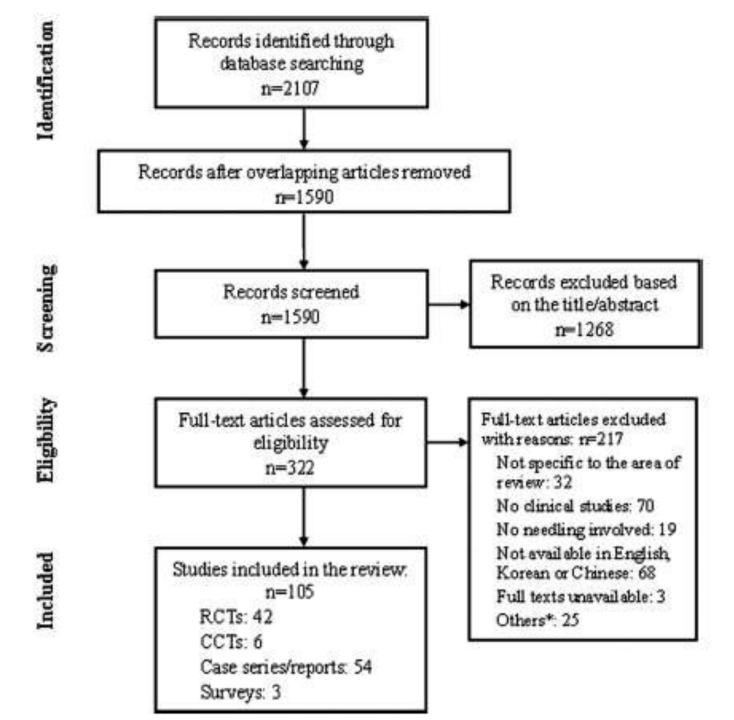
- 「Medical Subject Headings」
- 一套生物醫學領域的主題詞表(索引)
- 代表特定的主題範疇。



What is best?	Where do I find the information?	
The inclusion or exclusion of studies in a systematic review should be clearly defined a priori. The eligibility criteria used should specify the patients, interventions or exposures and outcomes of interest. In many cases the type of study design will also be a key component of the eligibility criteria.	The <b>Methods</b> section should describe in detail the inclusion and exclusion criteria. Normally, this will include the study design.	
This paper: Yes No 🗆 Unclear 🗆 Comment:		

## • Methods 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



What is best?		Where do I find the information?
The article should describe how the quality of each study was assessed using predetermined quality criteria appropriate to the type of clinical question (e.g., randomization, blinding and completeness of follow-up).		The <b>Methods</b> section should describe the assessment of quality and the criteria used. The <b>Results</b> section should provide information on the quality of the individual studies.
This paper: Yes 🗹 No 🗆 U	Inclear 🗆	
Comment:		
The quality assessment of AE CCTs included in our review following items, which were from previous suggestions. 9-12  • Methods	adopted and n  1. Was the de  2. Was the reported?  3. Were the reported in  4. Was the sev  5. Was the assessed?  6. Were the	on the nodified finition of AEs given? method used to monitor or collect AEs type and frequency of AEs in each group

unclear reporting. Disagreements were resolved by discussion.

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?	Were the participant withdrawals and drop-outs due to AEs described adequately?
RCTs/quasi-RCTs						5
Vas (2013)*	N	Y	N	N	N	Y
Guerreiro da Silva (2012) <sup>23</sup>	N	N	Υ	N	N	Υ
Manber (2010) <sup>28</sup>	N	Y	Y	N	Υ	Y
Guerreiro da Silva (2009) <sup>24</sup>	N	N	Υ	N	N	Υ
Wang (2009) <sup>29</sup>	N	N	Y	N	N	N
Elden (2008) <sup>46</sup>	N	N	Y	N	N	Y
Guittier (2008) <sup>36</sup>	N	Y	Y	N	N	Υ
Guerreiro da Silva (2007) <sup>25</sup>	N	N	Y	N	N	Y
Guerreiro da Silva (2005) <sup>26</sup>	N	Y	Y	N.	N	Υ
Elden (2005) <sup>18 20</sup>	N	Υ	Y	N	N	Y
Du (2005) <sup>30</sup>	N	N	Y	N	N	Υ
Cardini (2005) <sup>31</sup>	N	N	Y	N	N.	U
Guerreiro da Silva (2004) <sup>27</sup>	N	N	Y	N	N	Y
Kvorning (2004) <sup>32</sup>	N	N	Y	N	N	N
Smith (2002) <sup>19</sup> <sup>21</sup>	Y	Y	Υ	N	N	Y
Knight (2001) <sup>33</sup>	N	Y	Y	N	N	Y
Wedenberg (2000) <sup>34</sup>	N	Y	Y	N	N	Y
Cardini (1998)35	N	N	N	N	N	Y
CCTs						
Liang (2004) <sup>37</sup>	N	N	Y	N	N	Υ
Cardini (1993) <sup>38</sup>	N	N	Y	N	N	Y

AE, adverse event; CCT, controlled clinical trial; N, no; RCT, randomised controlled trial; U, unclear; Y, yes.

