Effects of acupuncture on preeclampsia in Chinese women: a pilot prospective cohort study

Yingchun Zeng,1 Bing Liu,1 Taizhen Luo,1 Yun Chen,1 Guangen Chen,2 Dunjin Chen1

ABSTRACT
Objective To investigate the acceptability and feasibility of acupuncture treatment as an adjunct to usual care in Chinese women with preeclampsia.
Methods This was a pilot prospective cohort study. Pregnant women with a diagnosis of preeclampsia were offered acupuncture and allocated into groups based on their choice: the acupuncture group (n=11) comprised women electing to receive treatment (up to 10 sessions over 2 weeks). The control group (n=11) was made up of women who declined and was matched for age, gestation at diagnosis, and parity. All women received usual care and underwent measurement of blood pressure (BP) at four time points: at baseline, at the end of the intervention, immediately before delivery, and postpartum (within 24 h).
Results Patients in the acupuncture group had significantly lower BP at time of delivery, and postpartum, than patients in the control group (p<0.05). The individual change in BP between baseline and the end of treatment was significantly greater in the acupuncture group versus the control group for both systolic BP (median (IQR) −8 (−3 to −14) vs +1 (−7 to +9) mm Hg, p=0.007) and diastolic BP (−3 (−1 to −3) vs +2 (−2 to +7) mm Hg, p=0.013). There were no significant differences between the groups in perinatal outcomes and no adverse effects of treatment.
Conclusions Acupuncture plus usual care was associated with a greater reduction in BP than usual care alone. Further studies are needed to clarify the role of acupuncture in the treatment of preeclampsia.

INTRODUCTION
Preeclampsia is a specific disorder of pregnancy, which is characterised by gestational hypertension together with proteinuria or other stigmata, such as thrombocytopenia, impaired liver function, renal impairment, pulmonary oedema or new-onset cerebral or visual disturbances.1 It remains a leading cause of maternal and perinatal mortality and morbidity, and complicates 2–8% of all pregnancies.2 3 In China, the prevalence of preeclampsia is approximately 5%.4 The global incidence of preeclampsia appears to be increasing, most likely due to advancing maternal age, the higher prevalence of obesity and medical comorbidities, and the use of assisted reproductive techniques.4 Women with preeclampsia are at risk of various complications including eclampsia, renal failure, placental abruption, and preterm birth in the peripartum period.5 Furthermore, following the pregnancy, they have an increased risk of cardiovascular disease throughout their lives.6

Approximately one-half of patients with high blood pressure (BP) outside of pregnancy are non-compliant with drug therapy for various reasons, including adverse effects and complications.7 During pregnancy, in particular, several antihypertensive agents can have significant side effects. For example, the use of β-blockers is associated with fetal growth restriction, and ACE inhibitors such as captopril can cause fetal renal impairment and reduce placental perfusion.8 For this reason, there has been a growing interest in alternative therapies such as acupuncture for the treatment of preeclampsia.

In China, acupuncture has been used to treat disease for more than 2500 years.9 There is an increasing body of evidence supporting the effectiveness of acupuncture in the treatment of hypertension in general.7 10–12 However, to date there have been only two observational studies of acupuncture for treatment of hypertension during pregnancy, both of which...
suggested that acupuncture was safe and effective but were conducted in women with pregnancy-induced hypertension (PIH) without associated proteinuria or systemic features of preeclampsia. Moreover, both studies lacked a control group with which to draw any comparisons. Accordingly, the aim of the present study was to investigate the acceptability and feasibility of acupuncture treatment in women with a formal diagnosis of preeclampsia, and to examine its effects on the condition relative to a contemporaneous control group of women not receiving acupuncture.

METHODS

Ethical approval and study procedure

This was a pilot prospective cohort study, undertaken at the Third Affiliated Hospital of Guangzhou Medical University. The study was conducted in accordance with the Declaration of Helsinki code of ethics. Ethical approval was obtained from the ethics review committee of the Third Affiliated Hospital of Guangzhou Medical University (reference no. 2014#028). All patients participated on a voluntary basis and gave their written informed consent before data collection. A research nurse was responsible for recruiting subjects and for providing a full explanation of the study, while a dedicated acupuncturist performed the interventions. A second nurse collected the outcome data and was deliberately kept blind as to whether or not patients had been treated.

