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REVIEW ARTICLE

Complementary and alternative medicine in obstetrics

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Complementary and

Abstract

Objective: To identify, survey and review randomized controlled studies of the use of complementary and alternative medicine (CAM) for obstetric treatment or health promotion. *Methods*: The MEDLINE database was searched to identify randomized controlled trials of CAM treatment and therapies in obstetrics. Studies examining modalities for treatment or improvement of health status were reviewed. *Results*: Fifty-four articles assessing a variety of health modalities met the criteria for inclusion. Acupressure and ginger for prenatal nausea and vomiting, moxibustion for version of breech presentation, sterile water injections for back pain relief in labor, and perineal massage to prevent perineal trauma have three or more studies demonstrating beneficial effect. Other interventions have been studied less, and evidence for them is limited. *Conclusions*: Some CAM interventions have evidence of effectiveness for use in obstetric patients, while others require further investigation before they can be considered for use in practice.

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1. Introduction

Complementary and alternative medicine (CAM) modalities are increasingly used by physicians and

patients in addition to or in lieu of allopathic or

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biomedical therapy [1,2]. In many countries, Complementary or traditional medicine models form the basis of the primary care system [3]. There have been "substantial shifts in (CAM's) scientific base and organizational structure complementary medicine is becoming more integrated" [4].

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The Cochrane Collaboration defines CAM as:

"...a broad domain of healing resources that encompasses all health systems, modalities, and practices and their accompanying theories and beliefs, other than those intrinsic to the politically dominant health system of a particular society or culture in a given historical period" [5].

CAM medical interventions reportedly act through both measurable and immeasurable mechanisms. For example, acupuncture stimulates Qi [6], homeopathic medications contain a potentiate memory of molecules [7], and herbal medicines can contain any number of bioactive substances [8]. Given the sheer magnitude of the use of these therapies despite limited scientific evidence, it is imperative to assess their potential role in obstetric practice.

Numerous case reports, case series, and uncontrolled trials of varying quality have been carried out and there exists an increasing number of published randomized clinical trials testing CAM modalities [9].

This paper provides a comprehensive overview of the current state of evidence-based CAM modalities in obstetrics.

2. Methods

A preliminary search of the MEDLINE and Cochrane data bases was performed using the keywords 'CAM,' 'alternative medicine,' 'acupuncture,' 'acupressure,' 'herbal medicine,' cross-referenced with 'prenatal,' 'pregnancy,' 'labor,' 'delivery,' and 'postpartum.' The results and their bibliographies were analyzed and used to develop a search of the MEDLINE database on February 15, 2005,

using the keywords 'CAM,' 'alternative medicine,' 'acupuncture,' 'acupressure,' 'moxibustion,' 'herbal medicine,' 'ginger,' 'raspberry leaf,' 'cabbage leaf, ''jasmine, ''St. John's Wort, ''aromatherapy, ' 'lavender oil' 'massage,' 'homeopathy,' and 'fenugreek,' and cross-referenced with the keywords 'obstetrics,' 'labor,' 'delivery,' 'prenatal,' 'intrapartum, ''postpartum, ''lactation, ''perineal repair' and 'pregnancy.' These results were searched for articles involving alternative medicines including herbal medicines, acupuncture/acupressure, massage therapies, and their therapeutic use in obstetrics. The sequence and criteria for exclusion are given in Fig. 1. Papers were excluded at the first criteria on which both authors could agree and exclusion of papers was only executed following agreement of both authors. Spiritual therapies, multivitamin therapies and exercise modalities were not included in this review.

Selection of articles was limited to randomized clinical trials that involved human subjects published in the English language after January 1, 1986. Observational and quasi-experimental studies were excluded from review, as were studies that primarily assessed the safety of therapies. Due to the large number of outcomes reported in many of the studies reviewed, not all results are included in this review.

