

Dual method P6 acupressure to overcome nausea and vomiting during early pregnancy

Tuti Meihartati,¹ Leny Suzana Suddin,² Zatul Akmar Ahmad³

¹Department of Midwifery, Institute of Health Technology and Science Wiyata Husada Samarinda, Indonesia; ²Department of Public Health Medicine, Faculty of Medicine, Universiti Teknologi MARA, Selangor; ³Department of Obstetrics and Gynaecology, Faculty of Medicine, Universiti Teknologi MARA, Selangor, Malaysia

Abstract

Pregnancy can lead to nausea and vomiting, commonly affecting women during the first trimester but sometimes continuing throughout the entire pregnancy. This study utilized a quantitative, non-equivalent control group design, a prevalent approach in quasi-experimental research. It involved 120 pregnant women

Correspondence: Tuti Meihartati, Department of Midwifery, Institute of Health Technology and Science Wiyata Husada Samarinda, Indonesia. E-mail: tuti@itkeswhs.ac.id

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Conflict of interest: the authors declare no conflict of interest.

Ethics approval and consent to participate: the research has been registered in the Indonesia Clinical Research Registry (Registry ID: INA-DOBP5OS0) and received ethical approval from the Health Research Ethics Committee of the Health Polytechnic, Ministry of Health, East Kalimantan, Indonesia (Ethics No. LB.01.01/7.1/005627/2021). Throughout the research, the researcher adhered to the ethical norms of informed consent, respect for human rights, beneficence, and non-maleficence.

Consent for publication: written informed consent was obtained for anonymized patient information to be published in this article.

Availability of data and materials: all data generated or analyzed during this study are included in this published article.

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between 6 and 16 weeks of gestation who were experiencing moderate to severe symptoms of nausea and vomiting in pregnancy (NVP). Participants were recruited from four private maternity clinics in Samarinda, Indonesia. The study was registered with the Indonesia Clinical Research Registry (INA-DOBP5OS0). The results indicated that the Pregnancy-Unique Quantification of Emesis (PUQE) scores for the participants in the intervention group were significantly lower than those in the control group after the intervention period ($P < 0.01$). Furthermore, no adverse effects were reported following the intervention. Regarding the satisfaction variable, the study found that the dual methods of P6 acupressure resulted in a statistically significant improvement in satisfaction among pregnant women with NVP ($Z = 1830$, $P < 0.01$). Based on our findings, the use of dual P6 acupressure, which includes both pressure application and an acupressure band, is effective in reducing nausea and vomiting experienced by pregnant women.

Introduction

Pregnancy can cause nausea and vomiting, and although it most commonly affects women in the first trimester, it can last throughout pregnancy.¹ The exact cause of the etiologic and pathophysiology of nausea and vomiting is still unknown;² However, this condition is an early indication of pregnancy in reproductive women.^{3,4}

Pregnant women might also experience varying degrees of morning sickness and hyperemesis gravidarum and thus have concerns for the health of both the mother and the growing fetus.² Nausea and vomiting during pregnancy can have a significant impact on family life, hinder the ability to carry out normal daily activities, affect social functioning, and lead to stressful situations. Additionally, these symptoms may cause fatigue, impaired nutrition, dehydration, weakness, weight loss, and electrolyte imbalances in pregnant women.⁵

Pregnant women experiencing nausea and vomiting in pregnancy (NVP) have a significant impact of over 85% on their physical health and psychosocial quality of life.¹ An increase in NVP cases can have implications for maternal health, especially when accompanied by symptoms like dehydration, vomiting, acidosis, alkalosis, and weight loss.^{2,6} Some pregnant women experience a more severe and persistent form of vomiting called hyperemesis gravidarum. This condition can lead to various complications, including dehydration, electrolyte imbalances, liver damage, and, in extreme cases, maternal death. Additionally, it can have negative effects on the fetus.⁶

NVP occurs early in the first trimester, and only 23.5% of pregnant women are symptomatic until the third trimester.^{1,7} Both patients and physicians are hesitant to use drugs during pregnancy,

especially in the first trimester, due to the possibility of harming the unborn fetus.⁸ Pregnant women commonly experience nausea and vomiting upon waking, a phenomenon called morning sickness.^{1,3} Although morning is the most common time for this discomfort, it can also occur throughout the day or at night.¹

According to data from multiple Kalimantan provinces, East Kalimantan had the greatest rate of continuous vomiting among pregnant women (21.9% of 1,176 pregnant women), while Central Kalimantan had the lowest rate (14.6% of 871 pregnant women). When compared to other pregnancy-related issues, the most common condition or complication in East Kalimantan is persistent vomiting, which affects 78.07% of pregnant women.⁹