Inclusion and exclusion criteria

Pregnant women with a diagnosis of preeclampsia (defined as new-onset hypertension after 20 weeks gestation with evidence of maternal liver, renal, neurological or haematological abnormalities ± proteinuria) were invited to participate. Exclusion criteria included multiple pregnancy, pre-existing hypertension and/or secondary causes of hypertension (such as underlying renal disease) and PIH (defined as new-onset hypertension without any additional features of preeclampsia, as listed above). Between January and mid-May 2015, a total of 47 women with preeclampsia met the above inclusion criteria: 43 were willing to participate and four declined. Women who accepted the offer of acupuncture treatment formed the intervention group (n=11). The contemporaneous control group was selected from the 32 women who declined acupuncture (usually based on personal opinion or the advice of friends and/or family) but otherwise met inclusion criteria and were willing to contribute outcome data to the study. According to the pre-agreed study protocol, in order to achieve a 1:1 ratio in the intervention and comparator groups, women were chosen based on age (within 1 year), gestational age at diagnosis (within 2 weeks), and parity in order to form the matched control group (n=11).

Outcome measures

The primary outcomes were the changes in systolic BP (SBP) and diastolic BP (DBP), averaged over a 24 h period, between baseline (T0) and completion of the course of acupuncture treatment (T1). Secondary outcomes included BP at the time of delivery (T2) and within 24 h of delivery (T3), gestational age at delivery, birth weight, incidence of low birth weight (<2.5 kg), rate of admission to the neonatal intensive care unit (NICU), and rates of maternal or neonatal complications (to assess safety). In addition, all patients in the intervention group were asked to rate their satisfaction with the acupuncture treatment by selecting one of the following options in response to the statement that acupuncture was helpful for them: ‘extremely agree’, ‘agree’, ‘disagree’ or ‘extremely disagree’.

Data collection and analysis

All data are presented as mean±SD unless otherwise stated. SPSS V.20.0 was used for statistical analysis (SPSS, IBM Corp, Armonk, New York, USA). Categorical data were compared by the χ² test. Continuous data were checked for normality of distribution and analysed using the independent samples t test (to compare between study groups) and repeated measures analysis of variance followed by post-hoc Bonferroni test (to compare BP between different time points). All statistical tests were two-tailed, and p<0.05 was taken to indicate statistical significance.

RESULTS

Table 1 shows the baseline data in the acupuncture and control groups (n=11 each). After selecting

Acupuncture treatment

The acupuncture group received manual acupuncture, which was provided by a single acupuncturist trained in Traditional Chinese Medicine. Sterile, disposable, stainless steel needles (length 4 cm, diameter 0.25 mm, HuanQiu, China) were inserted at a combination of the following seven acupuncture points: GB20 (Fengchi), LR3 (Taichong), LI11 (Quchi), ST36 (Zusanli), LI4 (Hegu), SP6 (Sanyinjiao) and GV20 (Baihui), unilaterally or bilaterally, depending on each woman’s traditional diagnosis (constitution) as determined by the acupuncturist. The total number of points needled was 12 in all participants, the duration of needling was 20 min, the frequency of treatment was five times per week, and the total number of treatments was intended to be 10 per patient. The depth of needling varied between 25 and 40 mm depending upon the individual point.

Both groups received usual care, which included oral antihypertensives for BP control, diazepam for sedation, and magnesium sulfate to reduce the risk of seizures. When necessary, glyceryl trinitrate (nitroglycerine) was used to keep BP below 160/100 mm Hg to minimise the risk of intraventricular haemorrhage.

Table 1 shows the baseline data in the acupuncture and control groups (n=11 each). After selecting

controls on the basis of maternal age (range 25–41 years), gestational age at diagnosis (range 21–34 week gestation) and parity, the two groups were highly similar with respect to these four variables, confirming balanced matching. Due to China’s one child policy, most women were nulliparous. In addition, there were no significant differences at baseline in gravidity or BP. Three of 11 patients did not complete 10 sessions of acupuncture: one patient went into preterm labour secondary to placental abruption and two patients were medically induced by their physicians as they were approaching term (37 weeks gestation).

