



## Acupuncture to treat common reproductive health complaints: An overview of the evidence

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### ABSTRACT

**Background:** Women specific health complaints are common, and women are higher users of complementary therapies and medicines. Acupuncture is one modality used by women. The aim of this paper was to summarise the evidence from scientific trials and systematic reviews assessing the effectiveness of acupuncture to treat the most common women specific reproductive health complaints.

**Methods:** We conducted a search of the major databases PubMed, CINAHL, and the Cochrane Library from their inception to Sept 2009, to obtain English language texts of randomised controlled trials (RCTs) and systematic reviews. The following English Australian search terms were used: acupuncture and period pain or dysmenorrhea, or premenstrual syndrome, or poly cystic ovarian syndrome/PCOS, or menstrual headache, or irregular periods/menstruation, or amenorrhea, or heavy menses/periods, or menorrhagia, or menopause, and randomised controlled trial and systematic review. Both authors extracted data and reviewed each trial and systematic review for methodological quality.

**Results:** Five systematic reviews were included, and six RCTs. The symptoms of the menopause and dysmenorrhea have been subject to greater clinical evaluation through RCTs, and the evidence summarised in systematic reviews, than any other reproductive health complaint. The evidence for acupuncture to treat dysmenorrhea and menopause remains unclear, due to small study populations and the presence of methodological bias. Acupuncture to treat PMS, PCOS and other menstrual related symptoms is under-studied, and the evidence for acupuncture to treat these conditions is frequently based on single studies.

**Conclusion:** Further research is needed.

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### 1. Introduction

Women specific health complaints are common. Data from the 2000–02 National Medical Expenditure Survey of the USA non institutionalised population reported the annual prevalence of female specific conditions among women aged greater than 14 years to be 21% (Kjerulff et al., 2007). In this survey the most common complaints were gynecological disorders (7.4%), pregnancy related conditions (6.4%), followed by menopausal symptoms (5.3%). The prevalence of specific disorders within these generic categories is less well documented. One earlier study reported that the most prevalent gynecological conditions were menstrual disorders, with an annual prevalence of 53.0 per thousand women, followed by adnexal conditions (Kjerulff et al., 1996). In a separate study hot flushes were the most commonly reported menopausal symptom, experienced by more than 50% of menopausal women (Nelson et al., 2005).

Complementary therapies are widely used by the population. The characteristics of users have consistently identified women to be

higher users of these modalities compared with men. Complementary medicine is used across all age groups, with greatest use by women aged 50–59 years, followed by women aged 40–49 and 30–39 years (Upchurch et al., 2007). In general, research suggests that people choose to use acupuncture because they believe that acupuncture combined with conventional health care would help them (Burke et al., 2006). Acupuncture, one form of traditional Chinese medicine, has attracted significant public interest. Data from a national cross-sectional survey in the United States reported lifetime use of acupuncture to be 4%, or 1% in the previous 12 months (Barnes et al., 2004). Amongst the 1% of individuals reported to have used acupuncture in the previous 12 months, 52% were women (Burke et al., 2006). Limited data was available on patterns of use, but utilisation data from the United Kingdom indicate that acupuncture was used by women to assist with the management of gynaecological or obstetric conditions by 8% of the study population (MacPherson et al., 2006). Medical and personal health practices have been documented to influence women's decision to use acupuncture (Upchurch et al., 2007).

An increase in the use of acupuncture has been mirrored by an expansion in the number of clinical trials and systematic reviews to study acupuncture. The aim of this paper was to summarise the

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evidence from scientific trials and systematic reviews assessing the effectiveness of acupuncture to treat the most common women specific reproductive health complaints.

## 2. Methods

We conducted a search of the major databases PubMed, CINAHL, and the Cochrane Library from their inception to Sept 2009, to obtain English language texts of randomised controlled trials (RCTs) and systematic reviews. The following English Australian search terms were used: acupuncture and period pain or dysmenorrhea, or premenstrual syndrome, or poly cystic ovarian syndrome/PCOS, or menstrual headache, or irregular periods/menstruation, or amenorrhea, or heavy menses/periods, or menorrhagia, or menopause, and randomised controlled trial and systematic review. Asian databases were not accessed due to insufficient resources.

