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Acupressure treatment of morning sickness in pregnancy

A randomised, double-blind, placebo-controlled study

Arne Johan Norheim[1], Erik Jesman Pedersen[2], Vinjar Fønnebø[2] and Lillian Berge[3]

[1]Havnegata General Practice, Harstad, [2]Institute of Community Medicine, University of Tromsø, [3]Maternity Unit, Aker Hospital, Oslo, Norway.

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Objective **– To find out whether acupressure wristband can alleviate nausea and vomiting in early pregnancy.**
Design **– Double-blind, placebo-controlled study.**
Subjects **– 97 women with mean gestational length completed 8–12 weeks.**
Main outcome measures **– Symptoms were recorded according to intensity, duration and nature of complaints.**
Results **– 71% of women in the intervention group reported both less intensive morning sickness and reduced duration of symptoms. The same tendency was seen in the placebo group, with 59% reporting less intensity and 63% shorter duration of symptoms. However, a significance level of 5% was reached only in the case of duration of symptoms, which was reduced by 2.74 hours in the intervention group compared to 0.85 hours in the placebo group ($p = 0.018$).**
Conclusions **– Acupressure wristband might be an alternative therapy for morning sickness in early pregnancy, especially before pharmaceutical treatment is considered.**

Key words: nausea, pregnancy, acupressure, acupuncture, alternative medicine.

Arne Johan Norheim, Havnegata General Practice, Havnegata 1, NO-9479 Harstad, Norway.

Traditional Chinese acupuncture has for years been presented as a useful antiemetic (1). The acupuncture point most often used for antiemetic action is point 6 on the Pericardium channel according to traditional Chinese medicine. The point is located on the forearm, approximately 3 inches proximal to the distal wrist crease between the tendons of the flexor carpi radialis and palmaris longus muscles, about 1 cm deep.

A recent review included 33 controlled trials concerning acupuncture, acupressure or electrostimulation for treatment of nausea and/or vomiting associated with chemotherapy, surgery or pregnancy (2). Acupuncture administered under anaesthesia seemed to have no effect, but the reviewed papers showed consistent results across different investigators, different groups of patients, and different forms of acupuncture stimulation. A majority of them showed effect of acupuncture on nausea and vomiting.

Six of the studies in this review reported acupuncture stimulation for morning sickness (3–8). The methodological quality in these studies varied greatly, as some were non-randomised, some were not placebo-controlled, while most of them were based on small samples. All but one study favoured acupuncture/acupressure over control. Aikins (9) carried out a review of papers published in later years on the same topic, concluding that acupressure was the best studied alternative remedy that could afford relief to many women. However, another paper on acupressure for morning sickness with opposite results has recently been published (10). By improving previous research models, we have performed a randomised, double-blind, placebo-controlled study utilising acupressure in the treatment of nausea and vomiting in early pregnancy.

MATERIAL AND METHODS

Participants

Flyers inviting pregnant women to enter the study were made available by all general practitioners and pharmacies in the urban area of Tromsø municipality. A response was obtained from 139 pregnant women. However, symptoms disappeared in 9 women before randomisation, and 1 became too ill to participate. Four other women were unable to travel to the University Hospital, another 4 did not show up for the agreed-upon interview, 3 miscarried before entering the study, and 2 withdrew after they had received more detailed information about the study design. Of the remaining 116 women, 19 were excluded because they had gone beyond 12 weeks gestational age before entry. This study thus comprises 97 pregnant women.

Study selection criteria were: 1) presence of nausea for at least 1 week before trial entry, 2) no concomi-

tant diseases causing nausea and vomiting, 3) no concomitant therapy for nausea at enrolment or during the trial, and 4) no abnormalities discovered at regular pregnancy follow-up. Gestational length was estimated by the Naegeles method.

Methodology

The acupressure treatment was given by the use of a wristband with a knob on the inside. Groups of 20 pregnant women were block-randomised in either an active acupressure-wristband or a placebo wristband. For each 20 patients, 10 were randomised to either group. From the outside, the placebo-wristband looked identical to the acupressure-wristband. On the inside, the placebo-wristband had a felt patch, while the acupressure-wristband had a protruding button. The button, made of plastic, was approximately 1 cm in size, round in shape and protruded about 1 cm below the inside of the wristband. There was no way of adjusting the pressure of the wristband, which was made of elastic material. The bands used in our study were delivered free of charge by Sea Band UK Ltd, through B&T Akupressur, Oslo, Norway.