Studies included in the review: n=105

RCTs: 42

CCTs: 6

Case series/reports: 54

Surveys: 3

T - Were the results similar from stu What is best?	Where do I find the information?				
Ideally, the results of the different studies should be similar or homogeneous. If heterogeneity exists the authors may estimate whether the differences are significant (chi-square test). Possible reasons for the heterogeneity should be explored.	The <b>Results</b> section should state whether the results are heterogeneous and discuss possible reasons. The forest plot should show the results of the chi-square test for heterogeneity and if discuss reasons for heterogeneity, if present.				
This paper: Yes No 🗆 Unclear 🗆 Comment:					

### Mild Adverse effect – Maternal 302/22283

- 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 paraesthaesia down the leg to the foot by needling, breech engagement, threatened preterm labour which spontaneously disappeared completely within a day followed by a normal delivery in the 42nd week (n=1 in each)

### Mild adverse effect – Fetal 20/22283

 small for date (n=13) and multiple twists ofthe umbilical cord around the neck (n=4) or shoulder (n=3)

### Moderate Adverse effect 6/22283

- fainting (n=5)
- transient fall in blood pressure (n=1)

#### Supplementary Table 2. Mild/Moderate adverse events in acupuncture studies for pregnant women

Author (year) Country	Condition/ mean gestational weeks	Acupuncture group (A) and control group (C)	How AE data were collected	Details of AEs	Incidence per group	Severity	Association with acupuncture	Practitioner
RCTs/quasi-RC	Victoria de la constanti de la	177						
Vas (2013)¹ Spain	Fetal malposition/ A: 34.0 C1; 33.0 C2: 34.0	A: Moxa plus usual care C1: Sham moxa plus usual care C2: Usual care	(Presumably) Participant/ obstetrician reported	Maternal:  Burn during combustion of the moxa  Dizziness  Gastrointestinal disturbances (heartburn, nausea and vomiting)	(Probably A or C1) 1/3730 A 2/1865; C1 2/1865 8/NA	Mild	Possible	Family member
				Mild hypertensive disorders Oligohydramnios Abdominal pain	7/NA 2/NA C1 1/1865			
Guerreiro da Silva (2012) <sup>2</sup> Brazil	Tension-type headache/ A: 19.8 C: 19.4	A: MA plus usual care C: Usual care	(Presumably) participant reported	Maternal: Ecchymosis at needling points	A 2/200	Mild	Certain	Acupuncturist
Manber (2010) <sup>3</sup> United States	Depression/ A: 19.8 C1: 21.3	A: MA C1: Sham MA C2: Prenatal	Participant/ practitioner reported	Maternal: Transient discomfort at needling points	A 14/456; C1 7/407	Mild	Certain	Acupuncturist
Critica States	C2: 21.1	massage	13631113	Local bleeding Tiredness	A 1/456 A 10/456; C1 9/407; C2 4/NA	Mild Mild	Certain Possible	
				Irritability or agitation Sleep disturbance Headache Nausea Worsened symptom	A 2/456; C1 2/407 A 1/456; C1 2/407 A 3/456; C1 1/407 A 2/456 A 1/456; C1 1/407	Mild Mild Mild Mild Mild	Possible Possible Possible Possible Possible	
Guerreiro da Silva (2009) <sup>4</sup>	Dyspepsia/ A: 20.5 C: 21.3	A: MA C: No MA	(Presumably) participant reported	Transient discomfort related with massage Maternal: Ecchymosis at needling points	C2 5/NA A 1/201	Mild	Certain	Acupuncturist
Brazil Wang (2009) <sup>5</sup> United States	Low back and pelvic pain/ A: 30	A: AA plus PRLP self-care <sup>§</sup> C1: Sham AA	(Presumably) Participant	Maternal: Transient ear tenderness resolved	A 1/112; C1 3/104	Mild	Certain	Acupuncturist
United States	C1: 29 C2: 29	plus PRLP self- care C2: PRLP self- care	reported	spontaneously Bed rest after the study period	A 1/112; C1 1/104; C2 1/NA	Mild	Possible	