Studies were included if they were RCTs or systematic reviews comparing acupuncture with a control group. Comparison groups could include the following: sham or placebo control acupuncture, no additional treatment, standard treatment, or other treatment. Additional RCTs were included if they were published since the last published systematic review. Trials were excluded if they were cross-over trials. Data was extracted from trials and systematic reviews describing the number of trials, the number of participants and description of the study participants, details of the acupuncture and control groups, and outcomes. Both authors (CS and BC) extracted data and reviewed each trial and systematic review for methodological quality.

To assess the internal validity of each study a modified version of a published scale was used (van Tulder et al., 1997). In all cases, an answer 'Yes' indicated a low risk of bias and awarded one point, and an answer 'No' indicated a high risk of bias and awarded 0 points. A judgement described as unclear was reported if insufficient detail was reported of what happened in the study. A total potential score of 10 was obtained from adding up the score for each item. The assessment of systematic reviews and meta-analyses was undertaken using the Overview Quality Assessment Questionnaire (OQAQ) (Dixon et al., 2005). This nine-item checklist has been validated, including face and construct validity. The OQAQ allocates a score for nine items, with 2 points awarded if the method criteria were "fully met," 1 point if the methods were "reported incompletely," or 0 points if the author "could not tell" if the items were met or if the criteria were "not reported at all." The maximum possible score was 18 points, but a study scoring "no" to items 2, 4, 6, or 8 was considered to have a major flaw.

## 3. Results

Searches of the computerised databases identified 198 potentially relevant studies for screening. Forty three articles were retrieved for further evaluation. Five systematic reviews were included, and six RCTs. Three generic narrative reviews of complementary and alternative therapies and medicines were identified from the search (Beal, 1999, White, 2003, Kessel and Kronenberg, 2004.). Although these reviews covered acupuncture the reviews were not included in this paper because the studies were included in the review articles below.

Three reviews were found on menopause, and two reviews on dysmenorrhea. The number of primary trials included within a review ranged from six to 20. The majority of trials included were randomised or quasi randomised. The majority of interventions included manual acupuncture rather than electro-acupuncture. Control interventions included self care, wait list control, medication or sham controls. The quality of the methodology of the included reviews is presented in Table 1. Methods used to search the evidence (item 1), strategy for the evidence (item 2), and conclusion (item 9)

were reported as being mostly adequate. The item describing avoiding selection bias (item 4) was not well reported. Most reviews made no attempt to combine data in a meta-analysis. The overall total quality score suggests there were two well conducted reviews for dysmenorrhea and one review for the menopause.

Five RCTs were included since the publication of the most recent systematic reviews (Table 2). Two trials were conducted in Germany, and one each in Norway, Croatia, Sweden and Korea. Selection bias was described in sufficient detail and was at a low risk in three trials (Linde et al., 2004, Witt et al., 2008, Borud et al., 2009). Four trials had a high risk of bias due to withdrawal bias, two trials were at a low risk of contamination bias due to co-interventions, four trials were at a high risk of bias due to a lack of subject blinding, and two trials were at a high risk of compliance bias. Measurement bias was at a low risk of bias for all trials. Overall there were two trials of good-moderate quality (Linde et al., 2004, Borud et al., 2009).

## 4. Menopause

Three reviews were included and no review included a meta-analysis (Carpenter and Neal, 2005, Alfahly and Ewies, 2007, Lee et al., 2009). Carpenter included five controlled trials and found acupuncture did not consistently improve hot flashes, menopausal symptoms, sleep or mood when compared with non specific acupuncture, oestrogen therapy or sham acupuncture (Carpenter and Neal, 2005). Comparisons between RCTs were complicated due to differences in the type of acupuncture, technique and timing. Needle insertion varied from 5 mm to 250 mm, and needle insertion varied from 20–40 min. There was variation in the selection of acupuncture points and frequency of treatments varying from once to twice weekly, with 9–14 sessions. The outcomes and measurements varied between studies. Hot flushes and menopausal symptoms were measured by symptom checklists in three trials, however not all trials were consistent in reporting of the frequency and intensity of hot flushes.

Alfahly reviewed five controlled trials of acupuncture to treat menopause (Alfahly and Ewies, 2007). The majority of women treated with acupuncture had a reduction of more than 50% in hot flushes with the effect continuing for six months post treatment. The authors concluded that most studies were flawed by methodological limitations including poor design, lack of follow up data and standard treatment. Study sizes were small and many used inadequate controls.

