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Acupuncture for dyspepsia in pregnancy: a prospective, randomised, controlled study

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ABSTRACT

Objectives: This study was undertaken to describe under real-life conditions the effects of acupuncture on symptomatic dyspepsia during pregnancy and to compare this with a group of patients undergoing conventional treatment alone.

Methods: A total of 42 conventionally treated pregnant women were allocated by chance into two groups to be treated, or not, by acupuncture. They reported the severity of symptoms and the disability these were causing in daily aspects of life such as sleeping and eating, using a numerical rating scale. The study also observed the use of medications.

Results: Six women dropped out (one in the acupuncture group and five in the control group). Significant improvements in symptoms were found in the study group. This group also used less medication and had a greater improvement in their disabilities when compared with the control group.

Conclusions: This study suggests that acupuncture may alleviate dyspepsia during pregnancy.

groups treated conventionally, with one group also treated with acupuncture.

PATIENTS AND METHOD

The Research Ethics Committee of the Federal University of São Paulo, Brazil approved this study. From January to December 2003, a study on use of acupuncture on pregnant women attending the prenatal programme of Santa Casa of São José do Rio Preto, Brazil was initiated with the aim of treating the most common non-obstetrical complaints. This is a state-funded service that receives pregnant women from the local area who participate in a prenatal programme. This paper relates an outcome of those patients with dyspepsia. After giving their informed consent, 42 patients that satisfied the study criteria were selected and randomly allocated into two groups. Randomisation was achieved by a nurse from the research team selecting from a box a closed piece of paper with a treatment order written on it. Both groups were counselled by a group of nurses about lifestyle modifications and dietary changes to alleviate dyspepsia. They were also allowed to receive antacids from their obstetricians. After that, the study group visited the acupuncturists. With the exception of the acupuncture treatment, there was no difference between the groups.

The inclusion requirements were: aged from 15 to 39 years, at 15–30 weeks of pregnancy and dyspepsia symptoms. They should not have any underlying disease as a possible cause of the symptoms nor have a history of similar symptoms prior to pregnancy. They should not belong to a high-risk pregnancy group or have been treated by acupuncture in the preceding year.

Heartburn is the most typical symptom of dyspepsia and it was considered the primary outcome. It was defined as burning substernal discomfort with no radiation component and described with common words.¹⁵ The women estimated both the severity and frequency of heartburn using a numerical rating scale (NRS) ranging 0–10, where 0 meant no symptom and 10 the greatest imaginable. Secondary efficacy variables were antacid consumption (a 600 mg tablet = 1 dose) and the effects of their symptoms in relation to sleeping and eating. Also by means of the NRS, the highest score, 10, indicated the greatest inability to perform these tasks.

At baseline and every 2 weeks until completion of the treatment at 8 weeks, the pregnant women were interviewed by the research assistant—a medical student who was appropriately trained,

Digestive disorders constitute one of the most frequent complaints of pregnancy.¹ Heartburn, epigastric pain or discomfort, regurgitation, belching and bloating occurs in approximately 45% to 80% of gravid women and are associated with symptomatic reflux.² Effects on the gastrointestinal tract are caused primarily by hormonal changes and not the physical effects of the gravid uterus.³ Prolongation of gastrointestinal transit times,^{3 4} enlargement of gallbladder and its sluggish emptying, and pressure reduction of lower oesophageal sphincter can be the main causes.^{3 5} They are mediated by progesterone, with oestrogen probably acting as a primer.³ These symptoms worsen with the progression of gestation and, although in the majority of cases are not severe, they provoke a considerable drop in the quality of life of the gravida.

Several studies have suggested the promise of acupuncture in dyspeptic problems^{6–10} although there is a lack of properly randomised controlled trials. Much evidence exists about the use of acupuncture for nausea and vomiting in pregnancy^{1–14} but no evidence was found for acupuncture studies into other complaints.

The aim of this study, therefore, was to observe the effects of acupuncture in practice on the treatment of dyspepsia in pregnancy. We established an acupuncture service in prenatal care and through that we sought to determine the effects of a policy of “use acupuncture” compared with a policy of “avoid acupuncture” by comparing two

and had the minimal contact with the other members of the study—to collect these values.

At the baseline, all the women were also requested to fill in a questionnaire covering background data, disease history before the first visit and previous obstetric history. They were then referred to their obstetricians and after that the study group went to the acupuncturist.

The treatment of acupuncture was performed once a week, occasionally twice when it was deemed necessary, during 8 weeks, making a minimum of eight and a maximum of 12 sessions. Traditional acupuncture was used, respecting the classical acupuncture points including depth of insertion. Sterilised stainless steel needles of 40 mm in length and 0.2 mm diameter were used. Neither electro-stimulation nor ear acupuncture was used. On average 12 needles were used, always attempting to achieve the *de qi* sensation (sensation of soreness, numbness or distension around the point). Needles were left at place for about 25 minutes.

