Efficacy of P6 acupressure in the treatment of nausea and vomiting during pregnancy

Beverley O'Brien, DNSc,[a] M. Joyce Relyea, MPH,[a] and Terry Taerum, PhD[b]

Edmonton, Alberta, Canada

OBJECTIVE: Our purpose was to investigate the efficacy of P6 acupressure in reducing or relieving symptoms of nausea with or without vomiting and retching during pregnancy.

STUDY DESIGN: Symptomatic pregnant volunteers ($n = 161$) participated in a 7-day community-based clinical trial. All participants were assigned to one of three groups (i.e., P6 acupressure, placebo [acupressure bands inappropriately placed], or control) on the basis of a process of blocked randomization. Data were analyzed by error bar charts and analysis of variance of difference scores.

RESULTS: Of 161 women, 149 (92.5%) completed the protocol. Irrespective of group assignment, participants reported significant decreases in nausea ($p < 0.0009$) and vomiting or retching ($p < 0.0009$). However, there was no differential treatment effect as a result of acupressure.

CONCLUSION: There was no apparent medical benefit from the use of P6 acupressure. Our findings differ from other recently published studies that did not include a control group. (Am J Obstet Gynecol 1996;174:708-15.)

Key words: Nausea and vomiting during pregnancy, acupressure, emesis gravidarum

Nausea and vomiting during prengancy is a significant problem affecting about 70% of pregnant women.[1-3] Although the study of this disorder has generated much research interest for centuries, the cause remains unknown and there is a dearth of specific and useful interventions that can be used either to relieve symptoms or to help women cope with them.[4]

Most relief measures for nausea and vomiting during pregnancy found in obstetric, midwifery, and nursing textbooks have not been evaluated with controlled, double blind studies.[4, 5] Few women report complete relief after any nonpharmaceutic intervention.[6-8] Beginning with the thalidomide tragedy of the 1960s, pregnant women and their providers have been concerned about the use of pharmaceutic interventions to control or relieve symptoms of nausea and vomiting during pregnancy. In 1983 manufacturers withdrew an effective antiemetic, doxylamine succinate and pyridoxine hydrochloride (Bendectin), from the market in many countries, including the United States. Although Bendectin, a drug studied extensively for use during pregnancy, was never found to contribute to any reproducible birth defect, many manufacturers made this decision to avoid the cost of extensive and continuous litigation associated with recommending any pharmaceutic agent during the early months of pregnancy. This has left a therapeutic gap in the pharmacologic treatment of nausea and vomiting during pregnancy.[9]

There has been increasing interest in the clinical application of P6 (or Neiguan point) acupressure as a treatment for nausea and vomiting resulting from a variety of causes, including anesthesia,[10] motion,[11, 12] chemotherapy,[13] and early pregnancy.[14-17] Acupressure involves constant pressure to specific anatomic areas and is a noninvasive variation of acupuncture. The use of acupressure wrist bands (Sea-Band, Sea Band International, Greensboro, N.C.) to treat nausea is appealing because this intervention is apparently safe, cost effective, and easy to apply. However, scientific evidence that supports the efficacy of acupressure in treating any type of nausea is weak, and a physiologic basis for acupressure was not found outside explanations offered by traditional Chinese medicine.[18] Familiarity with this paradigm would be needed to fully evaluate the physiologic framework that is offered.

The purpose of this investigation was to test the directional hypothesis that P6 acupressure is more effective than either a placebo treatment or no treatment in relieving symptoms of nausea and vomiting during pregnancy.

Material and methods

Plan. After approval of the study design and instruments by the appropriate ethics review committee, participants were primarily recruited through paid newspa-

From the Faculty of Nursing[a] and Computing and Network Services,[b] University of Alberta.

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Reprint requests: Beverely O'Brien, DNSc, 3rd Floor, Clinical Sciences Building, Faculty of Nursing, University of Alberta, Edmonton, Alberta Canada T6G 2G3.

