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A study protocol to explore the effectiveness of point 6 acupressure therapy in nausea and vomiting in early pregnancy in Samarinda, Indonesia

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Abstract---Nausea and vomiting in pregnancy (NVP) is a diagnosis of exclusion and a medical condition associated with adverse physiological and psychological disorders. More research is needed on the technique that could effectively treat this condition and an alternative medicine therapy in terms of acupressure had not been widely researched. Pharmacological treatments are available for this disease, but concerns about fetal health effects have led healthcare providers and recipients to prefer non-pharmacological treatments. Objective: This study examined the effectiveness, safety, and satisfaction of the P6 acupressure method to reduce nausea and vomiting during the first 16 weeks of pregnancy. Design and participants: The mixed-methods sequential explanatory study design consists of two phases: quantitative followed by qualitative. Non-equivalent (pre-test and post-test), control group technique was applied for this research. A total of 58 pregnant women with symptoms of moderate to severe NVP at 6 to 16 weeks period of gestation will be recruited. Setting: The participants were selected from 4 private maternity clinics in Samarinda, Indonesia. Conclusion: The evidence on the effectiveness of P6 acupressure intervention can provide the knowledge to speed up the development of new interventions to treat NVP in early pregnancy, which could be more effective and safer.

Keywords---acupressure therapy effectiveness, early pregnancy, nausea, pericardium 6 (P6), vomiting.

Introduction

Nausea and Vomiting in Pregnancy (NVP) is a common disorder associated with adverse physiological and psychological events (Bustos, 2017), where physiologically, this event is influenced by changes in pregnancy hormones. In contrast, the psychological impact that may occur is due to the increasing severity of nausea and vomiting symptoms, leading to anxiety. The incidence of NVP is generally underestimated and assumed as a normal consequence in early pregnancy without realizing the risk factors that will occur. The American College of Obstetricians and Gynecologists (2018) defines NVP as a common condition experienced by pregnant women in the form of nausea and vomiting, which has a severity category based on the duration of nausea and vomiting in the first trimester.

In pregnant women, if all their food is vomited, they lose weight, their skin turgor drops, and acetonuria develops. Nausea and vomiting can have a significant impact on health, such as severe dehydration from severe vomiting brings on the hypovolemic shock. Finally, the severity of NVP symptoms ranges from mild to moderate nausea and vomiting to pathological cases of women with a severe form of NVP called hyperemesis gravidarum (Bustos, 2017). The American College of Obstetricians and Gynecologists (2018) stated that the management of nausea and vomiting in pregnancy consists of pharmacology and non-pharmacology. Non-pharmacological therapy is done by way of diet, emotional support, and acupressure. Non-pharmacological therapy is a type of complementary therapy that can be used as an intervention to treat nausea including acupressure, acupuncture, relaxation, and therapy.

One of the non-pharmacological therapies to treat nausea and vomiting is acupressure at the Pericardium 6 (P6) point, which is a Chinese treatment for Pericardium 6. In "Clinical Practice in Acupressure" it is stated that the stimulus at point P6 is an important point that acupressure is given to clients with nausea and vomiting. The stimulating effect at this point is able to increase the release of beta-endorphins in the pituitary and adrenocorticotrophic (ACTH) along the chemoreceptor trigger zone (CTZ) which can inhibit the vomiting center (Mehta, Dhapte, Kadam, & Dhapte, 2017). Pericardium 6 (P6) is one of the acupressure points that can help with nausea and vomiting (Galeshi, Ghanbarpour, Naeimi Rad, & Asghari, 2020). Nausea and vomiting is a phenomenon where the energy flow (Qi) of the stomach is reversed upwards, where P6 suppresses the reverse Qi of the stomach which is heading upwards, then P6 can restore the Qi of the stomach in the chest and lowers it down again, thereby suppressing nausea and vomiting (Kim, Kismali, & Gupta, 2018).