One effort that pregnant women can make to relieve nausea and vomiting during pregnancy is through acupressure therapy. Acupressure, which is a supplementary therapy that consists in applying pressure to acupuncture points, can assist pregnant women balance their hormones by stimulating the central nervous system via the limbic and hypothalamus systems.^{10,11} One of the acupressure points that is scientifically proven to reduce nausea and vomiting is the pericardium point (PC 6).¹² This point sends signals to the heart organ, which physiologically can balance hormones, reduce nausea, and trigger relaxation. This point is located on the inner arm, exactly three fingers from the inner wrist. PC 6 can be stimulated continuously in pregnant women without side effects, and there is no concept of overdose in acupressure.¹³

With the publication of the Republic of Indonesia Minister of Health Decree No.1076/Menkes/SK/VII/2003 on July 24, 2003, which governs acupressure services and other traditional treatments, acupressure's status as a medical service is becoming more widely acknowledged in Indonesia. The severity of nausea and vomiting during pregnancy can be minimized, especially when symptoms are moderate to mild, by administration of pharmacological and nonpharmacological options (vitamin B6, ginger, and acupressure with peppermint oil).¹⁴

P6 activation has been shown in several clinical investigations to be effective for NVP.¹³ However, other research found no significant impacts. The lack of control groups, the application of pressure on non-P6 locations in placebo groups, the use of varied techniques for P6 stimulation, and the underreporting of dietary alterations have all contributed to the variance in these studies' results. More clinical investigations are thus required to overcome these flaws.^{14,15,16}

Therefore, it is very important to have a well-designed study that allows a comprehensive and critical evaluation of the available evidence and to bridge the health literacy gap on the intervention of dual method P6 acupressure for handling nausea and vomiting during the early trimester of pregnancy. Bridging the health literacy gap in this area will help ensure that P6 acupressure can be effectively integrated into antenatal care services.

Materials and Methods

Study design, setting, and population

This study was carried out at four private maternity clinics in Samarinda City, East Kalimantan Province, with a sample of pregnant women who experienced moderate to severe nausea and vomiting in early pregnancy. Descriptive analysis studies use quantitative approaches. This sort of research employs a non-equivalent control group design (pre- and post-test). In this design, a popular strategy is quasi-experimental, with intervention group A and con-

trol group B chosen without random assignment. In this study, the intervention group received P6 acupressure on both arms; one arm received manual massage, and the other employed an acupressure band. In contrast, the control group experiences NVP without dual P6 acupressure or pharmaceutical intervention.

To determine the appropriate sample size for this study, we utilized G* Power Software version 3.1.9.7. This analysis is based on research conducted by Mobarakabadi et al. regarding the effect of P6 acupressure on nausea scores. The mean (SD) for the intervention group was 6.24 (4.1), while the mean (SD) for the control group was 9.23 (3.7). We calculated the sample size to be 24 participants per group, with an alpha error of 0.05, a power of 0.80, and an allocation ratio of 1. However, a sub-analysis of satisfaction was carried out for the intervention group, which required a recalculation of the number of respondents in the group. According to our literature research, no proportion of satisfaction was included in the sample size calculation. As a result, we decided to double the minimum sample size needed to examine satisfaction data in the intervention group. Thus, each group had a sample size of 60 participants, for a total of 120 people recruited for the study. The sampling technique was a convenience sampling method because there was more than one maternity clinic location. The eligibility criteria for both the intervention group and control group were: pregnancy with nausea and vomiting, consent to participate in this study, a PUQE score of more than 6 to 15 (mild to severe category NVP), a period of gestation of 6 weeks during the time of study recruitment, an age of more than 17 years, and singleton pregnancy. This is to ensure that all selected samples proportionally represent each maternity clinic.

Study instrument

The Pregnancy-Unique Quantification of Emesis and Nausea (PUQE) questionnaire (3 items) was widely used in previous research, was based on three questions, and has been validated in clinical use. The instrument had undergone reliability testing and was translated (back-to-back) into Indonesian language. In a previous study conducted in Indonesia using the PUQE questionnaire, the Cronbach's alpha value was found to be 0.846.¹⁸

In this study, the effectiveness of dual P6 acupressure will be determined as an NVP category using the PUQE questionnaire, comparing the intervention between dual P6 acupressure and routine prenatal care. The PUQE Questionnaire with 3-item will be assessed as scores. Then, based on the score obtained, NVP will be classified as follows: a total score of 3 = no NVP, a score between 3 and 6 = mild NVP, a score between 7 and 12 = medium NVP, and a score between 13 and 15 = severe NVP.