In our pre-trial power calculations we chose a significance level of 0.05 and a power of 0.8. We assumed that 30% of those wearing placebo wristbands would experience symptom alleviation and we wanted to be able to detect a beneficial effect among 60% in the acupressure group. According to these calculations, 100 participants should be enough to significantly demonstrate a difference of this magnitude between use of the acupressure and placebo-wristbands. Owing to expected drop-outs, we invited 139 pregnant women to participate (see previous section). The investigators were blinded to the choice of wristbands as a study assistant was hired to instruct the pregnant women. Written informed consent was obtained from all participating women. The study was approved by the regional Ethics Committee.

Table I. Acupressure treatment for morning sickness in pregnancy. A randomised, double-blind, placebo-controlled study among 97 women. Comparison of subjects in the active treatment and placebo groups.

	Active group	Placebo group
Mean age (years)	28.3	28.5
Mean parity	1.6	1.5
Nausea in previous pregnancy(ies)%	87.5	87.5
Mean height (cm)	166.1	166.3
Mean pre-pregnant weight (kg)	63.2	63.4
Mean hours of nausea/vomiting in the run-in period	9.7	8.9
Mean VAS-score in run-in period	2.7	2.8

Procedure

The study was carried out from January 1995 until March 1996. Every pregnant woman participated for 12 days: a 4-day run-in, a 4-day intervention, and a 4-day follow-up period. Symptoms of nausea and vomiting were recorded daily during this 12-day period. Participants were asked to make three recordings of their problems every evening. The first registration was to determine what problems they had had that particular day: 1 = no problems, 2 = nausea, but no vomiting, and 3 = vomiting, but regardless of how often and how many times they vomited. The women were also asked to estimate how many hours they had suffered each day. Finally, every evening the women also filled in a score of overall evaluation of their symptoms on a visual analogue scale (VAS). A self-composed non-graded VAS was used, with 0 indicating no problems and 5 indicating the worst thinkable level of nausea and vomiting. The registration forms were returned by mail.

Thirteen women who did not complete all of the daily registration forms during the study period were assigned values equivalent to the last reported value on the outcome variables. This was done to ensure analysis according to the intention-to-treat principle.As part of the study entry interview, the participants were asked about previous pregnancies and related problems (Table I).

In the intervention period, participants used wristbands day and night on the "Neiguan" point of both arms. The women were asked to take off the wristband when they took a bath, or engaged in other activities where the wristband could get wet.

At the end of the 12-day period, an evaluation interview asked about possible problems the women had encountered during the trial. They were also asked what kind of wristband they thought they had used, and whether they had continued to use the wristband after the 12-day study period.

Statistics

Data from the first day of each period (run-in, intervention and follow-up) were not included in the analysis because of their transitional nature. All results were analysed with the use of Epi-Info software (11). Two-sample t-tests for paired data and chi-squared tests were used to compare the two groups.

RESULTS

In the active treated group, 71% of the women reported less intensity of morning sickness while

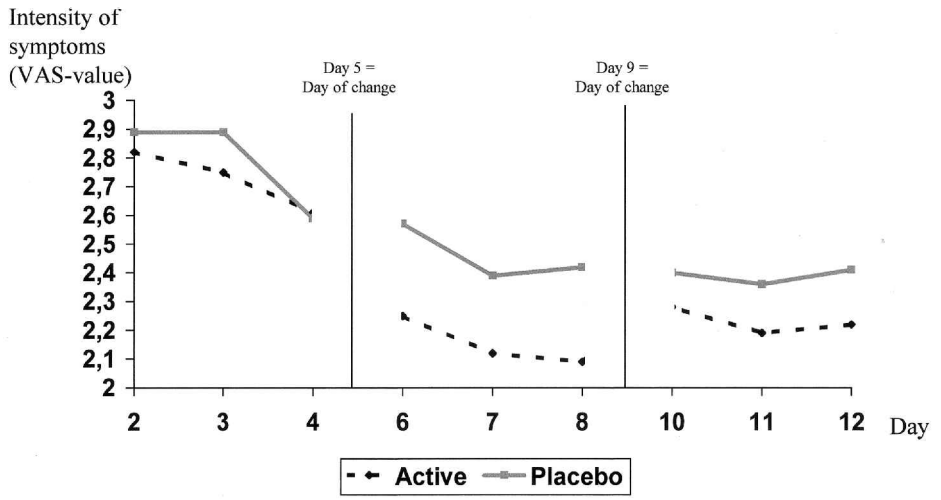

Fig. 1. The intensity of symptoms of morning sickness for active and placebo wristbands through the 12-day period as measured by visual analogue scale. The first day of each period, dayS 1, 5 and 9, were not included in the analysis because this was the day of introduction to registration or change of status (putting on wristbands or taking them off).

