

# Acupuncture for insomnia in pregnancy

## – a prospective, quasi-randomised, controlled study

João Bosco Guerreiro da Silva, Mary Uchiyama Nakamura, José Antonio Cordeiro, Luiz Kulay Jr

### Abstract

**Objective** This study was undertaken to test the effects of acupuncture on insomnia in a group of pregnant women under real life conditions, and to compare the results with a group of patients undergoing conventional treatment alone (sleep hygiene).

**Methods** A total of 30 conventionally treated pregnant women were allocated at random into groups with or without acupuncture. Seventeen patients formed the study group and 13 the control group. The pregnant women scored the severity of insomnia using a Numerical Rating Scale from 0 to 10. Women were followed up for eight weeks and interviewed five times, at two-week intervals.

**Results** Eight women dropped out, five in the study group and three in the control group. The study group reported a larger reduction on insomnia rating (5.1) than the control group (0.0), a difference which was statistically significant ( $P=0.0028$ ). Average insomnia scores decreased by at least 50% over time in nine (75%) patients in the study group and in three (30%) of the control group.

**Conclusion** The results of this study suggest that acupuncture alleviates insomnia during pregnancy and further research is justified.

### Keywords

Acupuncture, insomnia, pregnancy.

### Introduction

Insomnia appears to be common during pregnancy, although there have been few publications on the subject. One study of 192 pregnant women found that 88% suffered changes in their sleep patterns.<sup>1</sup> Insomnia tends to worsen during the evolution of the gestation,<sup>2</sup> mainly owing to back pain, an increased need to micturate, and the movement of the foetus.<sup>1</sup> Generally patients with insomnia are not treated with medications for fear of adverse effects, even though the lack of sleep can cause a reduction in the quality of life.

Acupuncture seems to offer an alternative treatment for insomnia, as was seen during our review of the literature. It improved the quality of sleep as judged by subjective assessment in one study,<sup>3</sup> and by objective evaluation using polysomnography in a second.<sup>4</sup> An increase in the serum concentration of melatonin is induced by acupuncture.<sup>5</sup> Since this is usually lowered in pregnant women with sleeping difficulties,<sup>6</sup> this may be one mechanism for the effect. Nevertheless, we found no reports of the use of acupuncture for treating insomnia in pregnancy.

Therefore the aim of this study was to observe the effects of acupuncture, in practice, on the treatment of insomnia during pregnancy. In a service where pregnant women were treated by counselling, the treatment of choice in pregnancy,<sup>7</sup> one group was also treated by acupuncture.

### Patients and Methods

This study was approved by the Research Ethics Committee of the Federal University of São Paulo, Brazil. From July to December 2002, a study using acupuncture for pregnant women attending the antenatal programme of Santa Casa of São José do Rio Preto was initiated with the aim of treating the most common non-obstetric complaints. This antenatal programme is a state-funded service for pregnant women from the local area. This paper reports the outcome among those patients who complained of insomnia. From the total group of 100 women, 30 complained of insomnia. The inclusion requirements for this study were: informed consent, age from 15 to 39 years, between 15 and 30 weeks of pregnancy (thus excluding women in the first trimester, and

João Bosco Guerreiro da Silva  
assistant professor in acupuncture  
Medical School of São José do Rio Preto  
Brazil

Mary Uchiyama Nakamura  
professor in charge obstetrics  
Federal University of São Paulo, Brazil

José Antonio Cordeiro  
professor in statistics  
Medical School of São José do Rio Preto  
Brazil

Luiz Kulay Jr  
professor in obstetrics  
Federal University of São Paulo, Brazil

Correspondence:  
João Bosco Guerreiro da Silva  
[jbgsilva@hotmail.com](mailto:jbgsilva@hotmail.com)

allowing time to measure the effect of a course of treatment) and insomnia. The pregnant women must not have suffered from insomnia before pregnancy, have belonged to a high-risk obstetric group, have been treated by acupuncture within the preceding year, or have been taking hypnotic drugs.