Elden (2008) <sup>6</sup> Sweden	Pelvic girdle pain/ A: 22.4 C: 23.6	A: MA plus usual care C: Sham MA plus usual care	Participant reported	Maternal: Fainting Slight bleeding Haematoma Needle pain Drowsiness	A 5/672; C 4/624 A 35/672; C 34/624 A 17/672; C 17/624 A 12/672; C 13/624 A 3/672; C 2/624	Moderate Mild Mild Mild Mild	Probable Certain Certain Certain Possible	Midwife
Guerreiro da Silva (2007) <sup>7</sup> Brazil	e Emotional complaints / A: 19.9 C: 21.0	A: MA plus counseling with or without phytomedicine C: Counselling with or without phytomedicine	(Presumably) participant/ obstetrician reported	Maternal: Ecchymosis at needling points	A 4/253	Mild	Certain	Acupuncturist
Guerreiro da Silva (2005) <sup>8</sup> Brazil	A: 20.6 C: 22.2	A: MA plus sleep hygiene C: Sleep hygiene <sup>††</sup>	(Presumably) participant reported	Maternal: Ecchymosis at needling points	A 1/125	Mild	Certain	Acupuncturist
Elden (2005) <sup>9-10</sup> Sweden	Pelvic girdle pain/ A: 24.4 C1: 24.4 C2: 24.4	A: MA plus usual care C1: Usual care C2: Usual care plus stabilizing exercise	(Presumably) Participant/ obstetrician reported	Maternal: Needle pain Worsened symptom  Unpleasant with treatment Drowsiness Feeling energised Headache plus severe drowsiness Headache only Rash at needling points Nausea Feeling faint Sweating Dizziness Thoracic pain Low back pain Discomfort because of rubbing from pelvic belt Uterine contraction Premature bleeding	A 23/1380 A 15/1380; C1 2/NA; C2 2/NA A 5/1380 A 12/1380 A 1/1380 A 1/1380 A 1/1380 A 1/1380 A 4/1380 A 4/1380 A 4/1380 C2 1/NA C2 17/NA C1 5/NA	Mild Mild Mild Mild Mild Mild Mild Mild	Certain Possible Possible Possible Possible Possible Certain Possible Probable Possible Possible	Acupuncturist
Du (2005) <sup>11</sup> China	Fetal malposition/ 24-28	A: Moxa plus knee-chest position C: Knee-chest position	(Presumably) Participant/ obstetrician reported	Maternal: Abdominal pain	C 5/NA			NR
Cardini (2005) <sup>12</sup> Italy	Breech presentation/ 32.4-33.4	A: Moxa C: No moxa	(Presumably) Participant/ obstetrician	Maternal: Unpleasant odour with or without nausea and throat problems	A 14/1085	Mild	Certain	Participant
italy	32,4-33.4		reported	Abdominal pain because of	A 11/1085	Mild	Possible	

				Other less frequently problems	A 2/1085	UA	UA	
Guerreiro da Silva (2004) <sup>13</sup> Brazil	Low back pain/ A: 19.9 C: 21.0	A: MA plus medication <sup>‡‡</sup> C: Medication	(Presumably) participant/ obstetrician reported	Maternal: Small bruise or ecchymosis Pain	A 5/270 A 1/270	Mild Mild	Certain UA	Acupuncturist
Kvoming	Low back and	A: MA	Participant/	Maternal:				NR
(2004) <sup>14</sup> Sweden	pelvic pain/ A: 30 C: 30	C: No MA	midwife reported	Local pain Heat or sweating Local haematoma Tiredness Nausea Weakness	A 6/222 A 5/222 A 2/222 A 2/222 A 1/222 A 1/222	Mild Mild Mild Mild Mild Mild	UA Possible Certain Possible Possible Possible	
Smith (2002) <sup>15-16</sup>	Nausea and vomiting/	A1: Traditional MA plus usual	Participant /	Fetal: Birth weight small for gestational	A1 8/668; A2 5/672; C1	Mild	Unlikely	Acupuncturist
Australia	8.5	A2: PC6 MA plus usual care C1: Sham MA plus usual care C2: Usual care	collected from case notes	age	7/668; C2 7/NA		CSC-886-588*	
Knight (2001) <sup>17</sup> UK	Nausea and vomiting/ A: 7.8 C: 8.0	A: MA C: Sham MA	Participant reported	Maternal: Tiredness Sleep disturbance Heaviness of arms More energy Altered taste Bruise Pressure in nose Headache Increased vomiting Flatulence Vivid dreams Feeling of coldness	A 2/103; C 2/100 A 2/103 A 2/103 A 1/103 A 1/103; C 2/100 A 1/103 A 1/103 C 1/100 C 1/100 C 1/100	Mild Mild Mild Mild Mild Mild Mild	Possible Possible Possible Possible Certain Possible Possible	Acupuncturist
Wedenberg (2000) <sup>18</sup> Sweden	Low back and pelvic pain/ A: 24.2	A: AA with or without MA C:	Participant reported	Maternal: Small subcutaneous haematomas in the ear	A 2/300	Mild	Certain	NR
	C: 24.2	Physiotherapy		Uterine contraction Preeclampsia	C 3/192 C 1/192			
Cardini (1998) <sup>19</sup> China	Fetal malposition/ 33	A: Moxa C: Usual care	(Presumably) participant/ obstetrician reported	Maternal: Braxton Hicks contraction Breech engagement Sense of tenderness and pressure in the epigastric region Epigastric crushing (one of the hypochondria)	A 1/1779 A 1/1779 NR NR	Mild Mild	Possible Possible	Participant