3. Results

Fifty-four randomized controlled trials from 17 different countries were identified (Fig. 1). The results are presented according to the period during which the intervention was administered: either prenatal, intrapartum, or postpartum, although

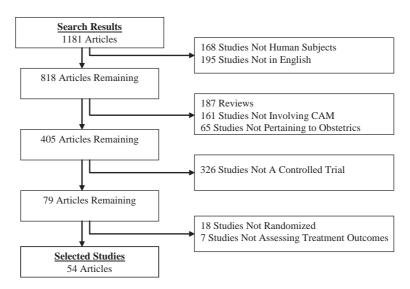


Figure 1 Search Methodology.

outcomes may have been measured in a subsequent period. Results are further categorized in terms of condition treated and then by intervention. Additional details of each trial are available on the website of the Global Initiatives Program [10].

3.1. Prenatal

Studies of CAM modalities utilized in the prenatal period for the reduction of nausea and vomiting in early pregnancy and adjunctive treatment of hyperemesis gravidarum, low back pain relief, treatment of foot edema, mood enhancement, breech version, prophylactic shortening of labor, and prevention of perineal trauma all met the criteria for this review.

3.1.1. Nausea and vomiting

Acupuncture, acupressure, and ginger for nausea and vomiting in pregnancy met the criteria for inclusion.

In the Chinese medical system, acupoint six (P6) is frequently stimulated for the relief of nausea. It is located three finger breadths proximal to the distal wrist crease, 1 cm deep between the tendons of the flexor carpi radialis and the palmaris longus muscles [11]. An acupoint can be stimulated by needle puncture (acupuncture), pressure (acupressure), electrical stimulation, or needle puncture with electrical stimulation (electro-acupuncture).

Three trials of acupuncture met criteria for inclusion [12–14]. In one trial, women experiencing nausea received a full Chinese medicine evaluation with acupuncture at a number of points, always including the P6 acupoint [12]. Controls received sham acupuncture where a blunt cocktail stick was placed through a guide tube onto the skin away from acupuncture points. Both groups improved with no significant differences in nausea scores. A second trial examined symptomatic women receiving traditional acupuncture, P6 acupuncture alone, sham acupuncture or no acupuncture [13]. There was no reduction in vomiting at any time, but traditional acupuncture reduced nausea and dry retching earlier than P6 acupuncture alone [15]. A time-related placebo effect occurred for some women receiving sham acupuncture. In a crossover study, P6 acupuncture decreased the number of vomiting episodes and the speed of reduction of nausea scores for patients with hyperemesis gravidarum [14]. The two groups had significantly different nausea scores at the start of intervention limiting analysis.

Acupressure can be applied manually or with wrist bands that, when applied correctly, apply constant pressure to the P6 acupoint. Seven studies

of acupressure are included [16–22], as well as one examining both acupuncture and acupressure [23].

Four studies found mixed evidence that acupressure is more effective than sham acupressure [16-19]. One wrist band study found no significant difference in the change in Rhodes Index of nausea, vomiting, and retching (RINVR) scores between the intervention, placebo and control groups despite improvement in all groups [17]. In a crossover trial to test the effectiveness of unilateral and bilateral acupressure, active and placebo wrist bands were positioned on both wrists in a different combination every 3 days during the 12 day study. Unilateral or bilateral acupressure had an equal effect on reducing emetic complaints in over 60% of cases, compared to 30% for placebo controls [18]. Two other studies have found similarly mixed results demonstrating a strong placebo effect [19,20]. A crossover trial of 16 participants compared acupressure wrist bands to no intervention, and found that acupressure significantly reduced nausea symptoms [21]. In a trial of manually applied acupressure, the severity of sickness, a scale developed by the authors, was reduced in those practicing P6 acupressure [19]. In another trial of manual acupressure, nausea improved significantly, although there were no differences in the severity or frequency of emesis between groups [16]. Additionally, one small trial compared both manual acupressure and acupuncture to sham procedures for the treatment of hyperemesis, and found both procedures effective [23].