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per advertisements. In addition, advertisements were placed in the offices of obstetricians and midwives. A pilot study ($n = 9$) was carried out to assess the feasibility of conducting the study and to evaluate participant compliance with the protocol.

Participants. Volunteers who denied previous experience with acupressure and reported current experience with pregnancy-related nausea with or without vomiting were eligible for inclusion in the study. By use of a process of blocked randomization, 161 participants were assigned to treatment ($n = 54$), placebo ($n = 53$), and control ($n = 54$) groups. Twelve (7.5%) participants withdrew at varying times during the 7-day study period. Reasons for withdrawal included (1) loss of interest in evaluating symptoms for various reasons during the study period ($n = 5$), (2) disappointment with assignment to the control group ($n = 3$), (3) hospitalization with severe symptoms ($n = 2$), and (4) refusal to discontinue the intervention at the appropriate time ($n = 2$).

Materials. Acupressure wristbands (Sea-Bands) were purchased, and participants in the treatment group were instructed to apply the bands three fingerwidths up from the wrist crease with the button between the flexor tendons on the medial aspect of both forearms. This information was consistent with detailed instructions provided by acupressure practitioners who were consulted and by the distributor of the wrist bands. Those in the placebo group were instructed to apply Sea-Bands at the same level on the forearms as those in the treatment group. However, the button was placed over the radius of both forearms. This location was chosen because it appears similar to the treatment point (i.e., Neiguan or P6) but is not near the treatment or any other acupressure point.

Both placebo and treatment groups were given a demonstration of how to apply the wrist bands as well as oral and written instructions. The written instructions for the two groups were identical except for the description and diagram of the location of the acupressure points. Participants were asked to wear the bands on both wrists as continuously as possible beginning on the morning of study day 3 and ending on the morning of study day 6. The effects of acupressure have been reported to last for 8 hours[17] or up to 24 hours if the point is stimulated every 2 hours,[13] but little information was found about how long wrist bands should be in place or how long the desired effect might be expected to last. Anecdotal reports from travelers suggest that those who wear the bands do so only while they are actually experiencing the motion that they feel will cause nausea.

Symptoms were evaluated with the Rhodes Inventory of Nausea and Vomiting (Form 2). This form is an eight-item, 5.0 Likert–type, pencil-and-paper instrument that measures the prevalence and amount of distress caused by nausea with or without vomiting or retching over a 12-hour period.[19] The instrument was previously validated by use of a population of pregnant women.[20] Copies were color coded for each day of the study. Three of the items were measures of nausea (scores ranged from 3 to 15) and the remaining five items were measures of vomiting and retching (scores ranged from 5 to 25). The reliability of nausea and vomiting or retching scores was estimated for each of the 13 occasions that participants evaluated their symptoms. The median reliability was 0.89 (range 0.81 to 0.93). The dichotomy of the instrument was established through factor analysis. The clustering of items during each of the 13 measures corresponded with the (1) nausea and (2) vomiting and retching items that make up two subscales of the instrument.

Controls. A control group was deemed necessary so that circadian variations and the natural progression of symptoms for those not receiving the intervention or placebo over the length of the study period could be evaluated. This is important because the effect of time on symptoms is always a rival hypothesis in studies evaluating interventions for nausea and vomiting during pregnancy.

Participants in all three groups were not expected to abandon other comfort measures, including antiemetics that they were using to relieve or control symptoms. However, it is acknowledged that if P6 acupressure is effective the pattern of taking antiemetics or using other comfort measures may not be evenly distributed across groups. Therefore all participants were given a diary and asked to report the frequency with which they used medication and other comfort measures.

Methods. Volunteers who met inclusion criteria were interviewed either in our research office or their home. This was considered day 1 of the study for that individual. Participants received a written explanation of the study and signed an informed written consent before being randomized to one of the three study groups (i.e., P6 acupressure, placebo or control). The blocks of group assignments were computer generated and placed in numbered sealed envelopes before the study was begun. Participants were given numbers that corresponded with their envelope numbers and this was determined by the order in which they were enrolled in the study. The researcher opened the envelope after the participant was enrolled. In this way the researcher could not influence the enrollment order and perhaps ensure that the more symptomatic women were in the treatment group. Only participants randomized to the control group were aware of their group assignments.