### Severe Adverse effect - Maternal 86/22283

- 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),
- cesaerean delivery (n=1),
- tachycardia and atrial sinus arrhythmia (n=1)

## Severe Adverse effect - Fetal 5/22283

- congenital defects (n=12)
- preterm delivery (n=1)

- stillbirth (n=1)
- neonatal death (n=1)

#### Supplementary Table 3. Severe adverse events/death in acupuncture studies for pregnant women

Author (year) Country	Condition/ mean gestational weeks	Acupuncture group (A) and control group (C)	How AE data were collected	Details of AEs	Incidence per group	Severity	Association with acupuncture <sup>‡</sup>	Practitioner
RCTs/quasi-R		(0)						
Vas (2013) <sup>1</sup> Spain	Fetal malposition/ A: 34.0	A: Moxa plus usual care C1: Sham moxa	(Presumably) Participant/ obstetrician	Maternal: Did not progress due to lack of uterine contractions	6/NA			Family member
	C1; 33.0 C2: 34.0	plus usual care C2: Usual care	reported	PROM Fetal:	5/NA			
				Fetal hiccup	5/NA			
201.00			D 41 1 41	Cord pathology	6/NA			2 277
Manber (2010) <sup>2</sup>	Depression/ A: 19.8	A: MA C1: Sham MA	Participant/ practitioner	Maternal: Preeclampsia	A 2/456	Severe	Unlikely	Acupuncturist
United States	C1: 21.3	C2: Prenatal	The second state of the se	Preterm delivery of twins	A 1/456	Severe	Unlikely	
United States	C2: 21.1	A CONTRACTOR OF THE PARTY OF TH	reported	Pregnancy loss	C1 1/407	Severe	Unlikely	
	62. 21.1	massage		Hospitalisation for oesophageal	C2 1/NA			
				spasms	G2 1/NA			
				Hospitalisation for dehydration and low amniotic fluid	C1 1/407			
				Hospitalisation for isolated atrial fibrillation	C2 1/NA			
				Hospitalisation for premature contractions Fetal:	C2 1/NA			
				Neonatal death	A 1/456	Death	Unlikely	
						related to		
				Receiving prolonged NIC	A 1/456	Severe	Unlikely	
0.101		2002000	(D. 111)	Congenital defects Maternal:	A 1/456; C2 1/NA	Severe	Unlikely	
Guittier (2008) <sup>3</sup> Switzerland	Fetal malposition/ 34-36	A: Moxa C: No moxa	(Presumably) Participant/ obstetrician	Hypertension, later developed preeclampsia	A 1/56	Severe	Unlikely	NR
			reported	Cesaerean delivery	A 1/56	Severe	Unlikely	
			28	PROM	A 1/56	Severe	Unlikely	
Du	Fetal	A: Moxa plus	(Presumably)	Maternal:			012/03/09/02/ <b>05</b> 0	NR
(2005)4	malposition/	knee-chest	Participant/	Vaginal redness	C 5/NA			
China	24-28	position	obstetrician	Vaginal running water	C 3/NA			
		C: Knee-chest position	reported	Placental abruption Fetal:	C 3/NA			
				Abnormal fetal heart rate	C 5/NA			
	Fetal	A: Moxa	(Presumably)	Maternal:	and the state of t			Participant
Cardini	retal							