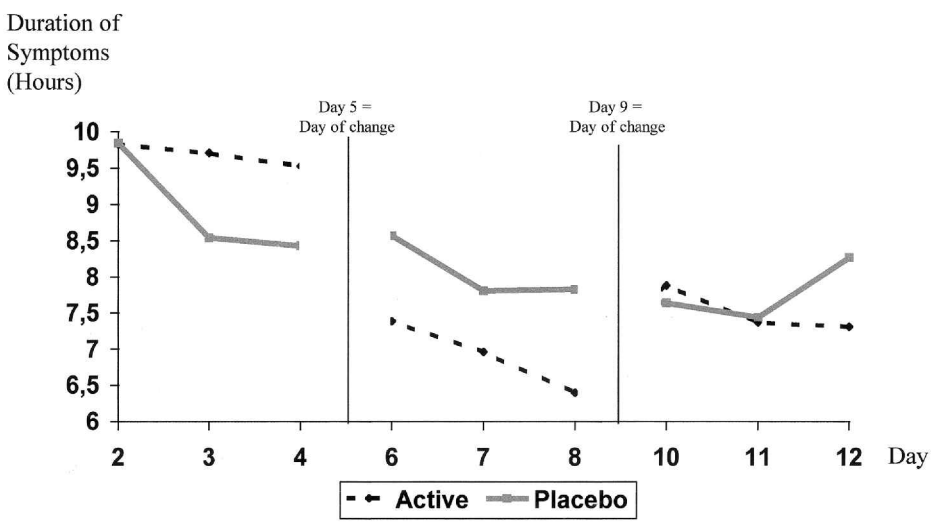

Fig. 2. The mean daily duration of morning sickness for active and placebo wristbands through the 12-day period. The first day of each period, days 1, 5 and 9, were not included in the analysis because this was the day of introduction to registration or change of status (putting on wristbands or taking them off).

Table II. Acupressure treatment for morning sickness in pregnancy. A randomised, double-blind, placebo-controlled study among 97 women. Difference between symptoms in the last 3 days of the run-in period and the last 3 days of the intervention period.

Difference in symptoms (Intervention period–Run-in period)	Active group	Placebo group	Difference	95% CI of difference
Graded symptoms	−0.50	−0.25	0.25	−0.12 to 0.62
Hours of discomfort	−2.74	−0.85	1.89	0.33 to 3.45

using wristbands; the corresponding figure for women in the placebo group was 63%. Duration of symptoms, too, was reduced in both the active and placebo groups, as an improvement was reported in 71% and 59%, respectively.

Figs. 1 and 2 show the mean intensity and duration of morning sickness, respectively, for both groups through the 12-day period. The mean difference between the last 3 days of the run-in period and the last 3 days of the active period is compared in Table II. The hours of complaint had been more reduced in the actively treated group than in the placebo-treated group; 2.74 hours and 0.85 hours, respectively ($p = 0.018$). In addition, there was a small non-significant difference with regard to symptoms on the visual analogue scale.

Based on the registration of daily symptoms, we further analysed the results according to a 5 degree grading of emetic symptoms similar to that in previous research: 1 = no problems (neither nausea nor vomiting), 2 = slight (occasional nausea without vomiting), 3 = moderate (daily nausea without vomiting), 4 = troublesome (periodic nausea with vomiting), and 5 = severe (daily nausea with vomiting) (3,6). An average improvement of 0.4–0.6 according to this 5 degree grading of emetic symptoms was obtained among 43% in the active group and 41% in the placebo group. However, there was no significant difference between the two groups. At the end of the follow-up period, 38% of those who had worn an active band thought they had used an acupressure-wristband, and 30% that they had used a placebo device. In the placebo group, 7% thought they had used an active wristband, and 59% thought they had used the placebo device. Just one-third, 32% and 33%, respectively, did not know what type of wristband they had used. There was no difference in terms of continuous use of the wristband after the 12-day study period between the two groups.