All participants were given a package containing 13 copies of the Rhodes Inventory of Nausea and Vomiting Form 2 and instructed to evaluate their symptoms every 12 hours (i.e., on admission to the study and twice daily for 6 consecutive days). They were also advised that they would be telephoned daily by a research assistant who would not know and should not be told their group assignments. The research assistant recorded nausea and

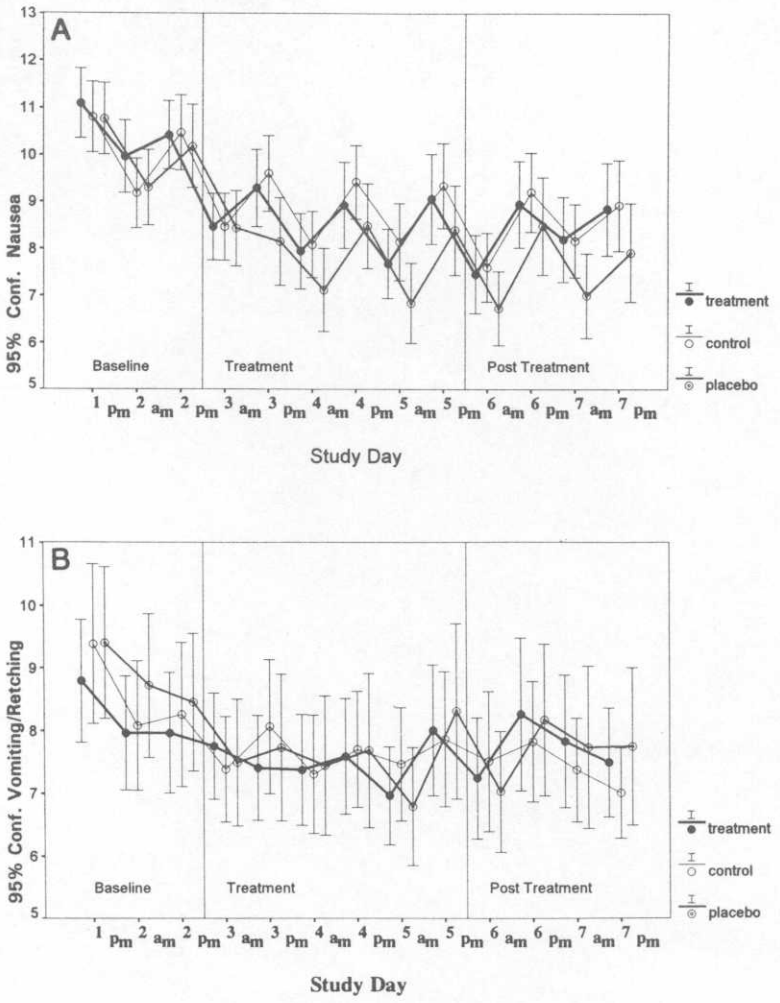

Fig. 1. Rhodes Inventory of Nausea and Vomiting Form 2 scores over time by group assignment. **A,** Nausea over time. **B,** Vomiting or retching over time.

vomiting scores for that day and the time, type, and amount of any antiemetics that were taken. The purpose of this was to make sure that symptoms were being accurately appraised as they occurred. Participants assigned to either the P6 acupressure or the placebo groups were advised that a research assistant would visit them on the morning of day 3 to provide them with acupressure wrist bands. Wrist bands were not offered until day 3 so that individual circadian patterns of nausea and vomiting during pregnancy could be assessed before the intervention. Participants were asked to wear wrist bands as continuously as possible on days 3, 4, and 5 of the trial and to remove them on the morning of day 6. They were asked to continue recording their symptoms on days 6 and 7.