The acupuncturists in the study (JBGS, RS) have completed 600 hours of postgraduate training in acupuncture, which included the theory and practice of Traditional Chinese Medicine. For the last 20 years they have run a public service that has been used to treat at least 50 patients per day. In order to facilitate protocols we decided to use pre-programmed points. Up to four points were permitted as optional points. The most commonly used points were: LI4 (hands); PC6 (forearms); CV12, ST21, LR13 (abdomen); ST36 (legs) and SP4, ST44 (feet).

Two-sample t tests were used to compare demographic variables, and when recommended, the nonparametric Kruskal-Wallis test was used. Changes overtime in the NRS assessments of symptoms intensity were analysed by Fisher test. The differences of mean values between initial and final sessions were analysed by two-sample t test. The questions about sleeping and eating, measured in medians were analysed by Mood's test for medians. Before any application of statistical test, the Anderson-Darling test for normality was performed to confirm the normal distribution of the data. A p value < 0.05 indicates a significant difference.

RESULTS

Six women dropped out. One in each group moved away and four in the control group missed two consecutive interviews. Thus, 20 patients in the acupuncture group and 16 in the control group completed the treatment and concluded all the interviews.

No important adverse effects were reported. Just one patient related little ecchymosis in some insertion points. Acupuncture (3204 g, SD = 466 g) and control patients (3236 g, SD = 297 g) did not differ significantly in respect to the birth weight of their infants (p = 0.80). The mean value for the one minute Apgar score was 9.0 (interquartile range (IQR) = 0.0) in the acupuncture

Table 1 Background data

	Acupuncture group		Control group		p Value
Age (years)*	28.0	6.3	24.8	5.5	0.11
Current weight (kg)*	65.8	11.0	61.9	11.2	0.30
BMI for GA*	24.6	3.5	23.8	4.3	0.60
Gestational age (weeks)*	20.5	5.4	21.3	4.3	0.60
Gestation†	1.5	1.7	2.0	1.7	0.71
Parity†	0	1.0	0	1.0	0.92
Miscarriages†	0	0.0	0	0.0	1.0

*Means, standard deviation and t test; †medians, interquartile range and Mood's test. BMI, body mass index; GA, gestational age.

group and 9.0 (IQR = 1.0) in the control group (p = 0.24). The median value for 5-minute Apgar was 10 (IQR = 0.8) for both groups (p = 1.0).

The two groups were similar in respect to age, number of previous pregnancies and body mass index. These data can be seen in table 1.

During the study period, the average heartburn intensity decreased by at least a half in 15/20 (75%) of patients in the study group and in 7/16 (44%) of those in the control group (p = 0.044). During treatment a diminishing trend of NRS values could be seen in both groups (p < 0.001), however this effect was greater in the study group (p = 0.001), notwithstanding control group global mean being significantly greater than that of study group (p = 0.001) as can be seen in fig 1 and table 2, despite that, at initial evaluation, there was no significant difference between them (p = 0.15).

After treatment, the NRS differences in the acupuncture group were significantly higher in comparison with the control group (NRS 5.1 (SD = 3.7) versus 0.9 (SD = 2.9) (p = 0.001).

Only 14 patients, seven in each group, took antacids. The study group had a mean reduction in the use of medications of 6.3 doses (SD = -6.9) whereas the control group had an increased use of 4.4 doses (SD = 5.5).

After treatment 15/20 (75%) of the members of the study group reported an improvement of at least 50% in respect to eating compared to only 5/16 (31%) of the control group (p value = 0.008). In respect to sleeping, 14/20 in the study group and 4/16 in the control group also reported improvements of 50% (p value = 0.009).

DISCUSSION

In our cohort, acupuncture proved to exert a great influence in minimising the heartburn in pregnancy (table 2) during treatment. This can be seen by the significant difference between groups, that is, although in both groups the symptoms dropped, the mean of the symptoms in the study group is lower than that of the control group at the end of treatment.

We had some difficulties in our study. It is not easy to evaluate upper dyspepsia. There are few published systematic reviews of the best approaches to symptom evaluation in upper dyspepsia.^{16 17} It is said that predominant heartburn is the feature that best identifies it, and both the severity and frequency seem to be important characteristics.¹⁸ They have been the focus of treatment trials and are the primary concern in everyday practice.¹⁵

Measurement of symptoms status among patients with upper dyspepsia has, to date, been conducted in a variety of

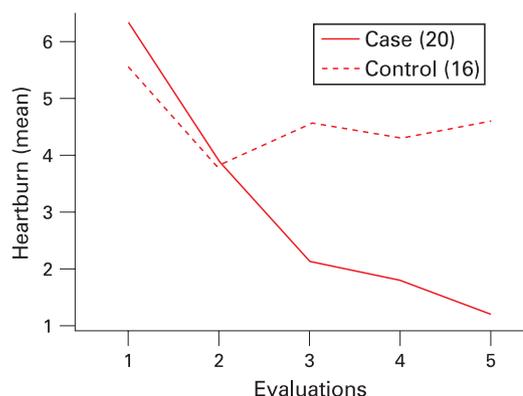


Figure 1 Comparison of heartburn levels during the evaluation period.