One multi-center study of electro-stimulation of the P6 acupoint found the time average change in the total experience as measured by the RINVR better in the treatment group [24]. There was no difference in ketonuria between groups but weight gain over a 3-week period was significantly improved in the treatment group.

Ginger (*Zingiber officinale*) has been studied in six randomized controlled trials [25–30]. One study of ginger extract, nausea and vomiting was assessed using the RINVR scores [25]. The ginger extract did not have a significant effect on vomiting compared to the placebo, retching was different for the first two days, and nausea improved after one day and the effect continued through day four. One placebo controlled trial of ginger capsules found reduced number of emetic episodes [29]. A separate study with limited statistical analyses has reported that divided doses of ginger syrup may have an effect in reducing nausea and vomiting episodes [26].

Two studies compared ginger to Vitamin B6 for treatment of nausea and vomiting, neither had placebo controls. One compared 1.05 g ginger to 75 mg Vitamin B6 daily for three weeks [27], the other compared 500 g ginger to 10 mg Vitamin B6

three times daily for three days [28]. Both trials found no statistical difference between ginger and Vitamin B6 and could not reject the null hypothesis that they were equivalent for treatment of nausea and vomiting.

One crossover trial for the treatment of hyperemesis gravidarum found ginger improved relief scores more than placebo [30].

3.1.2. Low back pain

Two studies examined acupuncture for the relief of prenatal back pain and pelvic pain [31,32]. In a study comparing physiotherapy to acupuncture, participants attended ten sessions of either physiotherapy or acupuncture at a variety of acupoints [31]. The acupuncture group reported significant improvement of pain and perception of disability compared to physiotherapy but disproportionate dropout and the dissimilarity of the type of back pain limit interpretation. In another trial of acupuncture at a variety of points specific to each subject, pain scores decreased in 60% of the intervention group and 14% of the control group. Pain with various activities was found to decrease in 43% and 9% of controls, both results were statistically significant [32].

3.1.3. Mood enhancement

Full body massage was compared to progressive muscle relaxation in one study [33]. Massaged subjects demonstrated improvement in various measures of mood, reduced anxiety levels and reduced norepinephrine levels at the last day of the study, but no differences in cortisol, epinephrine, dopamine, or serotonin levels were noted.

3.1.4. Foot edema

The use of "relaxing" or "lymphatic" foot reflexology techniques on resolution of foot edema were compared to rest during late pregnancy [34]. The study suffered from a high dropout rate and poor follow-up. Analysis did not demonstrate a difference in ankle or foot circumference measurements, but, participants demonstrated improvements in stress, tension, anxiety, discomfort, irritability, pain, and tiredness measurements.

3.1.5. Breech version

Acupuncture and moxibustion have been studied for converting a breech presenting fetus to vertex. Moxibustion combines acupuncture with heat applied to acupuncture needles by burning *Artemisia vulgaris*.

In a study of acupuncture, sixty-seven women with ultrasonographically verified breech singleton fetuses received either acupuncture at the BL67

acupoint at or no treatment [35]. The rate for version at 38 weeks was significantly increased.

In a study of moxibustion, primagravidas with breech presentation received moxibustion sessions at home and were compared to controls. Partners had been trained in treatment administration. Subjects reported increased fetal activity (P < .001) during treatment. At 35 weeks, 75% of exposed fetuses were cephalic compared to 48% in controls, and at delivery 75% and 62%, respectively. This difference was significant despite 19 in the control group undergoing successful external cephalic version [36]. Another trial compared electro-acupuncture in breech, transverse or occipitoposterior presentations in pregnancies greater than 28 weeks to moxibustion and controls over a six year period [37]. It demonstrated higher rates of "correction" in both treatment groups during a 6 day follow-up period. The rates of correction in the 3 malposition groups were not differentiated. An Italian Study found a significantly higher version rate to vertex in the moxibustion group (53.6%) than in the controls (37.7%) [38].