The safety of the P6 acupressure technique was assessed using the adverse event form. In the context of this study, safety was translated as no reported adverse events by the participants. The form consists of 9 items and was created by Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC. This form is used to record adverse events from medication.

This satisfaction questionnaire underwent a pilot study to determine feasibility with 30 respondents. The questionnaire showed a Cronbach alpha value of 0.763 and a median score of 74. This was taken as the cut-off point for the category of Yes (>74) or Not Satisfied (≤74). The level of satisfaction is quantified using measurement indicators from a Likert scale with four levels: a) Scale 1 = very unsatisfied, b) Scale 2 = unsatisfied, c) Scale 3 = satisfied, and d) Scale 4 = very satisfied. From this scale, the criteria for patient satisfaction levels can be classified into numerous

criteria that refer to the Likert scale, where item answers are grouped into two categories: a) satisfied if the respondent's total answer score is ≥ 74 , b) not satisfied if the respondent's total answer score is < 74 .

Statistical analysis

The data were analyzed using Statistical Product and Service Solutions (SPSS) version 26.0 for Windows. The Kolmogorov-Smirnov test was used to determine normality, while the analysis of different proportions was used to identify the level of severity of NVP in the intervention group pre- and post-test intervention with dual P6 acupressure therapy; this involved using pre- and post-mean values in the two groups to measure pre-test and post-intervention changes using the Wilcoxon test, which falls under the non-parametric category with two related samples (intervention and control groups). A p-value of less than 0.05 indicates statistical significance. Meanwhile, a one-sample Wilcoxon signed rank t-test was utilized to assess the impact of dual P6 acupressure intervention therapy on respondents' satisfaction levels.

Results

The study found that the intervention group's NVP score decreased by (-6.00 ± 1.53) in the medium NVP category and (-9.44 ± 2.06) in the severe NVP category, while the control group's NVP score decreased by (-3.56 ± 2.13) in the medium NVP category and (-6.43 ± 1.16) in the severe NVP category. These results demonstrated that the respondents' treatment appeared to be beneficial in the post-intervention period since the respondents' NVP ratings declined in each category (Table 1).

The level of safety post-test intervention with dual method P6 acupressure therapy

Descriptively, none of the 60 responders (100%) who got the P6 acupressure intervention suffered adverse events or side effects that harmed mother and fetal health. This indicates that the treatment or intervention given to the respondents resulted in significant improvements in the post-test scores, reducing the severity of nausea and vomiting.

Influence of post-test intervention with dual method P6 acupressure therapy on the level of respondents' satisfaction

The lowest score was 48, the highest was 90, and the median was 74 (IQR 16). The Shapiro-Wilks normality test was used to assess satisfaction variables. The p-value for the intervention group is 0.007, indicating that the satisfaction data is not normally distributed.

A Wilcoxon signed-rank test revealed that dual techniques P6 acupressure resulted in a statistically significant change in satisfaction in pregnant women with NVP ($Z=1830$, $p=0.000$). Indeed, the median satisfaction score was 74 before and after treatment. The SERVQUAL questionnaire (T3) was used to compare satisfaction levels within groups. This demonstrates that pregnant women who underwent dual technique P6 acupressure therapy, which was used to alleviate nausea and vomiting throughout early pregnancy, were satisfied.

Discussion

There was a significant difference between the intervention and control groups in terms of the effectiveness of interventions with Neiguan acupoint pressure P6 and the usage of band acupressure (3 times per week for 24 hours from 8 to 15 weeks of gestation). The results indicate that the change observed in the intervention group for the medium level of nausea and vomiting (NVP) was -6.00 ± 1.53 , while in the control group the result was -4.56 ± 2.13 . In terms of the severe level category score for NVP, the intervention group showed a change of -9.44 ± 2.06 , compared to -6.43 ± 1.16 in the control group. This suggests that the treatment provided to participants was more effective in the post-intervention phase, particularly with the combination of dual P6 acupressure and the use of acupressure bracelets, as evidenced by the reduction in NVP scores. These findings indicate that these interventions can effectively reduce nausea and vomiting in pregnant women during early pregnancy. These results showed that the respondents' treatment appeared to be effective in the post-intervention phase, as indicated by the respondents' NVP scores declining in each category.

Table 1. The difference in level of nausea and vomiting severity during early pregnancy between the pre-test and post-test of the intervention and control group.