Patients were allocated to the treatment group according to their day of attendance: 13 women attending programmes on Mondays and Wednesdays were treated by advice including sleep hygiene only (control group) and 17 women attending the Tuesday and Thursday programmes were treated by sleep hygiene and acupuncture (study group). With the exception of the acupuncture treatment, there was no difference between the treatments given to the groups.

Sleep hygiene was given by a nurse to groups from four to eight pregnant women, and consisted of instructions to avoid stimulants, heavy meals and liquid excess before bed time, and to establish a set bed time ritual including: fixed routine, bath before bed, no working late, use of relaxation techniques, and routine posture for sleep.

Both the definition and the evaluation of insomnia are difficult. Based on the *International Classification of Sleep Disorders (ICSD)* definition of 'an almost nightly complaint of an insufficient amount of sleep or not feeling rested after the habitual sleep episode',<sup>8</sup> we designed an ad hoc, self-reported measure. We asked the patients to think about seven common patterns of sleep disturbance: delayed sleep onset, frequent awakenings, early wakening, waking tired, disrupted sleep, day napping and nightmares; and then asked them to give a single rating on a Numerical Rating Scale (NRS) of zero to 10, where zero represented good sleep and 10 the worst insomnia possible.

At baseline and then every fortnight for eight weeks, the pregnant women were interviewed by an appropriately trained medical student in order to collect the scores. In addition, the student asked specifically about side effects from earlier treatment. The student had minimal contact with other members of the study. At baseline, the women were also requested to fill in a questionnaire covering background data, previous medical and previous obstetric history. Then they were referred to their obstetricians (control group) or to the acupuncturist (study group). The patients in the study group also

visited their respective obstetrician after the acupuncture session.

#### *Acupuncture treatment*

The acupuncture treatment was normally performed once a week but occasionally twice when it was deemed necessary for severe symptoms, over an eight-week period, making a minimum of eight and a maximum of 12 sessions.

Traditional acupuncture was applied, respecting the classic acupuncture points including depth of needle insertion. Sterilised stainless steel needles of 40mm in length and 0.2mm in diameter were used. Neither electrostimulation nor ear acupuncture was used. On average 12 needles were utilised, and an attempt was made to elicit *de qi* at each point. Needles were left in place for about 25 minutes.

The acupuncturist in the study has completed 600 hours of postgraduate training in acupuncture, which included the theory and practice of traditional Chinese medicine. During the last 15 years he has run a public service that commonly treats at least 50 patients per day. In order to simplify the protocol, it was decided to use pre-defined points, with an option of up to four points permitted in addition. The most commonly used points were: HT7, PC6, GB21 and *Anmian* (extra point midway between GB20 and TE17) bilaterally, and *Yintang*, GV20 and CV17 (midline points).

#### *Statistics*

After tests for normality using the Anderson-Darling test, repeated measures ANOVA was applied to test the effects of time, group and time-group interaction on the main outcome, NRS symptom scores. Within group changes were compared using a two-sample *t* test. Non-parametric data (baseline variables) were analysed with the Kruskal-Wallis test, and the numbers achieving 50% reduction in NRS assessments of symptoms were compared using the Fisher exact test. Results are reported as differences of means and standard deviations (SD) or medians and interquartile ranges (IQR). The level set for statistical significance was  $P < 0.05$ .

#### *Results*

Five pregnant women in the study group dropped out because they missed at least two consecutive interviews. In the control group, two dropped out

**Table 1** Background data of pregnant patients in controlled trial of acupuncture.

	Acupuncture group		Control group		P value
Age (years)*	26.5	(7.7)	26.5	(5.6)	1.0
BMI for gestational age *	24.1	(3.7)	26.7	(3.9)	0.13
Gestational age (weeks)*	20.6	(5.5)	22.2	(3.9)	0.43
Gestation †	1.5	(2.5)	2.5	(3.0)	0.22
Parity †	0.5	(1.0)	1.0	(3.0)	0.44
Miscarriages †	0.0	(0.7)	0.0	(0.0)	0.11

\*means (SD), groups comparison by t test.