3.1.6. Cervical ripening and labor induction

Acupuncture and electro-acupuncture have been studied for the induction of labor. One study examined the use of acupuncture delivered one time on the due date at the LI4 and SP6 acupoints [39]. The time from estimated delivery date (EDD) to labor was 2 days shorter in the acupuncture group. No differences in clinically significant outcomes such as Bishop's score or length of different labor stages were noted. Another study evaluated transcutaneous nerve stimulation given for 4 h at SP6 and LV3 acupuncture points 8 days after EDD [40]. Contractions were monitored by external tocograph both before nerve stimulation, and after 2 h of nerve stimulation. The number of contractions in the experimental group significantly increased from 63 at baseline to 116 in the fourth hour of stimulation, compared with a decrease in the control group from 84 to 75.

3.1.7. Prophylaxis to shorten labor

In a randomized controlled trial commencing at 32 weeks gestation, women who took red raspberry leaf extract tablets showed no significant difference in the length of gestation, incidence of labor induction or augmentation, length of the stages of labor, or mode of birth compared with controls [41].

3.1.8. Prevention of perineal trauma

Three studies examining antenatal perineal massage for the prevention of perineal trauma at delivery met the criteria. In one study, perineal

massage in women matched for previous vaginal delivery was studied for effect on subsequent perineal outcomes at delivery [42]. No significant differences were seen in second- and third-degree laceration rates or instrumental delivery rates; however, women over 30 years of age without massage were at greater risk to experience a tear compared to those who received massage (81.4% vs. 69.3%). Ten minutes of self-perineal massage led to an increased rate of intact perineum compared to no massage (24% vs. 15%) [43]. There was no difference in episiotomy use, or third- and fourth-degree lacerations. For multiparous women, perineal massage had no effect on outcomes. A follow-up at three months showed that the massage group had no functional difference [44]. Another study of daily perineal massage by the subject or partner found a significant reduction in the episiotomy and laceration rate, and an increase in the intact perineum rate [45].

3.2. Intrapartum

Studies of CAM modalities administered during the intrapartum period to prevent nausea at time cesarean section, shorten labor, reduce labor pain, and to prevent perineal trauma met the criteria for inclusion.

3.2.1. Labor pain

Interventions for the treatment of pain during labor include acupuncture, acupressure, massage, and sterile water injection.

One study of acupuncture utilized two to twelve of seventeen defined acupoints compared to "sham" acupuncture using vaccination sites [46]. Recipients of the acupuncture had significantly lower reported levels of pain throughout labor, and lower oxytocin, epidural and narcotic use. Nitrous oxide use did not differ between groups. Another study examined the effect of an individualized acupuncture regimen on those who also received standard analgesic care [47]. The protocol utilized a variety of thirteen different acupoints. There was no significant difference in pain intensity or delivery outcome, but observer-rated relaxation scores improved in the acupuncture group. Epidural use was 12% in the acupuncture group and 22% in the controls (RR 0.52, CI 0.3-0.92). In a third study meperidine use was 11% in the acupuncture group compared to 37% in a no-acupuncture group and 29% in a group of historical controls [48]. Sixty-six percent of the acupuncture group used some other form of analgesia compared with 82% of the no-acupuncture group and 79% of controls, both results were statistically significant.

Acupressure has also been studied for reducing pain in labor using a variety of acupoints. In a study of nurse delivered acupressure at LI4 and BL67 acupoints, both pain scores and duration of the first stage of labor were significantly reduced in the acupressure group compared to controls [49]. Results were also compared to a group receiving effleurage. Pain in the other stages of labor and uterine contractions were not different.

Two studies have examined the effect of general massage during labor [50,51]. One study examined the effect of general massage given for 30 min during each phase of labor at whichever sites subjects preferred administered first by the researcher, thereafter by the partner [50]. Pain reactions were assessed during labor by the attending nurse, and anxiety was self-reported. A significant improvement was noted in the measure of present manifestations of pain in all three phases of labor, but not in the measure for anxiety. The other study examined many stress and pain variables either assessed by the clinician or partner, or reported by the subject, and found an improvement in many measures [51].