Variables	With intervention PUQE score		Change of PUQE score	Without (Control Group) PUQE score		Change in PUQE score	p
	Pretest	Posttest		Pretest	Posttest		
NVP Category							
Medium NVP	8.75±1.20	2.75±1.54	-6.00±1.53	9.13±1.18	5.56±2.31	-3.56±2.13	<0.01*
Severe NVP	13.37±0.5	3.94±2.38	-9.44±2.06	13.57±0.51	7.14±1.09	-6.43±1.16	<0.01*

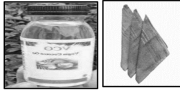
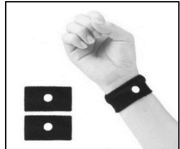



*Wilcoxon Test, * $p < 0.01$ taken as the level of significance.

Table 2. The level of nausea and vomiting severity from PUQE's score during early pregnancy in the intervention group pre-test and post-test intervention with dual method P6 acupressure therapy.

Group	Pretest	Posttest	Change	p
Intervention group	9.98±2.32	3.06±1.85	-6.92±2.26	<0.01
Control	10.16±2.17	5.93±2.19	-4.23±2.29	<0.01

*Wilcoxon Test, $p < 0.01$ taken as the level of significance.

Table 3. Intervention Protocol Dual Methods P6 Acupressure For NVP.

No	Pictures	Stages	Description
1	 	<p>Tool</p> <p>Orientation and Preparation Stage</p>	<ol style="list-style-type: none"> Vegetable Complex Oil Acupressure Bracelet Small Towel <ol style="list-style-type: none"> Confirm patient identity Explain to the patient or family about the intervention to be performed Position the patient comfortably (Sit)
2	  	<p>Work Stage</p>	<p>Determine the acupressure P6. Then press on the P6 acupressure point. Location: 2 Cun (1 Cun is one-thumb width) below the wrist.</p> <ol style="list-style-type: none"> Patients are taught about how to identify P6. A band acupressure will be placed on the left hand at the identified P6 point. This band can be used for up to 30 minutes per/day until the next follow-up. Right hand, the patient will be massaged at the identified point P6.
			<ol style="list-style-type: none"> Pressure is applied for approximately 10-15 minutes, and can be repeated at least 3 times for 1 week.
3		<p>Termination Stage</p>	<ol style="list-style-type: none"> Explain to the patient that therapy has been completed. Give positive reinforcement to the patient.
4		<p>Result Stage</p>	<ol style="list-style-type: none"> Evaluate the results of activities and the patient's response after the intervention. Make a contract for further therapy. End the activity in a good way. Wash hands.

Scientifically, this study contributes to the midwifery profession's knowledge of pregnancy with NVP patients by identifying new treatment techniques. Previous research has demonstrated that P6 acupressure alone can help reduce NVP symptoms. However, the findings of this study reveal a notable difference in the changes observed in the Pregnancy-Unique Quantification of Emesis (PUQE) score, with an effect size that is higher compared to earlier trials that used only P6 acupressure.^{16,17,20} Therefore, this could support the hypothesis that using dual P6 acupressure methods can be more effective compared to single-method therapy.

As far as we know, there was no previous research that recommended the dexterity of the arm when applying the P6 acupressure. In this study, participants were asked to choose one arm based on their preferences for manual finger pressure and band acupressure. To limit variability, they were told to use a comparable location until the completion of the study time. As a result, dual P6 acupressure's effectiveness was limited to single-arm applications. Furthermore, the respondents' freedom to choose was granted because the response time was considered and demonstrated to be more efficient. Another advantage of using the same arm is that it provides pregnant women with more options for P6 acupressure methods in future pregnancies, which means that if they become pregnant again, they can do the pressure themselves or purchase an acupressure band. Based on statistical tests, the value ($p < 0.01$) ≤ 0.05 was obtained, leading to the rejection of the null hypothesis (H_0), indicating a significant difference between the intervention and control groups. This study was conducted to determine the effectiveness of interventions with Neiguan acupoint pressure (PC6) and the use of acupressure bracelets (3 times per week for 24 times from 8-15 weeks of gestation). The results indicate that the change observed in the intervention group was -6.92 ± 2.26 , whereas the control group showed a change of -4.23 ± 2.29 . This suggests that the treatment provided to the respondents in the intervention group was more effective during the post-intervention phase compared to the control group. The effectiveness is further supported by a decrease in the NVP score (Table 2). This explains that P6 acupressure intervention and the use of acupressure bracelets can reduce nausea and vomiting experienced by pregnant women in early pregnancy. Other research shows equally positive results. According to a 2017 study, 12 hours of PC6 acupressure over three days can considerably reduce pregnancy-induced nausea and vomiting. Helmerich et al. conducted a meta-analysis of eight randomized controlled trials and six cross-sectional studies ($n=1,655$) to determine the effect of P6 acupoint pressure stimulation on the prevention of nausea and vomiting in pregnant women. The researchers discovered that this form of intervention can reduce nausea and vomiting by up to 50%.