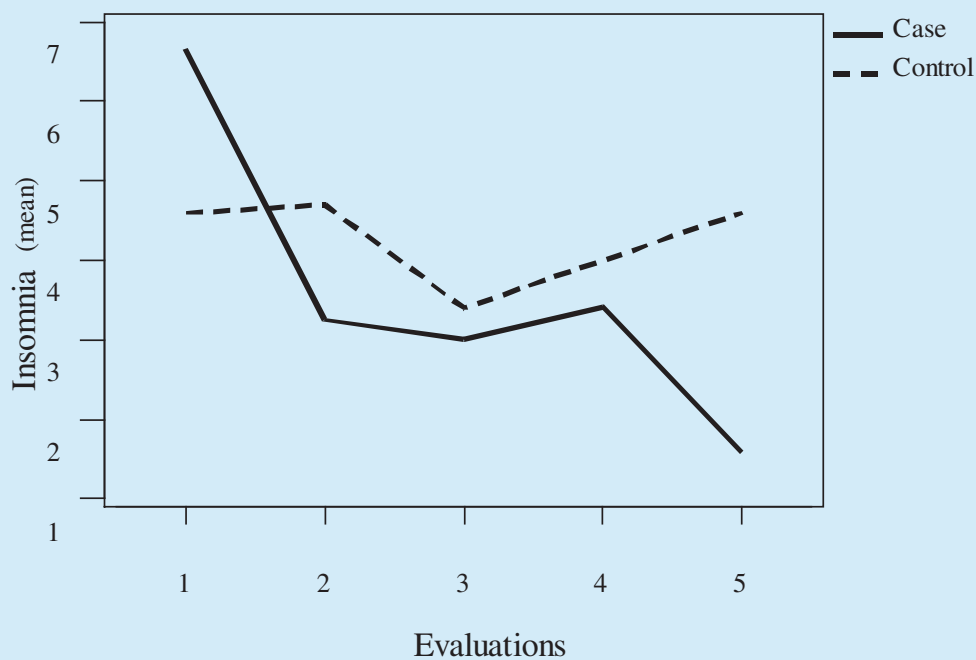
†medians (IQR), groups comparison by Kruskal-Wallis test for medians.

**Table 2** Patients' ratings of sleep disturbance on numerical rating scale at 14 day intervals.

	n	Baseline	2	3	4	5
Acupuncture	12	6.7 (3.5)	3.2 (2.4)	3.0 (2.7)	3.4 (3.7)	1.6 (1.7)
Control	10	4.6 (3.0)	4.7 (3.3)	3.4 (3.1)	4.0 (2.5)	4.6 (3.0)

Values are means (SD).

Changes from baseline to end of treatment were significantly greater in the acupuncture group ( $P=0.0028$ , *t* test).



**Figure 1** Insomnia scores at five measurement points, by group ( $P=0.008$ , ANOVA).

because of missing interviews and one moved away from the region. Thus, 12 patients in the acupuncture group and 10 in the control group completed the treatment and concluded all the interviews. The analysed data refer to these patients. No important adverse effects were reported, but one patient reported

ecchymoses at some insertion points. There were no significant differences between the birth weights of the babies of the acupuncture group (mean 3281g, standard deviation (SD) 428g) and control group patients (3212g, SD 343g). The median value for the one-minute Apgar score was 9.0 (IQR=0.0) in

the acupuncture group and 9.0 (IQR=1.0) in the control group ( $P=0.08$ ). The median value for five-minute Apgar was 10 for both groups (IQR=0.0).