Italy	32.4-33.4		obstetrician reported					
Smith	Nausea and	A1: Traditional	Participant	Maternal:				Acupuncturist
(2002) <sup>6-7</sup> Australia	vomiting/ 8.5	MA plus usual care	reported or study	Pregnancy termination due to unspecified reasons	A1 2/668; C1 2/668	Severe	Unlikely	
		A2: PC6 MA plus usual care	investigator collected data	Antepartum haemorrhage/ abruption or placenta praevia	A1 2/668; A2 4/672; C1 6/668; C2 4/NA	Severe	Unlikely	
		C1: Sham MA plus usual care	by a telephone with	Hypertension	A1 6/668; A2 10/672; C1 10/668; C2 5/NA	Severe	Unlikely	
		C2: Usual care	participants or from case	Preeclampsia"	A1 11/668; A2 7/672; C1 8/668; C2 7/NA	Severe	Unlikely	
			notes	Preterm delivery	A1 9/668; A2 5/672; C1 6/668; C2 12/NA	Severe	Unlikely	
				Miscarriage	A1 4/668; A2 11/672; C1 6/668; C2 9/NA	Severe	Unlikely	
				Fetal:				
				Stillbirth	A1 1/668; C1 1/668; C2 4/NA	Death related to AE	Unlikely	
				Congenital abnormality	A1 6/668; A2 5/672; C1 6/668; C2 5/NA	Severe	Unlikely	
				Musculoskeletal disorders congenital hip dislocations (8) polydactyly (1)	A1 4/668; A2 2/672; C1 2/668; C2 1/NA	Severe	Unlikely	
				Cardiovascular disorders (all congenital heart defects)	A1 1/668; A2 1/672; C1 2/668	Severe	Unlikely	
				Gastrointestinal disorders pyloric stenosis (1) cleft lip (2)	A2 2/672; C1 1/668	Severe	Unlikely	
				Urogenital disorders hypospadias (1) undescended testes (2)	A1 1/668; C2 2/NA	Severe	Unlikely	
				Metabolic disorders microphthalmia (1) cystic fibrosis (1)	C1 1/668; C2 1/NA			
				Chromosomal abnormality	C2 1/NA			
				Neonatal death	C1 1/668			
Cardini	Fetal	A: Moxa	(Presumably)	Maternal:				Participant
(1998) <sup>8</sup> China	malposition/ 33	C: Usual care	participant/ obstetrician	Tachycardia and atrial sinus arrhythmia	A 1/1779	Severe	Unlikely	155
Cillia	50		reported	PROM	A 4/1779; C 12/NA	Severe	Unlikely	
			0.00.00000	Preterm delivery <sup>††</sup> Fetal:	A 2/1779; C 3/NA	Severe	Unlikely	
				Intrauterine fetal death	C 1/NA			

# Adverse effect causality

 Certain (n=144), Probable (n=15), Possible (n=132), Unlikely (n=124), Unassessable (n=14)

- Certain, Probable, Possible
  - → mild or moderate adverse effect
- Unlikely
  - → severe AEs or death

## Incidence of Adverse effect

- Acupuncture group: 4.8% (1067/22283)
  - Certain, Probable, Possible: 1.9% (418/22283)