The most recent review received the highest score among the three menopause reviews (Lee et al., 2009). The review examined the effectiveness of acupuncture for treating menopausal hot flushes. Six trials and 309 women were included. Two trials were undertaken in Sweden, three in the USA and one in Korea. Four trials recruited only postmenopausal women. Manual acupuncture alone was used in four trials. Five trials used classical acupuncture using semi-standardised treatments, and one trial used a fixed standardised approach to acupuncture. Four trials used a sham non penetrating acupuncture control. Four trials used a fixed selection of acupuncture points for all patients, whilst two used an individualised treatment approach. Only one trial found a significant difference between acupuncture and the control group. Other RCTs reported a reduction in symptoms in both groups but no significant difference between groups. The methodological quality of these trials was described as high.

Since the publication of the most recent systematic review (Lee et al., 2009), one RCT of acupuncture has been published (Borud et al., 2009). Borud et al, evaluated the effect of acupuncture plus self care compared with self care only. Two hundred and sixty seven women were randomised to the trial. Women received 10 sessions of acupuncture over 12 weeks, with practitioners administering an individualised treatment. De qi was obtained if possible, and needle manipulation used an even, reducing or reinforcing technique. Point

**Table 1**  
Methodological quality of systematic reviews.

Study	Were the search methods used to find evidence stated	Was the search for evidence reasonably comprehensive	Were the criteria used for deciding which studies to include in the review reported	Was bias in the selection of studies avoided	Were the criteria used for assessing the validity of the included studies reported	Was the validity of all studies referred to in the text assessed using appropriate criteria	Were the methods used to combine the findings of the studies reported	Were the findings of the relevant studies combined appropriately relative to the primary question the overview addresses	Were the conclusions made by the author(s) supported by the data and/or analysis reported in the overview	Total score
<i>Menopause</i>										
Lee et al., 2009	2	2	2	1	2	2	0	0	2	13
Alfahily and Ewies, 2007	2	1	0	0	0	1	0	0	1	5
Carpenter and Neal, 2005	2	2	0	0	0	0	0	0	1	5
<i>Primary dysmenorrhea</i>										
Yang et al., 2008	2	2	2	1	2	2	0	0	2	13
Proctor et al., 2002	2	2	2	1	2	2	2	0	2	15

**Table 2**  
Quality rating for randomised controlled trials.

Study	Was the method of randomisation adequate	Was the treatment allocation concealed	Were the groups similar at baseline regarding prognostic factors	Was the patient blind to the intervention	Was the care provider blind to the study intervention	Were co-interventions avoided or similar	Was adherence similar in both groups?	Was drop out <15%	Was the timing of outcome assessment similar in both groups	Did the analysis include an intention to treat?	Total score
<b>Menopause Borud et al., 2009</b>	Yes	Yes	Yes	No	No	Yes	No	Yes	Yes	Yes	7
<b>Polycystic ovary syndrome Stener-Victorin et al., 2009</b>	Yes	Unclear	Yes	No	No	Unclear	Yes	Yes	Yes	No	5
<b>Primary dysmenorrhea Witt et al., 2008</b>	Yes	Yes	No	No	No	No	Yes	Yes	Yes	Yes	6
<b>Menstrual related headache Linde et al., 2004</b>	Yes	Yes	Yes	Yes	No	Yes	Yes	No	Yes	No	7
<b>Pre menstrual symptoms Habek et al., 2002</b>	Unclear	Unclear	Yes	Yes	No	No	No	Yes	Yes	No	5
<b>Shin et al., 2009<sup>25</sup></b>	No	No	Yes	No	No	Yes	Yes	No	Yes	No	4

location was not standardised but left to the acupuncturists to decide. The treatment group and control group were free to use any over the counter medication and self provided non pharmacological interventions, guided by a self care intervention leaflet. Hot flash frequency decreased by 5.8 per 24 h in the acupuncture group and 3.7 per 24 h in the control group ( $P < 0.001$ ). Hot flash intensity decreased by 3.2 units in the acupuncture group, and 1.8 units in the control group ( $P < 0.001$ ). Although selection bias was assessed at a low risk, there was a high risk of bias due to imbalance in drop out between groups and although blinding was maintained with study personnel the participants were not blind to group allocation.