Intracutaneous sterile water injections (ISW), given in a 0.1 ml dose at 4 points in the lumbar sacral region have been investigated to reduce lower back pain during labor in four studies [52-55]. In a small study, ISW during a contraction was compared to transcutaneous electrical nerve stimulation (TENS) or standard care [52]. ISW recipients reported significantly lower pain intensity and unpleasantness compared to both groups, although greater than 50% of participants in all groups requested an epidural. Two studies compared ISW with isotonic saline injections in the first stage of labor [53,54]. Both demonstrated analgesic effects with no difference in the use of adjunctive narcotics for pain relief. In a study comparing ISW, subcutaneous sterile water or subcutaneous isotonic saline (placebo), all three treatments had a beneficial effect on labor pain [55]. Women in the treatment groups had significantly improved pain reduction and midwives blinded to treatment group status assessed both interventions as effective. Intracutaneous and subcutaneous water injections caused the same amount of pain with administration, although a subsequent study found ISW to be more painful [56].

3.2.2. Shortening of labor

Chanlibao is a traditional Chinese herbal medicine that was studied for shortening the second stage of labor [57]. Chanlibao was given orally to the intervention group at the end of the first stage of labor. One control group received standard care, and another received standard care plus oxytocin. Length of the second stage of labor was significantly

lower in the chanlibao group compared to the control group (38.4 min vs. 53.1 min, respectively), although it was similar to oxytocin (41.6 min).

3.2.3. Operative nausea

The prevention of operative nausea and vomiting in women undergoing elective cesarean section was studied in two trials of acupressure [58,59]. The first randomized women undergoing elective cesarean section to receive either acupressure wrist bands with 2 ml IV saline, placebo wrist bands with 10 mg IV metoclopramide or placebo wrist bands alone [58]. All participants received subarachnoid injections of bupivicaine, dextrose and fentanyl as anesthesia. Acupressure group and metoclopramide group subjects were similar and had less nausea than those in the placebo group. In the second study, acupressure wrist bands were compared to placebo wrist bands for the prevention of post cesarean section nausea and vomiting [59]. Participants had received bupivacaine epidural and post operative epidural morphine for pain relief. Three percent of the acupressure group experienced nausea and none experienced vomiting compared with 43% and 27% in the control group, both results were significant.

3.2.4. Prevention of perineal trauma

In a study of perineal massage, subjects received either massage of the perineum during the second stage of labor or routine care [60]. The number of third-degree lacerations in the treatment group was significantly less than that of the control group. The number of first- and second-degree lacerations, episiotomies, and intact perineum did not differ.

3.3. Postpartum

Five alternative medicine modalities implemented in the postpartum period met inclusion for review. They include treatment for postpartum depression, breast engorgement and lactation suppression, perineal discomfort, and aiding postpartum recovery.

3.3.1. Postpartum depression

One clinical study examined the effect of infant massage on the mother—infant relationship and postpartum depression compared to support group only [61]. Massage classes were held weekly for five weeks, starting at a median nine weeks postpartum for women with depression. The median change in Edinburgh Postnatal Depression Scores was greater in the massage group however the effect occurred before the classes started and was maintained. An analysis of videotaped mother—infant interactions demonstrated improved changes in all dimensions.

3.3.2. Breast engorgement and lactation suppression

Cabbage products, tea bags and jasmine flowers have been studied in trials concerning lactation. In a trial of cabbage leaf extract cream vs. placebo cream, outcomes were measured by a number of measures of breast engorgement and hardness [62]. No statistical differences among the groups were found in any of the measures. Both groups demonstrated improvement with cream application. Cold cabbage leaf application after four consecutive feeds did not prevent the perception of breast engorgement in asymptomatic women [63].