Participants were given a demographic questionnaire, an information sheet outlining strategies for reducing or coping with symptoms, and a daily diary. They were asked to record, in daily diaries, strategies recommended on the information sheet as well and any other interventions that they used to reduce or relieve symptoms. It was hoped that the information sheet and diaries would redirect some of the attention that participants would otherwise be giving to acupressure and provide direction for the future investigation of other popular interventions.

A cross-over component was considered because of the greater sensitivity associated with this design. However, a control group was deemed necessary because spontaneous remission is an important confouding factor. We felt that three assignments (i.e., acupressure, placebo, control) would result in a complex cross-over design. In addition, because of uncertainty regarding the duration of the treatment effect, the period between treatments could result in a study that is unacceptably long for participants. We also felt that compliance would be reduced for symptomatic women who may, for example, be

Table I. Overall analysis of variance of nausea scores

	Nausea scores			
	Mean squares	*Degrees of freedom*	*F ratio*	*Probability*
Group	133.60	2	2.34	0.100
Time	158.05	12	33.40	0.000*
Group • time	4.73	24	1.00	0.464

Group: Differences in nausea scores across groups (i.e., P6 acupressure, placebo, control); *time:* observations of nausea scores over time (i.e., preintervention, intervention, and postintervention); *group • time:* differences in nausea scores across all groups over time.
*$p < 0.005$.

Table II. Overall analysis of variance of vomiting or retching scores

	Vomiting or retching scores			
	Mean squares	*Degrees of freedom*	*F ratio*	*Probability*
Group	0.54	2	0.01	0.993
Time	43.12	12	6.24	0.000*
Group • time	4.01	24	0.58	0.947

Group: Differences in vomiting or retching scores across groups (i.e., P6 acupressure, placebo, control); *time:* observations of vomiting or retching scores over time (i.e., preintervention, intervention, and postintervention); *group • time:* differences in vomiting or retching scores across all groups over time.
*$p < 0.005$.

tempted to wear wrist bands during the time that they are being assessed as a control participant.

Statistical methods. The final sample size was determined by doing an analysis of the statistical power that is required to reject the null hypothesis if an effect that could be considered clinically significant is observed (i.e., if scores in the treatment group are 30% lower than those observed in either the placebo or control groups). The power analysis was done with the best available estimate of the mean (12.4) and SD (5.39) from a previous study.[20] The power was set at 0.80. The number of participants completing the protocol exceeded the number required to exclude the likelihood of a β error.

Data were analyzed by use of analysis of variance of difference scores. This was done for total scores of the Rhodes Inventory of Nausea and Vomiting Form 2 and for the two subscales. Preintervention scores were averaged from scores recorded on days 1 and 2 of the study. Intervention scores were averaged from scores recorded on days 3, 4, and 5, and postintervention scores were averaged from scores recorded on day 7. Scores on day 6 were not used in the analysis because it is not known if they were affected by the intervention (effects of the intervention have been reported to last 8 to 24 hours).

Additional analysis of postintervention scores was done to estimate whether symptom scores returned to their original levels. Examination of scores from the pilot study suggests that there is considerable within-participant variability in nausea and vomiting scores and that variability can be seen over a short period. For this reason preintervention scores were estimated from days 2 and 3, whereas intervention means were estimated from days 4 and 5.

Results

Demographic information was provided by 157 women on admission to the study. Maternal age ranged from 18 to 43 years with a mean of 29.57 years (SD 4.54 years); gestational age ranged from 4.6 to 23.6 weeks with a mean of 10.1 weeks (SD 3.5 weeks). The gestational age for 121 (78.6%) participants was ≤12 completed weeks of pregnancy. The gestational age for the remaining women ranged from 13 to 24 weeks. Twenty-one (13.4%) of the 157 participants reported that they were cigarette smokers.

Eighty-six (54.8%) women worked outside the home. One hundred reported occupational status, which included menial laborers (10%); clerical and sales workers (25%); technical and semiprofessional workers (47%); and administrators, executives, and professionals (18%). The number of previous pregnancies for participants ranged from 1 to 8 with a mean of 2.71 (SD 1.39). Thirty (19.1%) women had not had a prior completed pregnancy (i.e., >20 weeks). Parity ranged from 0 to 5 with an average of 1.18 (SD 1.03).