#### 4.1. Polycystic ovary syndrome (PCOS)

There was one randomised controlled trial of acupuncture to treat PCOS (Stener-Victorin et al., 2009). This trial examined the effect of low frequency electro-acupuncture, exercise or a no treatment control on PCOS parameters. Twenty women participated in a 16 week intervention. The acupuncture points were located bilaterally in the abdominal muscles and the muscles below the knee in somatic segments according to the innervation of the ovaries (Th12-L2, S2-S4), with the aim of stimulation to modulate both segmental and central sympathetic nerve activity. Additional points were selected bilaterally, extra segmental to the ovaries in the muscles of the arms, to strengthen and lengthen the effect on the central nervous system. Acupuncture points CV4, CV6, ST29, SP6, SP9, LI4 and PC6 were selected. LI4 and PC6 were manually stimulated four times every 10 min. Other points were stimulated using electro-acupuncture at 2 Hz. Treatment lasted 30 min, and was given twice per week for two weeks, and then spaced to weekly and fortnightly. Needles were inserted to a depth of 15–35 mm. For women allocated to the exercise control group participants were requested to take up regular exercise comprising of brisk walking, cycling or any other aerobic exercise that could be sustained over 30 min. They were requested to exercise three days per week for 30–45 min, with a pulse frequency above 120/min. Women in the non treatment control were given information about the importance of physical activity and a healthy diet. There were no differences between groups in hormones, insulin sensitivity or blood lipids. The methodological quality of this small trial was moderate with selection bias unclear. There was no blinding of subjects, however outcome assessment was undertaken by independent assessor and analysis was undertaken blind.

#### 4.2. Primary dysmenorrhea

Acupuncture to treat dysmenorrhea has been summarised in two systematic reviews (Proctor et al., 2002, Yang et al., 2008). A Cochrane systematic review examined the evidence for acupuncture to treat period pain (Proctor et al., 2002). One small trial of 48 participants from the USA was included. Women were randomised to manual acupuncture, sham acupuncture, a visitation control or standard care. The acupuncture group received stimulation of points SP4, KD3, ST36, ST30, CV2, CV4 and CV6. Treatment was administered once a week for three weeks a month, for three months. The trial found pain relief was significantly greater in the acupuncture group compared with placebo acupuncture (Odds Ratio (OR) 9.5, 95%CI 1.7, 51.8). The two control groups also experienced less pain relief compared with the acupuncture group (OR 16.4, 95%CI 3.2–84.8, OR 22.0, 95%CI 4.12–117.1). The review concluded “there was insufficient evidence to determine the effectiveness of acupuncture in reducing dysmenorrhea, and that further research was needed”.

The most recent systematic review of primary dysmenorrhea included thirty RCTs, and included trials identified from the Chinese literature (Yang et al., 2008). Twenty one studies compared acupuncture with controls. Two trials were of reasonable quality. One of these trials was the trial described in the Cochrane review. The

second compared acupuncture with ibuprofen (Yang, 2007). The results found acupuncture was more effective for pain relief than ibuprofen (Relative Risk (RR) 1.2, 95%CI 1.02, 1.42). Overall trials were of low methodological quality. Nine studies combined acupuncture with other analgesics, and the overall results suggest acupuncture was more effective for pain relief than analgesic medication. Data was not combined in a meta-analysis due to heterogeneity. A further nine trials found no benefit from acupuncture. The review concluded acupuncture maybe effective for the treatment of primary dysmenorrhea, and further well designed trials are needed.

A new RCT suggests a benefit from acupuncture with reducing menstrual pain. In Germany 208 women were recruited to a trial comparing acupuncture with a wait list control (Witt et al., 2008). Each participant received a maximum of 15 treatments, and the acupuncture points and number of needles were administered at the practitioner's discretion. Co-interventions were allowed. The trial found acupuncture reduced the intensity of pain compared with the control group at three months (mean difference  $-2.3$ , 95%CI  $-2.9$ ,  $-1.6$ ,  $P < 0.001$ ), and improved the quality of life. The trial was at a low risk of selection bias, there was no subject blinding and although women completed self report outcome measures the blinding status of the analyst was unclear. Evidence of the effectiveness for acupuncture to treat dysmenorrhea remains unclear, and there is a need for further high quality research.

#### 4.3. Menstrual related headache

One RCT examined menstrual related headache among women treated with acupuncture or placebo acupuncture (Linde et al., 2004). Thirty one women were randomised to the trial, and data was complete for 28 women. The trial intervention was administered over 12 weeks. The intervention was administered on the 8th, 5th and third day before the estimated start of menstruation. A total of nine treatments were administered. A standardised treatment protocol was used with five fixed acupuncture points and additional points used depending on the location of the headache. The control group received placebo needles. This methodological robust trial found no difference on headaches between groups.