Acupuncture as an adjunct  Vas (2013) <sup>1</sup> 2/1865 (0.1) 0/NA (—) 2/1865 (0.1)  Guerreiro da Silva (2012) <sup>2</sup> 2/200 (1.0) 0/NA (—) 2/200 (1.0)  Do (2011) <sup>3</sup> 0/200 (0.0) 0/NA (—) 0/200 (0.0)  Wang (2009) <sup>4</sup> 2/112 (1.8) 1/NA (—) 2/112 (1.8)  Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6) 0/NA (—) 4/253 (1.6)  Yang (2006) <sup>6</sup> 0/1442 (0.0) 0/1442 (0.0) 0/1442 (0.0)  Elden (2005) <sup>7-8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>1</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Llin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)  Total 189/8785 (2.2) 21/4066 (0.5) 92/8785 (1.0)	Author (year)	(No. of AEs reported/ no. of sessions (%))	Control group (No. of AEs reported/ no. of sessions (%))	Incidence of AEs related to acupuncture treatment in acupuncture group (No. of AEs related/ no. of sessions (%))
Vas (2013) <sup>1</sup> 2/1865 (0.1) 0/NA (—) 2/1865 (0.1)  Guerreiro da Silva (2012) <sup>2</sup> 2/200 (1.0) 0/NA (—) 2/200 (1.0)  Do (2011) <sup>3</sup> 0/200 (0.0) 0/NA (—) 0/200 (0.0)  Wang (2009) <sup>4</sup> 2/112 (1.8) 1/NA (—) 2/112 (1.8)  Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6) 0/NA (—) 4/253 (1.6)  Yang (2006) <sup>6</sup> 0/1442 (0.0) 0/1442 (0.0) 0/1442 (0.0) 0/1442 (0.0)  Elden (2005) <sup>7-8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 (0.0) 0/454 (0.0)	RCTs/quasi-RCTs			27.20.00
Guerreiro da Silva (2012) <sup>2</sup> 2/200 (1.0) 0/NA (—) 2/200 (1.0)  Do (2011) <sup>3</sup> 0/200 (0.0) 0/NA (—) 0/200 (0.0)  Wang (2009) <sup>4</sup> 2/112 (1.8) 1/NA (—) 2/112 (1.8)  Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6) 0/NA (—) 4/253 (1.6)  Yang (2006) <sup>5</sup> 0/1442 (0.0) 0/1442 <sup>†</sup> (0.0) 0/1442 (0.0)  Elden (2005) <sup>7.8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>50</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>5</sup> (0.0) 0/454 (0.0)	Acupuncture as an adjunct			
Do (2011) <sup>3</sup> 0/200 (0.0) 0/NA (—) 0/200 (0.0)  Wang (2009) <sup>4</sup> 2/112 (1.8) 1/NA (—) 2/112 (1.8)  Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6) 0/NA (—) 4/253 (1.6)  Yang (2006) <sup>6</sup> 0/1442 (0.0) 0/1442 <sup>†</sup> (0.0) 0/1442 (0.0)  Elden (2005) <sup>7,8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Vas (2013) <sup>1</sup>	2/1865 (0.1)	0/NA (—)	2/1865 (0.1)
Wang (2009) <sup>4</sup> 2/112 (1.8) 1/NA (—) 2/112 (1.8)  Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6) 0/NA (—) 4/253 (1.6)  Yang (2006) <sup>8</sup> 0/1442 (0.0) 0/1442 <sup>†</sup> (0.0) 0/1442 (0.0)  Elden (2005) <sup>7,8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Guerreiro da Silva (2012) <sup>2</sup>	2/200 (1.0)	0/NA (—)	2/200 (1.0)
Guerreiro da Silva (2007) <sup>5</sup> 4/253 (1.6)  0/NA (—)  4/253 (1.6)  Yang (2006) <sup>5</sup> 0/1442 (0.0)  0/1442 <sup>†</sup> (0.0)  0/1442 <sup>†</sup> (0.0)  0/1442 (0.0)  Elden (2005) <sup>7-8</sup> 76/1380 (5.5)  8/NA (—)  76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8)  0/NA (—)  1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0)  21/700 <sup>†</sup> (3.0)  0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2)  0/NA (—)  5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0)  0/414 <sup>‡</sup> (0.0)  0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2)  53/NA (—)  0/1510 <sup>§</sup> (0.0)  0/454 (0.0)	Do (2011) <sup>3</sup>	0/200 (0.0)	0/NA (—)	0/200 (0.0)
Yang (2006) <sup>6</sup> 0/1442 (0.0) 0/1442 <sup>†</sup> (0.0) 0/1442 (0.0)  Elden (2005) <sup>7-8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Wang (2009) <sup>4</sup>	2/112 (1.8)	1/NA (—)	2/112 (1.8)
Elden (2005) <sup>7-8</sup> 76/1380 (5.5) 8/NA (—) 76/1380 (5.5)  Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0.0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>5</sup> (0.0) 0/454 (0.0)	Guerreiro da Silva (2007) <sup>5</sup>	4/253 (1.6)	0/NA (—)	4/253 (1.6)
Guerreiro da Silva (2005) <sup>9</sup> 1/125 (0.8) 0/NA (—) 1/125 (0.8)  Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0,0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Yang (2006) <sup>6</sup>	0/1442 (0.0)	0/1442† (0.0)	0/1442 (0.0)
Du (2005) <sup>10</sup> 0/250 (0.0) 21/700 <sup>†</sup> (3.0) 0/250 (0.0)  Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2) 0/NA (—) 5/270 (1.9)  Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0,0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Elden (2005) <sup>7-8</sup>	76/1380 (5.5)	8/NA (—)	76/1380 (5.5)
Guerreiro da Silva (2004) <sup>11</sup> 6/270 (2.2)       0/NA (—)       5/270 (1.9)         Neri (2004) <sup>12</sup> 0/456 (0.0)       0/NA (—)       0/456 (0.0)         Chen (2004) <sup>13</sup> 0/438 (0.0)       0/414 <sup>‡</sup> (0,0)       0/438 (0.0)         Smith (2002) <sup>14-15</sup> 96/1340 (7.2)       53/NA (—)       0/1340 (0.0)         Lin (2002) <sup>16</sup> 0/454 (0.0)       0/1510 <sup>5</sup> (0.0)       0/454 (0.0)	Guerreiro da Silva (2005)9	1/125 (0.8)	0/NA (—)	1/125 (0.8)
Neri (2004) <sup>12</sup> 0/456 (0.0) 0/NA (—) 0/456 (0.0)  Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0,0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Du (2005) <sup>10</sup>	0/250 (0.0)	21/700 <sup>†</sup> (3.0)	0/250 (0.0)
Chen (2004) <sup>13</sup> 0/438 (0.0) 0/414 <sup>‡</sup> (0,0) 0/438 (0.0)  Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0)  Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>§</sup> (0.0) 0/454 (0.0)	Guerreiro da Silva (2004) <sup>11</sup>	6/270 (2.2)	0/NA (—)	5/270 (1.9)
Smith (2002) <sup>14-15</sup> 96/1340 (7.2) 53/NA (—) 0/1340 (0.0) Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>5</sup> (0.0) 0/454 (0.0)	Neri (2004) <sup>12</sup>	0/456 (0.0)	0/NA (—)	0/456 (0.0)
Lin (2002) <sup>16</sup> 0/454 (0.0) 0/1510 <sup>5</sup> (0.0) 0/454 (0.0)	Chen (2004) <sup>13</sup>	0/438 (0.0)	0/414 <sup>‡</sup> (0,0)	0/438 (0.0)
	Smith (2002) <sup>14-15</sup>	96/1340 (7.2)	53/NA (—)	0/1340 (0.0)
Total 189/8785 (2.2) 21/4066 (0.5) 92/8785 (1.0)	Lin (2002) <sup>16</sup>	0/454 (0.0)	0/1510 <sup>§</sup> (0.0)	0/454 (0.0)
	Total	189/8785 (2.2)	21/4066 (0.5)	92/8785 (1.0)