In a similar study, Steele *et al.* found that the use of the Sea-Band at point P6 for four days reduced the severity of nausea compared to the placebo. Belluomini *et al.* investigated the effectiveness of P6 acupressure on NVP and found four days of P6 point stimulation for ten minutes daily was associated with a significant decrease in nausea compared to sham points, but they could not find a positive effect for this intervention with respect to vomiting.

The results of another study using the PUQE instrument to assess nausea and vomiting in pregnancy for 3 consecutive days with the use of 12 hours of wristband acupressure showed that the average result was (9.13 ± 2.02) which changed after 3 days of use with an average score of (4.40 ± 1.63) , this indicated that there was a significant influence on the use of the P6 acupressure wristband.^{20,21}

Several studies have shown that acupressure can effectively reduce nausea and vomiting during pregnancy. The findings from

this research can enhance the quality of healthcare services and provide an effective solution for pregnant women experiencing these symptoms. In this study, a dual P6 acupressure technique was implemented to optimize the intervention process, ensuring that the results were both effective and safe. As a result, pregnant women reported high levels of satisfaction with the outcome of the intervention.

Based on the descriptive data collected from 60 respondents, the safety variable in the intervention group indicated that participants did not experience any side effects, suggesting that the intervention was safe for their physical health. This finding demonstrates that the treatment provided to the respondents led to significant improvements in post-test scores, particularly in reducing nausea and vomiting.

Research conducted by Mehta *et al.* highlights that acupressure is a user-friendly therapy with minimal side effects. However, it is essential to note that acupressure should not be applied to areas with burned skin, swollen body parts, broken bones, or any other types of damage. Additionally, acupressure should not be performed in an emotional atmosphere or immediately after a meal.²² In addition to reducing NVP, acupressure can also increase body energy and blood flow to signal the endocrine system to release endorphins (happy hormones) according to the body's needs so that mothers feel safe, calm, and comfortable.

Based on the descriptive data for the variable "Satisfaction", it was found that minimum score was 48 and maximum score was 90, the median of 74 (IQR 16). A Wilcoxon signed-rank test showed that dual methods P6 acupressure did elicit a statistically significant change in satisfaction in pregnant women with NVP ($Z = 1830$, $p = 0.000$). Indeed, the median satisfaction Score rating was 74 both pre and post-treatment. This suggests that pregnant women who received the intervention of dual method P6 acupressure therapy, which was used to reduce nausea and vomiting experienced in early pregnancy, were satisfied. Patient satisfaction with the interventions performed was the level of satisfaction resulting from the health services received when the patient compares them with their expectations.

The results showed that the application of dual acupressure was more effective. The mother only needed to press and use the band acupressure on the three fingers below the wrist. The intervention encourages the mother to sit or lie down in a comfortable position and continue using the acupressure method. This intervention was considered safe, as there were no reported side effects. It also provides a feeling of comfort and relaxation for the mother, thereby reducing NVP and increasing satisfaction with non-pharmacological interventions.

Strengths and limitations of this research

The strength of this study lies in the development of new interventions using the dual P6 acupressure method. It aims to create a protocol for managing nausea and vomiting in pregnancy through the application of this dual P6 technique. The study adheres to standard operating procedures for the intervention sessions and includes clear instructions for patients to practice at home, encouraging consistency in the use of dual P6 acupressure for treating nausea and vomiting in early pregnancy. The findings demonstrate that the dual P6 acupressure method is both safe and satisfactory for patients. However, there are limitations to the study. The acupressure band used was not standardized, although it was recognized by the government. Additionally, the pressure applied was self-administered by the patients, which may lead to variability in the pressure applied by each individual. This was due to the nature of the protocol provided. (Table 3).

Conclusions

This study showed that the dual method of using P6 acupressure, consisting of manual pressure and using a band acupressure, was found to be effective, safe, and satisfactory for reducing NVP. In the future, maternity care providers may consider using this method as a therapeutic alternative for the management of nausea and vomiting during pregnancy.

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