**Figure 1** shows the mean SBP and DBP at the four assessment time points by group: baseline (T0), at the end of the treatment period (T1), before delivery (T2), and day 1 post-delivery (T3). The average 24 h SBP and DBP before delivery and postpartum were significantly lower in the acupuncture group than in the control group (p<0.05). Although mean SBP and DBP did not differ between groups immediately following treatment, the primary outcome (individual change in BP from baseline, ie, T0 to T1) was greater in the acupuncture group versus the control group for both SBP (mean (IQR) −8 (−3 to −14) vs +1 (−7 to +9) mm Hg, p=0.007) and DBP (−3 (−1 to −3) vs +2 (−2 to +7) mm Hg, p=0.013). In both groups, postpartum BP readings were significantly lower compared to time points T0, T1 and T2 (p<0.001–0.032), reflecting the natural history of preeclampsia (which resolves following delivery).

In terms of perinatal outcomes in the acupuncture and control groups (table 2), there were no statistically significant differences between the two groups for any parameter. With respect to maternal complications, two women experienced placental abruption (one each in the acupuncture and control groups). One patient developed pulmonary oedema and another experienced eclampsia, both in the control group. There were no other maternal complications. In terms of neonatal complications, one neonate was born with a traumatic injury to the urethra (very unlikely to be related to acupuncture). The number of neonates admitted to NICU was equivalent between the two groups and was predominantly due to prematurity. No significant adverse effects were reported as a result of the acupuncture treatments. Three patients in the study group reported minor complaints: needle-related bruising, needling pain, and spot bleeding, respectively. One patient in the acupuncture group experienced placental abruption during the intervention period; however, notably, the incidence of placental abruption in this group (one of 11) was identical to that in the control group. With respect to patient satisfaction, six out of 11 patients who received acupuncture reported that it was extremely helpful, four reported that it was helpful, and only one reported that it did not help.

**DISCUSSION**
This is the first pilot study to investigate the effects of acupuncture treatment on preeclampsia. The results showed that acupuncture reduced systolic and diastolic

Table 1 Baseline data

<table>
<thead>
<tr>
<th>Variables</th>
<th>Acupuncture group (n=11)</th>
<th>Control group (n=11)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (years)</td>
<td>31.9 (3.96)</td>
<td>32.7 (4.47)</td>
<td>0.65</td>
</tr>
<tr>
<td>Gestational age at diagnosis (weeks) (21–34)</td>
<td>28.2 (3.74)</td>
<td>28.4 (3.69)</td>
<td>0.95</td>
</tr>
<tr>
<td>Parity (0–1)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>0</td>
<td>10 (90.9)</td>
<td>9 (81.8)</td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>1 (9.1)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>Gravidity (1–3)</td>
<td></td>
<td></td>
<td>0.75</td>
</tr>
<tr>
<td>1</td>
<td>9 (81.8)</td>
<td>8 (72.7)</td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>1 (9.1)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>1 (9.1)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Systolic blood pressure (mmHg)</td>
<td>152.6 (12.79)</td>
<td>152.5 (13.87)</td>
<td>0.975</td>
</tr>
<tr>
<td>Diastolic blood pressure (mmHg)</td>
<td>99.9 (13.08)</td>
<td>99.7 (8.41)</td>
<td>0.969</td>
</tr>
</tbody>
</table>

Data are mean (SD) for continuous variables and number (%) for categorical variables.
Table 2  Perinatal outcomes