Author (year)	(No. of AEs reported/ no. of sessions (%))	Control group (No. of AEs reported/ no. of sessions (%))	Incidence of AEs related to acupuncture treatment in acupuncture group (No. of AEs related/ no. of sessions (%))
RCTs/quasi-RCTs			2000
Acupuncture vs. sham acu	ouncture		
Vas (2013) <sup>1</sup>	2/1865 (0.1)	3/1865 (0.2)	2/1865 (0.1)
Manber (2010) <sup>17</sup>	40/456 (8.8)	24/407 (5.9)	34/456 (7.5)
Wang (2009) <sup>4</sup>	2/112 (1.8)	4/104 (3.8)	2/112 (1.8)
Elden (2008) <sup>18</sup>	72/672 (10.7)	70/624 (11.2)	72/672 (10.7)
Smith (2002) 14-15	96/1340 (7.2)	53/668 (7.9)	0/1340 (0.0)
Knight (2001) <sup>19</sup>	11/103 (10.7)	8/100 (8.0)	11/103 (10.7)
Carlsson (2000) <sup>20</sup>	0/212 (0.0)	0/207 (0.0)	0/212 (0.0)
Total	223/4760 (4.7)	162/3975 (4.1)	121/4760 (2.5)

Author (year)	Acupuncture group (No. of AEs reported/ no. of sessions (%))	Control group (No. of AEs reported/ no. of sessions (%))	Incidence of AEs related to acupuncture treatment in acupuncture group (No. of AEs related/ no. of sessions (%))
RCTs/quasi-RCTs			KANK
Acupuncture vs. usual care			
Manber (2010)17	40/456 (8.8)	13/NA (—)	34/456 (7.5)
Guittier (2009) <sup>21</sup>	0/1050 (0.0)	0/NA (—)	0/1050 (0.0)
Mao (2009) <sup>22</sup>	0/420 (0.0)	0/630**(0.0)	0/420 (0.0)
Yang (2007) <sup>23</sup>	0/1967 (0.0)	0/1956 <sup>†</sup> (0.0)	0/1967 (0.0)
Wedenberg (2000) <sup>24</sup>	2/300 (0.7)	4/192 <sup>††</sup> (2.1)	2/300 (0.7)
Cardini (1998) <sup>25</sup>	9/1779 (0.5)	16/NA (—)	2/1779 (0.1)
Total	51/5972 (0.9)	4/2778 (0.1)	38/5972 (0.6)
Acupuncture vs. no treatment			
Guerreiro da Silva (2009) <sup>26</sup>	1/201 (0.5)	0/NA (—)	1/201 (0.5)
Guittier (2008) <sup>27</sup>	3/56 (5.4)	0/NA (—)	0/56 (0.0)
Cardini (2005) <sup>28</sup>	29/1085 (2.7)	0/NA (—)	25/1085 (2.3)
Kvorning (2004) <sup>29</sup>	18/222 (8.1)	0/NA (—)	12/222 (5.4)
Habek (2003) <sup>30</sup>	0/204 (0.0)	0/NA (—)	0/204 (0,0)
Total	51/1768 (2.9)	0/NA (—)	38/1768 (2.1)
RCTs total	374/17512 (2.1)	187/10819 (1.7)	251/17512 (1.4)

#### What were the results?

#### How are the results presented?

A systematic review provides a summary of the data from the results of a number of individual studies. If the results of the individual studies are similar, a statistical method (called meta-analysis) is used to combine the results from the individual studies and an overall summary estimate is calculated. The meta-analysis gives weighted values to each of the individual studies according to their size. The individual results of the studies need to be expressed in a standard way, such as relative risk, odds ratio or mean difference between the groups. Results are traditionally displayed in a figure, like the one below, called a **forest plot**.