Table 2 Comparison of heartburn levels at each evaluation

Group	n	Evaluations								
		Initial	2 nd	3 rd	4 th	Final				
Acupuncture	20	6.3 (3.0)	3.9 (2.5)	2.1 (2.7)	1.8 (2.2)	1.2 (1.9)				
Control	16	5.6 (2.8)	3.8 (3.3)	4.6 (3.5)	4.3 (4.0)	4.7 (3.8)				

All scores are in means of NRS (SD); p value (differences of NRS) = 0.001
NRS, numerical rating scale; SD, standard deviation

ways and uncertainty remains on the best methods for measuring the symptoms.¹⁹ Although there are several drawbacks, visual analogue scale or NRS formats yield theoretically continuous response data which simplifies computations and analyses of these data.^{19, 20} In order to minimise those drawbacks, we outlined, in interviewer training, four cognitive steps that respondents must traverse when answering questionnaire items:

1. Interpret what is being asked
2. Retrieve relevant information
3. Make a summary judgement
4. Convey that judgement to examiner

Our aim was to observe the result of treating dyspeptic complaints with acupuncture under real-life conditions, compared with a group that were not treated in this way. We used a fifth category as described by Hammerschlag:²¹ "acupuncture plus standard care versus standard care only". This may be the most ethical option in that there is no attempt to deny subjects effective standard treatment.²² Patients in the trial were not blinded, but the interviewer was, or at least it was an attempt.

Dyspeptic complaints are very often seen in prenatal programmes. Thus, we observed in our cohort an incidence of 41%. These complaints, as well as their intensity, during pregnancy may be associated to certain variables such as age, gestational age, previous pregnancies, parity, previous miscarriages and body mass index. Hence these were analysed in the study and control groups so that they could be excluded as a cause of differences in the results.

Although just a small part of the women took antacids, if we analyse these subgroups we can see that the control group used more medication than the study subgroup, which suggests that the difference in the symptoms' intensity between the two groups would have been even greater with time.

We could also see, in the case group, an increase in the capacity to sleep and eat, some aspects that usually deteriorate during the evolution of the gestation. A situation that is worse when a gravida suffers from dyspeptic disorders.

One important point of our work is its originality. Although there is proof of the positive effects of acupuncture on the digestive tract, both in animals^{23, 24} and humans,^{7, 8, 25} there are practically no prospective randomised clinical studies relating to this subject. The exceptions are the varying well-conducted studies about anti-emesis.¹¹⁻¹⁴ Because of the proven effects of acupuncture in modulating gastric motor activity and in the motility of the oesophagus and lower oesophageal sphincter,¹⁰ improvements in our patients were expected. Clinical studies in the literature are exclusively case reports.²⁶⁻²⁹ While these papers describe clinical experience, prospective randomised clinical data are lacking.

Many acupuncturists fear the use of acupuncture in pregnant women, as they believe that some points might trigger uterine contractions. We did not find in scientific literature or even in interviewing many obstetric acupuncturists in Brazil and China any real evidence that some distant points could be harmful to pregnancy. However, until more research is done, we do not recommend sacral or low abdominal points. In this work no important adverse effects were seen during the study. We could

Summary points

- We could find no previous published research on acupuncture for dyspepsia in pregnant women.
- In this RCT, acupuncture was compared with usual care in 36 pregnant women.
- The acupuncture group had significantly reduced symptoms as well as improved sleeping and eating.

not see any significant differences between infants from one group compared to the other. These data are congruent with results reported by other authors as no maternal or obstetric side-effects have been found during or after more than 3300 acupuncture stimulations in 573 pregnant women.^{12, 14, 23, 30-34}

CONCLUSION

Dyspepsia in pregnancy is a very common problem. The use of medication is always a concern. Acupuncture, as was demonstrated in this study, seems to be an effective means of reducing the symptoms and improving the quality of life for gravidas. This technique should be further studied in prospective randomised studies of large populations to confirm our findings in effectiveness and the absence of adverse effects. It is simple to apply and if used in an appropriate manner can reduce the need for medication.

Competing interests: None.

Ethics approval: This study has been approved by the Research Ethics Committee of the Federal University of São Paulo, São Paulo, Brazil.

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