Sixty-three percent of participants in the active group and 90% in the placebo group experienced problems when using the wristband ($p = 0.004$). Pain, numbness, soreness and hand-swelling were those most often reported. No serious adverse effects were mentioned, but three women (two with the acupressure-wristband and one with the placebo-wristband) said that they felt more sick during the study period.

DISCUSSION

Bias consideration

There are three possible sources of bias in our study: selection, information and performance bias. Following the annual number of births at the University Hospital of Tromsø, about 1500 women became pregnant during the study period. The prevalence of morning sickness in early pregnancy has been estimated at 75%. In other words, more than 1000 potentially eligible women could have suffered from morning sickness during the study period.

The 97 participants in our study might thus be a non-random subgroup among those with such problems. Some women might consider nausea and vomiting as a normal part of pregnancy and therefore did not give much attention to our study. Perhaps those who volunteered also "believed in" alternative methods, and therefore do not represent the true "nausea population". The women who entered the study might also be those who suffered most from morning sickness.

Even if the general prevalence of morning sickness among pregnant women is less then 0.75%, our study group would still be a selected subgroup. We hold that this selection limits only the generalizability of our results. Perhaps our selected women were the "worst" non-hospitalised cases, and therefore the results would only apply to this group.

Filling in forms is another possible source of bias. The recording could be an invalid estimate of the real experience of the women. If the participants were truly blinded as to their treatment allocation, any loss of validity in the data collected would dilute the results, not change the main findings.

There is always a chance of performance bias in intervention studies, especially when using therapy administered by the patient herself. The instructor, however, trained the patient carefully in placing the wristband, with both groups being given the same information and instruction. No patient recognised the type of wristband they were given by the instructor, but participants in the control group guessed better what type of band they had used. This could have been either because they were simply better able to detect their type of band or due to the lack of any effect from it. There was no contact between participants in the study as long as it proceeded.

In previous studies, objections have been raised about what should be considered as a true placebo. Our placebo can be considered as the most equal technique following the choice of study design. Further, there has been a request for cross-over design for these kinds of study. We claim that a cross-over design would have biased the study more seriously, as participating women could more readily have distinguished active from placebo treatment. We believe that our methodology leaves little chance of performance bias. Further, a natural decrease in symptoms with increase in gestational age might have diluted the effect if a cross-over design had been chosen.

Effect of acupressure

We find it interesting that stimulating a certain point on the forearm might reduce complaints from morning sickness. One could of course be sceptical to acupuncture and acupressure and claim that *any* physical stimulation of the body would give the same result. However, our study was performed with the idea that stimulation of certain points according to traditional Chinese medicine is more effective that stimulating random points or areas of the body.

We were unable to demonstrate the same degree of symptom reduction by acupressure stimulation at Pericardium 6, as in most previous studies (2). Thus, the intensity of nausea measured by VAS was reduced in both groups. However, the proportion of participants who experienced fewer symptoms was larger in the acupressure-wristband group, and the reduction was more pronounced.

The results were not statistically significant at the 5% level. Compared with Dundee (3) and De Aloysio (6) in the 5 degree grading of emetic symptoms, our study did not fully support their findings. Our randomised, double-blind, placebo-controlled research model differs from previous studies on acupressure for morning sickness. Our methodology therefore possibly leaves less chance of bias. A lack of sufficient blinding and other problems in previous research have been discussed in detail by O'Brian et al. (10).

Our study, on the other hand, showed that acupressure might be effective in shortening the hours of discomfort from morning sickness in early pregnancy. Although there was a statistically significant reduction of duration of symptoms, the clinical relevance might be discussed. One could say that reducing sickness and discomfort from 9.7 hours to 7 hours per day still leaves the patient with considerable incapacity. However, every pregnant woman who suffered fewer hours of emesis welcomed any small improvement.

Conclusion

Our study could not support previous claims of a substantial effect of acupressure on morning sickness. The beneficial response in the placebo group shows that any intervention against morning sickness may be effective. However, the hours of discomfort seemed to be reduced by wearing the acupressure wristband, which might therefore be recommended for morning sickness in early pregnancy, especially before pharmaceutical prescriptions are considered.

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