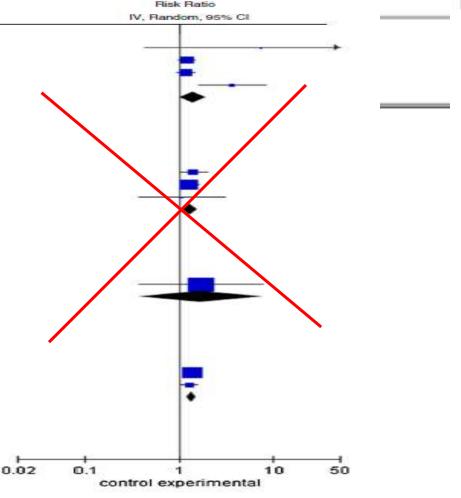
This paper: Yes 🗆

No V

Unclear 🗆

Comment: No forest plot





## Discussion

#### 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).

#### Original paper

Table 1 Estimated AE incidences associated with acupuncture treatment compared with previous studies\*

Author (year) Country	Design	Condition	No. of patients	AE incidence (per 10 000 sessions)	Most frequent AEs	Authors' comments
Yamashita (2000) <sup>44</sup> Japan	Prospective survey	NR†	391	6849	Tiredness, drowsiness, symptom aggravation, minor bleeding on needle withdrawal	'Although some adverse reactions associated with acupuncture were common even in standard practice, they were transient and mild.'
White (2001) <sup>45</sup> UK	Prospective survey	NR‡	NR	671	Bleeding or haematoma, needling pain	'All AEs were mild and no serious AE occurred.'
Witt (2009) <sup>5</sup> Germany	Prospective survey	Chronic OA, LBP, neck pain, headache, allergic rhinitis, asthma or dysmenorrhoea	229 230	111	Bleeding or haematoma, pain	'Acupuncture provided by physicians is a relatively safe treatment.'
Park (2009) <sup>7</sup> Korea	Retrospective survey	CVA, headache, hypertension, dizziness, numbness and others	1095	339	Minor bleeding	'Acupuncture treatment is safe if the practitioners are well educated, trained, and experienced.'
Present study (2013) Various	Systematic review	Various conditions in pregnant women	2460	131§/188¶	Needling pain	'Acupuncture during pregnancy appears to be associated with few AEs when correctly applied.'

<sup>\*</sup>Incidence rate may slightly vary as definition of AEs, survey methods or acupuncture methods are all different across studies.

<sup>†</sup>Patients receiving acupuncture treatments at Tsukuba College of Technology Clinic in Japan.

<sup>‡</sup>Patients receiving acupuncture treatments from medical doctors and physiotherapists in the UK.

<sup>§</sup>AE incidence varies: 193 per 10 000 acupuncture sessions when the analysis included reported AEs in the original reports; 131 per 10 000 acupuncture sessions when the calculation is limited to the AEs evaluated as certain, probable or possible in the causality assessment.

<sup>¶</sup>AE incidence varies: 479 per 10 000 when the calculation is expanded to poor pregnancy outcomes which were not originally reported as acupuncture-related AEs and, among them, 188 were evaluated as certain, probable or possible in the causality assessment.

AE, adverse event; CVA, cerebrovascular accident; LBP, low back pain; NR, not reported; OA, osteoarthritis.

## Limitation

- the first systematic review on this topic
- lack of appropriate information regarding obstetric complications
  - difficult to make meaningful conclusions about important AEs
- focus on the benefit of the intervention
  - neglect the information on harm
- inadequate reporting of harms
  - observational studies: no incidence of AEs
  - Clinical trials: unsuitable for new, rare or long-term AEs exclude high comorbidity patient

## Limitation

- Predefined poorly
  - the definition and severity of AEs
  - causality between the intervention and AEs
  - the collecting and monitoring methods of AEs

## Conclusion

- Acupuncture during pregnancy appears to be associated with few AEs when correctly applied.
- Large prospective studies would give us better information and a more accurate estimate of AEs associated with acupuncture in pregnant women.
- Trimester? Acupoint? Intensity? Frequency?

# Step 4: Apply

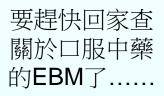
- 1. 我們的病人是否與研究中的病人類似?
  - 同樣是罹患有懷孕的病人
- 2. 此治療目前是否可行?
  - 本院目前並無明文規定孕婦不得針灸,可行
- 3. 我們的病人是否可以從該項治療中獲益?
  - 若病患因其它考量不想使用西藥時,可以考慮使用針刺治療替代,且相關副作用多屬輕微
- 4. 我們的病人如何看待此治療結果?
  - 正向,可參考

# 替代方案

- 口服中藥?
- 灸療?
- 復健治療?

- 芳香治療?
- 音樂治療?
- 氣功治療?





醫生,懷孕的人針 刺治療後會不會有 甚麼副作用?

目前的研究顯示孕婦在 針刺治療後,僅約有2% 的病人有輕微的副作用。 例如......



# 謝謝聆聽敬請指教

https://www1.cgmh.org.tw/intr/intr5/c6g100/learning/pdf/20140715.pdf

http://mulicia.pixnet.net/blog/post/20902397-

%E8%AD%89%E6%93%9A%E5%BC%B7%E5%BA%A6-strength-of-evidence

http://tul.blog.ntu.edu.tw/archives/7253