The nausea and vomiting or retching subscales were first analyzed by means of error bar plots and analysis of variance with repeated measures. If acupressure is effective, we anticipated that we might see a dramatic drop in nausea and vomiting or retching scores for the treatment group, whereas scores would remain the same or possibly increase for those in the control group because those

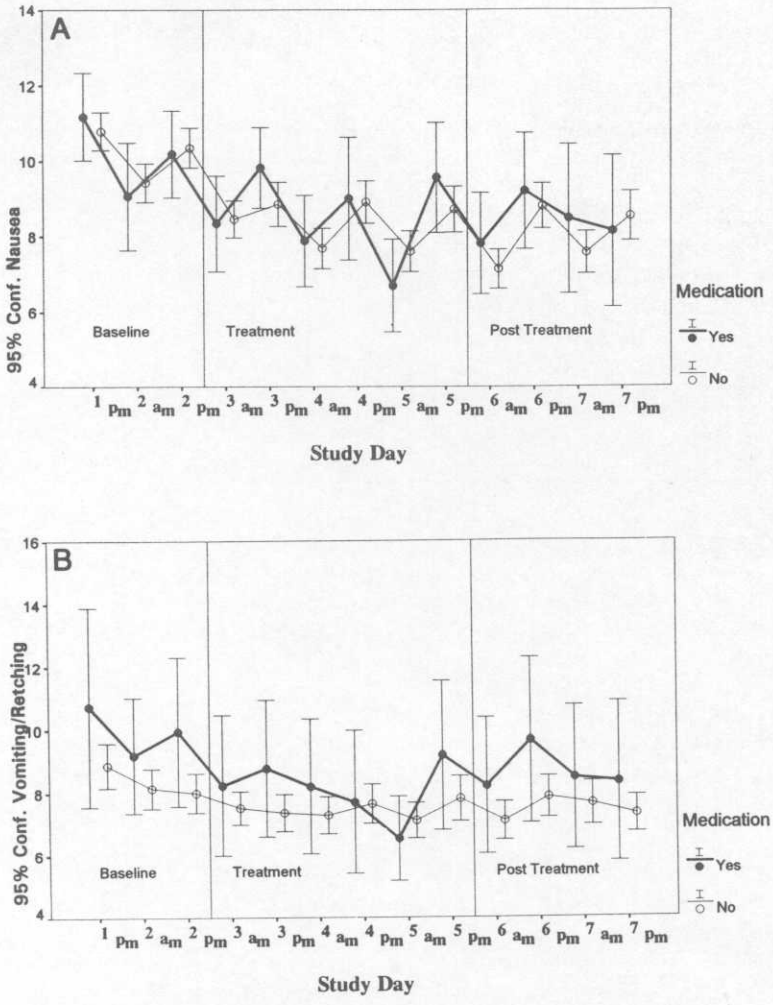

Fig. 2. Rhodes Inventory of Nausea and Vomiting Form 2 scores over time by medication use. **A,** Nausea over time. **B,** Vomiting or retching over time.

participants recognize that they are not receiving the treatment. We also anticipated that we might see a decrease in scores for those in the placebo group if they believed that they were receiving an effective treatment (i.e., Hawthorne effect).

Examination of an error bar plot for nausea scores indicates that the greatest drop from preintervention to treatment scores was in the placebo group (Fig. 1, *A*). The treatment and control groups are virtually indistinguishable although there are consistent but extremely small differences over days of treatment. With respect to vomiting or retching, no group appears to have consistently lower values over time (Fig. 1, *B*). Analysis of variance with repeated measures was carried out on the nausea and the vomiting or retching scores to determine whether there was a differential effect because of P6 acupressure. No differential treatment effect was observed. However, irrespective of the group assignment, significant changes in nausea ($F = 33.40$, 12 degrees of freedom, $p < 0.0009$) and in vomiting or retching scores ($F = 6.24$, 12 degrees of freedom, $p < 0.0009$) were observed over the 13 observations. Simple effects analysis confirms these conclusions. Results of analysis of variance are presented in Tables I and II.