One trial studied four groups of asymptomatic postpartum primiparous women receiving one of the following immediately after breastfeeding to prevent pain: a warm water compress, a warm tea bag compress, expressed milk massaged into the nipple and dried, or education only control [64]. The tea bag compress and expressed milk group did not differ significantly from the education group in any of the variables measured.

Jasmine flowers are a traditional treatment in South India for suppression of puerperal lactation and were studied following still birth or early neonatal death [65]. Application of a 50 cm string of jasmine flowers (*Jasminum sambac*) to each breast for 24 h, changed every day for five days was compared to the standard therapy controls of 2.5 mg bromocriptine mesylate taken every 8 h for five days. Prolactin levels and lactation scores were measured 24 h after delivery and 72 h after the initiation of therapy. Lactation score, based on milk secretion and breast engorgement, did not differ between groups. Prolactin levels decreased in both groups, but with jasmine flowers to a lesser degree.

3.3.3. Perineal discomfort

A pilot study of different concentrations of the homeopathic remedy *Arnica montana* to design a larger trial failed to demonstrate efficacy [66].

In a study of aromatherapy, six drops of lavender oil were added to the mothers' daily bath water for ten days following delivery. No significant differences were noted in the perineal discomfort scores or other outcomes measured, although the intervention was reported to be a pleasant experience [67].

3.3.4. Postpartum restoration

Kyuki-chouketsu-in is a traditional Japanese medicine consisting of the extract of thirteen herbs. One trial compared Kyuki-choketsu-in to ergometrine on physical assessment of fundal height and laboratory measures [68]. All subjects also received cefditoren pivoxil 300 mg/day and serrapeptase 30

mg/day. The fundal height, as assessed by physical exam, was 1.6 cm lower in the intervention group on day 5 (P=.0071), and various metabolic measures were affected.

4. Conclusion

Despite the limitations of many of the CAM studies, the results of some CAM interventions suggest that these modalities may be effective in obstetrics. At least three trials with consistent results have examined perineal massage for the prevention of perineal trauma, sterile water injection for low back pain, moxibustion for breech presentation or acupressure and ginger for nausea in early pregnancy. Evidence for ginger and acupressure is reflected by the consideration of their use to treat nausea and vomiting in pregnancy in the ACOG Practice Guidelines [69]. The evidence is weaker for other modalities, having been studied with few or single trials. In combination with the design limitations of these trials, many sample sizes are small and there are scenarios in which misinterpretation can occur. Some analyses rely on pre-test results in the intervention group for controls instead of data from the control group, effectively negating the strength of the experiment. In a number of studies, insignificant results are claimed as trends, and conclusions are often not based on the findings presented. In studies where the partner implemented the modality, the question of bias arises.

While this survey has attempted to review these papers, methodological issues are frequently so pervasive that brevity precludes their full discussion. Results put forth are those offered by respective authors, and the evidence should be examined further where interest warrants. In consideration of these issues, generalizability of results is sometimes limited and most modalities require more research before any conclusions of effectiveness and treatment recommendation can be made [70]. Additionally, this survey is limited to the studies in the English language, which can limit a full assessment of the spectrum of CAM in obstetrics [71]. The safety of CAM in obstetrics has drawn attention, although it is not reviewed here, and should be considered when exposing a pregnant or postpartum woman to biologically active compounds [72].

CAM is common in many parts of the world and much of this current practice is not based on clinical evidence. The use of CAM modalities arises from cultural norms and/or dissatisfaction with access to, effectiveness of and cultural appropriateness of western biomedicine [3]. Further investigation into

the fundamental basis of certain CAM modalities and development of theories of biologic plausibility and mechanism would aid in the ability to integrate these modalities into the biomedicine model for further clinical research and implementation. As documented research into the effectiveness of these modalities accumulates at a slower rate than the rate of CAM users, people caring for pregnant women will increasingly be called upon to assess the efficacy and safety of CAM modalities. Knowledge of the true benefits and risks of these medicines and therapies are needed to best serve the obstetric patient.

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