<table>
<thead>
<tr>
<th>Variables</th>
<th>Acupuncture group (n=11)</th>
<th>Control group (n=11)</th>
<th>p Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gestational age at delivery (weeks) (26–38)</td>
<td>34.2 (2.82)</td>
<td>32.1 (3.83)</td>
<td>0.16</td>
</tr>
<tr>
<td>Mode of delivery</td>
<td></td>
<td></td>
<td>0.59</td>
</tr>
<tr>
<td>Vaginal delivery</td>
<td>2 (18.2)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>Caesarean section</td>
<td>9 (81.8)</td>
<td>10 (90.9)</td>
<td></td>
</tr>
<tr>
<td>Maternal complications</td>
<td></td>
<td></td>
<td>0.26</td>
</tr>
<tr>
<td>Yes</td>
<td>1 (9.1)</td>
<td>3 (27.3)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>10 (90.9)</td>
<td>8 (72.7)</td>
<td></td>
</tr>
<tr>
<td>Birth weight (g)</td>
<td>1517 (986)</td>
<td>1471 (1160)</td>
<td>0.11</td>
</tr>
<tr>
<td>Apgar score</td>
<td></td>
<td></td>
<td>0.59</td>
</tr>
<tr>
<td>&lt;7</td>
<td>1 (9.1)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
<tr>
<td>≥7</td>
<td>10 (90.9)</td>
<td>9 (81.8)</td>
<td></td>
</tr>
<tr>
<td>Neonatal complications</td>
<td></td>
<td></td>
<td>0.30</td>
</tr>
<tr>
<td>Yes</td>
<td>0 (0.0)</td>
<td>1 (9.1)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>11 (100)</td>
<td>10 (90.9)</td>
<td></td>
</tr>
<tr>
<td>Admission to NICU</td>
<td></td>
<td></td>
<td>1.00</td>
</tr>
<tr>
<td>Yes</td>
<td>9 (81.8)</td>
<td>9 (81.8)</td>
<td></td>
</tr>
<tr>
<td>No</td>
<td>2 (18.2)</td>
<td>2 (18.2)</td>
<td></td>
</tr>
</tbody>
</table>

Data are mean (SD) for continuous variables and number (%) for categorical variables.

NICU, neonatal intensive care unit.

BP over the study period. After matching for subjects’ baseline BP, age, gestational age at diagnosis and parity, there were no significant baseline differences between the acupuncture and control groups, so imbalance of any of these variables is unlikely to account for the observed positive effects of acupuncture on BP in women with preeclampsia. However, the lack of any randomisation means that the possibility of residual confounding cannot be completely ruled out.

In the present study, there were no statistically significant effects of acupuncture on perinatal outcomes, which is likely to reflect the small number of patients included. Previous retrospective clinical observations have also indicated that acupuncture can help treat PIH, thereby improving perinatal outcomes. Although it has been reported anecdotally that acupuncture treatments can be dangerous during pregnancy, this study did not find any significant adverse effects during the entire study period. In this pilot study, there were only minor adverse effects, including needle pain and spot bleeding. This study finding was congruent with previous observations that acupuncture imposes no significant risks for pregnant women.

This pilot study has two main limitations. Firstly, there was no sham acupuncture procedure provided in the control group, so we are unable to exclude placebo effects. As group assignment was based on patient cooperation, patients in the acupuncture group may have received more attention, which may have had a psychological effect. The sample size of this study was very small, which may have been compounded by the fact that some pregnant women and their obstetricians hold conservative attitudes toward applying acupuncture during pregnancy. Moreover, many acupuncturists fear the fact that certain acupuncture points (eg, SP6) can trigger uterine contractions in pregnant women, although there is no scientific evidence that stimulating such acupuncture points is harmful during pregnancy. A sham-controlled trial would be needed to control for the non-specific effects of acupuncture treatment; however, this poses an ethical dilemma in view of the serious nature of preeclampsia and need for effective treatment. Zaslawski argues that a trial comparing acupuncture plus conventional care versus conventional care alone is the most ethical option, because there is no attempt to prevent patients from receiving conventional treatment. Ultimately, a randomised controlled trial will be required to examine whether acupuncture has positive effects on reducing BP in women with preeclampsia.

In conclusion, this pilot study shows that acupuncture appears effective at reducing BP in women with preeclampsia when used as an adjunct to standard care; however, this needs to be verified by further research including a larger sample size and randomisation. Future studies need to be sufficiently powered to determine whether acupuncture, in addition to potentially reducing BP, can improve perinatal outcomes for women with preeclampsia and their babies, in order to guide clinical practice in the future.

Contributors YZ, BL and TL designed the study. YC collected the data. GC provided the acupuncture. DC diagnosed participants and supervised the research project. YZ drafted the manuscript. All authors approved the final version of the manuscript.

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Competing interests None declared.

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Observation

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