The possible confounding effect of some participants taking medication was addressed because it is possible that if the treatment was effective those in the placebo and control groups would be more likely to take medication to reduce symptoms than those in the treatment group. Therefore error bar plots were examined to determine whether taking medication was associated with less nausea and less vomiting or retching. No consistent pattern emerged with nausea scores (Fig. 2, *A*), but use of medication was associated with higher vomiting or retching scores (Fig. 2, *B*). This was expected because participants who are vomiting or retching are more likely to take medication. The proportion of medication taken by the three groups over time is presented in Fig. 3.

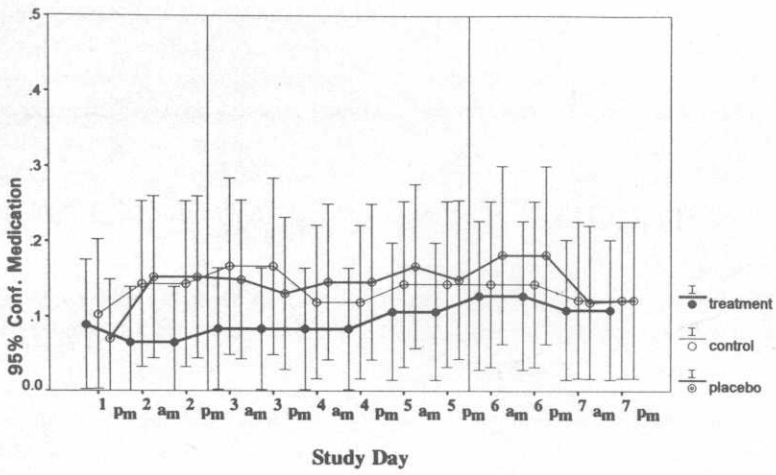

Fig. 3. Medication over time. Rhodes Inventory of Nausea and Vomiting Form 2 over time by medication use and group assignment.

The treatment group reported consistently lower frequencies of taking medication, so the possibility of a differential treatment effect from medication was considered. However, the treatment group had a very low rate of taking medication before the treatment was introduced. There was a gradual increase beginning on day 3, which peaked on day 6. During this time there was a random fluctuation of medication use on the part of the control and placebo groups. Results of analysis of variance support the conclusion that these variations are random and that, although the treatment group had the least amount of medication during all three phases of the study, there is no differential treatment as a result of medication.

It might be argued that our method of analysis is not sufficiently sensitive to detect any differential effects. To address this concern, participants were grouped according to whether the gestational age was ≤80 days or whether it was >80 days. Analysis of variance indicates that the method of analysis is sufficiently sensitive to detect differences in respect to the overall impact of gestational age on nausea ($F = 26.28$, mean squares 122.77, degrees of freedom 12, $p < 0.0009$) and the differential effect of gestational age over time ($F = 2.13$, mean squares 9.94, degrees of freedom 12, $p = 0.01$).

Sawtooth effects were observed in error bar charts of nausea and vomiting over time (Figs. 1 and 2). This effect is attributable to participants reporting less nausea and vomiting or retching during the evening and through the night than through the day. Analysis of variance results indicated that morning measures are different from evening measures of nausea and vomiting ($F = 3.61$, mean squares 11.68, degrees of freedom 5, $p = 0.003$ for nausea scores; $F = 3.02$, mean squares 15.64, degrees of freedom 5, $p = 0.01$ for vomiting or retching scores). It appears that our method of analysis is sufficiently sensitive to detect differential effects of interest.

Participants in the treatment and placebo groups who reported in their diaries that the intervention was very effective were identified. Their scores were plotted and the Rhodes Inventory of Nausea and Vomiting Form 2 results were consistent with the diary reports (Fig. 4). Therefore the instrument is sensitive enough to detect positive changes in scores when they occur.