#### 4.4. Premenstrual symptoms

Two RCTs evaluated the effect of acupuncture on premenstrual syndrome (PMS) (Habek et al., 2002, Shin et al., 2009). Thirty five women recruited from Croatia were randomised to acupuncture or to a minimal sham acupuncture group (Habek et al., 2002). Subjects were treated in the luteal phase of the menstrual cycle every second day for 30 min. A fixed treatment protocol was used with acupuncture points GV20, LI4, Liv3, CV3, CV4, CV6, PC6, GB34, BL23 and auricular point Shenmen selected. The control group received superficial sham acupuncture. A success rate of 77% was found in the acupuncture group compared with 5% in the control group. This study was poorly reported and the risk of bias unclear.

A more recent RCT of acupuncture to treat PMS was conducted in Korea (Shin et al., 2009). Participants were randomised to hand acupuncture, hand moxibustion and a non treatment control. Subjects in the active intervention groups received 10 sessions over a four week period. Treatments were administered to the female corresponding huyls on the Im Ki Mek of both hands: A5, A6, A8, A12, A16, A18, Liver Ki Mek N18; and Spleen Ki Mek F6. Twenty women completed the study. Pre menstrual symptoms as measured by the Menstrual Symptom Severity List found significant reductions in PMS symptoms between treatment groups and the no treatment control. The methodological reporting of this study was poor and the risk of bias unclear.

## 5. Discussion

Acupuncture is increasingly being used by women to complement their health care and over the same time period there has also been a growth in acupuncture research. The findings from this review conclude that there is insufficient evidence to support the use of acupuncture to treat reproductive health complaints.

The symptoms of the menopause and dysmenorrhea have been subject to greater clinical evaluation through RCTs, and the evidence summarised in systematic reviews, than any other reproductive health complaint. The evidence for acupuncture to treat dysmenorrhea and menopause remains unclear, due to small study populations and the presence of methodological bias. Acupuncture to treat PMS, PCOS and other menstrual related symptoms is under-studied, and the evidence for acupuncture to treat these conditions is frequently based on single studies.

The critical appraisal of trials and systematic reviews highlights improvements in some aspects of study design that reduces the potential for bias. The majority of trials were assessed at a high risk of bias, or the risk of bias unknown due to insufficient reporting. Trials were also characterised by a high degree of heterogeneity. Clinical heterogeneity was reflected by diversity within the acupuncture treatment as demonstrated by the use of fixed or semi-standardised treatment protocols, frequency of treatment, duration of intervention, form of stimulation. Overall there were two high quality reviews. Our results highlight a need for further attention to be given to the development of skills with the assessment of bias and reporting of sufficient detail when undertaking systematic reviews.

Although the evidence base for acupuncture in relation to reproductive health complaints is limited, there is larger research base in relation to pregnancy and delivery. In a recent review we reported that evidence was beginning to consolidate for the use of acupuncture to assist with the management of some complaints during pregnancy and birthing (Smith and Cochrane, 2009). Our review included 16 studies, eight randomised controlled trials (RCTs) and eight systematic reviews. Evidence of an emerging benefit was found for the use of acupuncture and related modes of stimulation for treating nausea and vomiting in early pregnancy. There was a small but promising body of evidence for the use of acupuncture to treat back pain during pregnancy, pain relief during labour and the use of moxibustion to correct a breech presentation (Coyle et al., 2005). Evidence from three trials of acupuncture with the management of back pain has been summarised in two systematic reviews (Ee et al., 2008 and Pennick and Young, 2007). These reviews found acupuncture as an adjunct treatment was superior to standard treatment alone and physiotherapy in relieving pain. An additional trial by Lund and colleagues found no difference between acupuncture and a sham control (Lund and Lundeberg, 2006). The use of moxibustion has been evaluated in two systematic reviews both of which suggest promising evidence of an increase in cephalic presentation (van den Berg et al., 2008, and Smith et al., 2008). Two systematic reviews found a benefit from acupuncture with providing effective pain relief in labour (Smith et al., 2008, Lee and Ernst, (2004). Evidence is mixed for the use of acupuncture with the management of emotional disorders during pregnancy, acupuncture for cervical ripening and induction of labour, and breastfeeding. In response to the growing evidence base examples exist of acupuncture being incorporated into integrated health care settings.

To conclude, the evidence for acupuncture to treat the most prevalent gynecological conditions is unclear. There is a need for the evidence base to grow, with high quality trials undertaken and reported.

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