The two groups were similar in respect of age, number of previous pregnancies and body mass index (Table 1). The average insomnia score decreased during the study period by 50% or more in nine patients (75%) in the study group compared with three (30%) in the control group ( $P=0.042$ ). An overall reduction in NRS values could be seen (time effect,  $P=0.001$ ), but the reduction was greater in the study group (group effect,  $P=0.008$ ), as can be seen in Table 2 and Figure 1. The change in the insomnia scores during the course of acupuncture treatment was significantly higher than in the control group (NRS 5.1 (SD=3.8) vs 0.0 (SD=3.7) ( $P=0.0028$ )).

### Discussion

The results of our cohort study of acupuncture for insomnia in pregnancy found a significant between-group difference in insomnia scores, suggesting that acupuncture has a positive effect in reducing insomnia in pregnancy.

Insomnia, as well as its intensity during pregnancy, may be associated with certain variables such as age, gestational age, previous pregnancies, parity, previous miscarriages and even body mass index.<sup>9</sup> These variables were therefore measured and found not to differ between the study and control groups, so they can be excluded as an explanation for the findings.

One important point of our work is its originality. Although acupuncture is being used for insomnia, and even though pregnancy is a special time during the life of women that requires the greatest restriction on the use of drugs as possible, we did not find any publications that specifically studied acupuncture and insomnia during gestation. In fact, there are very few prospective randomised studies on acupuncture and insomnia. However, because of good results from those few studies,<sup>5,10</sup> improvements in our patients were anticipated.

There are some limitations in our study. Evaluation of insomnia is a problem. Although objective measures such as polysomnography and actigraphy are considered the best, subjective self-reported measures are well accepted.<sup>11-14</sup> The problem is choosing the most appropriate. In a recent review, many questionnaires are presented, each with its

advantages and drawbacks.<sup>14</sup> According to the author, even an ad hoc questionnaire could be used 'if one is venturing into a new and unique area'.<sup>14</sup> This allowed us the flexibility to develop the measure for this study. We accept that a specially tailored questionnaire can limit the study but that was our choice. We would like to see our work repeated using validated measures.

Our patients did not receive a sham acupuncture intervention, and this was not a blind study. The acupuncture group received more attention, which could have produced a 'placebo effect'. We could not exclude non-specific effects. Like Vickers et al,<sup>15</sup> we used a pragmatic policy of 'using acupuncture' versus 'avoiding acupuncture'. The term *placebo* has not been clearly defined in relation to acupuncture yet. Effects can be found even using non-traditional points.<sup>16</sup> Other authors also found effects using cocktail sticks as sham procedures, on true or dummy points.<sup>17,18</sup> Our aim was to observe the result of treatment by acupuncture on insomnia under real-life conditions compared with a group not treated in this way. We used the third category of research design described by Hammerschlag:<sup>19</sup> acupuncture plus standard care versus standard care only. In many situations this may be the most ethical option in that there is no attempt to deny subjects effective standard treatment.<sup>20</sup> In order to reduce bias we minimised contact between therapist and interviewer, as well as talking to the pregnant women about bias.

It has been reported anecdotally that acupuncture can be dangerous in pregnancy. We did not find any important adverse effects during the study. There were no significant differences between infants born to the two groups. These data are congruent with results reported by other authors as no maternal or obstetric side effects have been reported during or after more than 2300 acupuncture stimulations in 421 pregnant women.<sup>18,21-25</sup>

### Conclusion

Insomnia is a common problem in pregnancy. The use of medications is always a concern. Acupuncture, as was evidenced in this study, seems to be an efficacious means of reducing the symptoms. This technique should be further studied in prospective randomised studies with large cohorts and validated scales to confirm our findings relating to its efficacy and the absence of adverse effects. The treatment is

simple to employ and when used appropriately may reduce any need for medications.

#### Summary points

Insomnia is common in pregnancy

There are few studies of acupuncture for this indication

This controlled trial finds that acupuncture in addition to sleep counselling is superior to sleep counselling alone

Further controlled trials using validated measures are justified

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