Participants with the most severe symptoms were identified so that we could investigate the possibility that a treatment effect is associated only with severe symptoms (i.e., Rhodes Inventory of Nausea and Vomiting Form 2 scores >10). Graphs and analysis of variance results were virtually identical for those with high scores and for the group as a whole. There was a treatment effect over time ($F = 7.58$, mean squares 35.16, degrees of freedom 12, $p < 0.0009$ for nausea scores; $F = 7.58$, mean squares 54.26, degrees of freedom 12, $p < 0.0009$ for vomiting or retching scores), but between-group differential effects were not found ($F = 4.64$, mean squares 6.55, degrees of freedom 24, $p = 0.98$ for nausea scores; $F = 0.66$, mean squares 8.04, degrees of freedom 24, $p = 0.87$ for vomiting or retching scores).

Comment

We were able to demonstrate, within a symptomatic pregnant population, acceptable levels of validity and reliability for the instrument that we used to evaluate nausea and vomiting or retching. However, we did not see a differential reduction in either mean scores or variability. This would suggest that the treatment (P6 acupressure) is not effective.

Others have reported symptom reduction in participants receiving P6 acupressure for the treatment of pregnancy-related nausea and vomiting.[14-17] However, methodologic problems were identified in these studies. For example, Dundee et al.[16] reported that significantly less

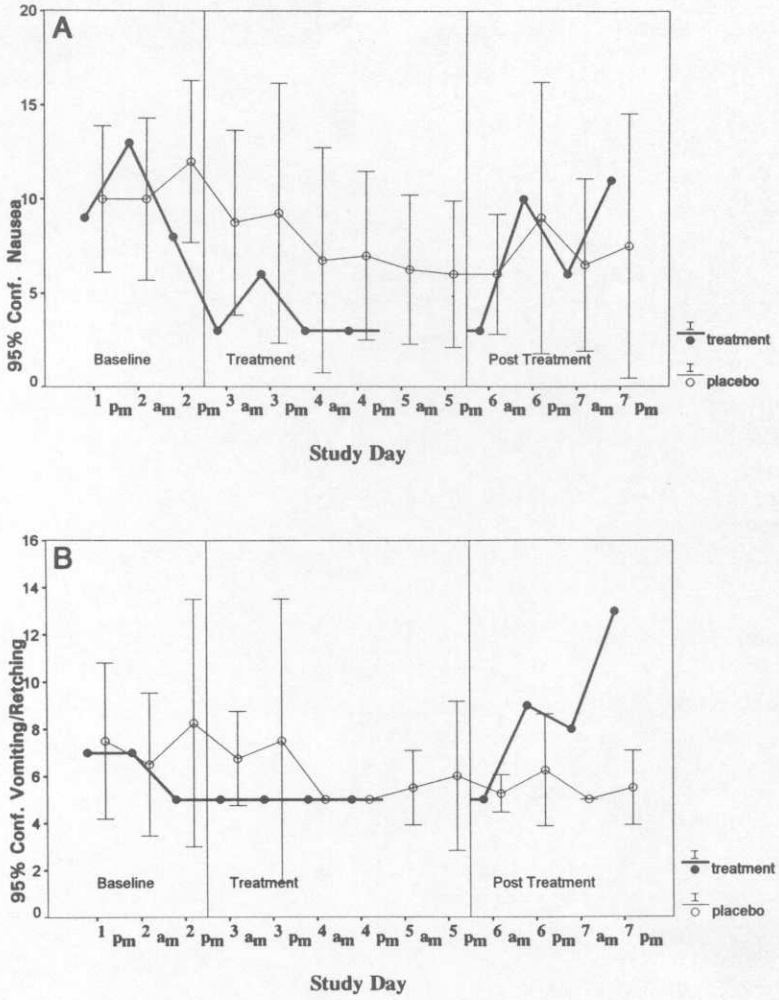

Fig. 4. Participants with severe symptoms by treatment or placebo group assignment. **A,** Nausea over time. **B,** Vomiting or retching over time.

"troublesome sickness" was found in acupressure and placebo groups than in control groups. However, they acknowledge that the attrition rate for participants enrolled in their clinical trial was high (50%) and that a disproportionate percentage of those who failed to complete the trial were in the acupressure and placebo groups (i.e., 50% of the treatment and placebo groups submitted fully completed returns as opposed to 70% of the control group). Follow-up information for dropouts was not available, but disappointment because the treatment did not work may have been a reason participants dropped out.[21] This would create a bias that could affect the results.

With a two-group cross-over design where group assignment was not blind, Hyde[17] reported that acupressure was effective in reducing symptoms of nausea and vomiting during pregnancy in 12 of the 16 participants who completed the study. Both groups received the intervention and served as their own controls (i.e., one group during the first 5 days and the other group during the second 5 days). In addition, the exact gestational age of the participants during the time that they were receiving the intervention was not reported, so the effect of time on the results could not be determined. The length of time that participants wore acupressure bracelets was also not reported. Eight of the participants reported that acupressure "never helped" or "sometimes helped a little," which would indicate that only half the participants reported improvement that could be regarded as clinically significant.

Cross-over designs were also used in the remaining two studies. Although sample sizes were larger (60 in both cases), neither study included a control group, so the independent effects of history on symptoms could not be evaluated.[14, 15] Belluomini et al.[14] reported that acupressure was effective in reducing nausea but not the frequency of vomiting.

De Aloysio and Penacchioni[15] reported that acupres-

sure on the Neiguan (P6) point relieves morning sickness, but they also reported that the effect of acupressure was selective. Participants wore bands on both wrists for the 12 study days (i.e., participants were randomly assigned to all the following groups for a 3-day period: acupressure to both wrists, placebo to both wrists, placebo on left wrist and treatment on right, and treatment on left wrist and placebo on right). It is important to note that the placebo treatment in this study (i.e., wrist bands with blunted buttons) should have been easily detected by participants because they wore a combination of the placebo and treatment bands for 6 days during the 12-day study. In addition, both the placebo and the treatment would exert varying degrees of pressure on the P6 (Neiguan) point. Therefore, if there was a treatment affect, it should be seen with the placebo group as well. A standardized interviewer rather than the participants themselves determined whether symptoms were reduced, increased, absent, or unchanged. The interviewer passively recorded the women's report of symptoms, but it was not reported whether the interviewer was blind to group assignment.

Across groups participation in our study was an effective intervention (Tables I and II). It is important to note that a therapeutic effect was seen in the control group, although members knew that they were not receiving P6 acupressure. The therapeutic effect may have been due to information about nonpharmaceutic interventions that was provided to all participants on study day 1. The information sheet included dietary and activity recommendations suggested by participants ($n = 147$) in a previous study.[8] It is also possible that participating in the study was a source of support for affected women and served to validate their symptoms. It is important to note that, although symptom reduction was reported, most women continued to report some degree of nausea and vomiting or retching (Fig. 1).

Participants reported more severe symptoms during the day than during the night. It is possible that this is because they sleep through periods of nausea. However, it has been reported that recumbent rest is the most effective intervention for symptoms of nausea and vomiting during pregnancy.[7, 8] Controlled studies that evaluated the effect of body position and rest on symptom severity were not found. This is an area that warrants further investigation.

It is of interest that authors of most published studies designed to evaluate the efficacy of an intervention for the treatment of nausea and vomiting during pregnancy report that their intervention is effective.[4] In spite of this, distress caused by symptoms is frequently underestimated, and few pregnant women report complete relief after any usually recommended intervention.[5] In our study women reported that antiemetics reduced but did not eliminate nausea and particularly vomiting (Fig. 2). In fact, women who took antiemetics because of very severe symptoms usually did not achieve symptom reduction that could be considered equal to the level experienced by those who did not take medication.

Many recommended interventions found in medical, midwifery, and nursing textbooks are based on outdated and poorly controlled studies. These interventions and new remedies currently being advanced need to be evaluated in controlled, preferably double-blind, clinical trials. Only then can providers confidently offer appropriate and useful recommendations to distressed pregnant women.

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