The application of point P6 acupressure to pregnant women in the first trimester who experience nausea and vomiting is an alternative non-pharmacological treatment that can reduce emesis. In addition, P6 point acupressure therapy is considered to have minimal side effects and is easily administered to pregnant

women who experience emesis by applying P6 point acupressure will produce increased cortisol and induce relaxation responses, modulate physiological responses by increasing the transmission of endorphins and serotonin to the brain and certain organs. through nerves and meridians, changing the concentration of stress hormones and lactic acid (Galeshi et al., 2020). Based on results of a study conducted by Aga-Miri et al in a review article Ozgoli, G showed that 70% of patients with NVP had reduced the frequency and severity of nausea after using P6 massage at the Nei Guan point (Ozgoli & Saei Ghare Naz, 2018). A wristband with a button was more effective than placebo in alleviating the severity of nausea and was more effective than control group in reducing the frequency of vomiting. The mechanism of acupressure is unknown, but low-frequency transcutaneous stimulation may change the transmission of neurotransmitters. Acupressure also has an inhibitory effect on the secretion of gastric acids.




The role of acupressure, especially in the treatment of NVP, is by releasing endorphins from the hypothalamus to the spine, causing an analgesic and sedative effect from β -endorphins that facilitate the reduction of NVP, the analgesic and sedative effects of β -endorphin facilitate the reduction of NVP (Chen & Michalsen, 2017; Fejzo et al., 2019; Tang, Yin, Liu, Rubini, & Illes, 2019). In Indonesia, P6 point acupressure is well known for controlling nausea, vomiting associated with various disease conditions. P6 acupressure can be performed by healthcare workers and therapists who are certified by the Indonesian Aesthetic and acupressure course and training institution, and can be done in all places, including maternity clinics, hospitals, communities, or private sectors.

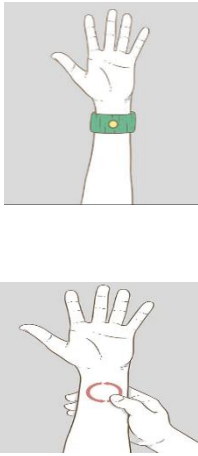
Acupressure demands the application of physical pressure to specific trigger points, acupressure points or pressure points positioned along the meridians. Activation of certain points on the meridians by pressure facilitates the reduction of pain at local sites and, also relieves pain from other parts of the body. It is a pressure point, hand mediated energy healing technique that is considered a useful strategy for the management of several symptoms, along with beneficial physical effectiveness, safety, and satisfaction. Overall, acupressure is a manually operated, needle-free, non-invasive, cost-effective and non-pharmacological healing intervention to improve patient well-being (Mehta et al., 2017). Therefore, it is imperative to have well-designed studies that allow a comprehensive and critical evaluation of the available evidence on the effectiveness and safety of P6 point acupressure in reducing nausea and vomiting in the first trimester of pregnancy.

Table. 1

Protocol for Handling Nausea Vomiting in Pregnancy with Acupressure P6 Method

ITEM	STANDARD OPERATING PROCEDURE (SOP) POINT PERICARDIUM 6 ACUPRESSURE FOR NVP
Definition	Acupressure is a non-invasive form of acupuncture in which practitioners use the tips of their fingers, elbows, or other instruments e.g. acupressure wrist bands or electrical nerve stimulation to stimulate acupressure points based on the meridian principles of traditional Chinese medicine
Aim	1. Reducing nausea and vomiting in pregnancy

		<ol style="list-style-type: none"> 2. Minimize the frequency of nausea and vomiting in women with NVP 3. Relieve muscle tension and relax the body 4. Lowering heart rate and blood pressure 5. Stimulate the brain to release endorphins 	
Policy		<ol style="list-style-type: none"> 1. Regulation of the Minister of Health of the Republic of Indonesia Number 1909/MENKES/PER/IX/2007 concerning the implementation of alternative complementary medicine in health care facilities 2. Regulation of the Minister of Health of the Republic of Indonesia Number 8 of 2014 concerning SPA Health Services 3. Regulation of the Minister of Health of the Republic of Indonesia Number 15 of 2018 concerning the implementation of complementary traditional health services 	
Therapist		<ol style="list-style-type: none"> 1. Researcher 2. Maternity clinic midwife who has acupressure competence or training 	
Time of intervention		The intervention was carried out at 8 to 15 weeks period of gestation (24 times intervention), 3 times a week on Tuesday, Wednesday and Thursday	
Place		Home of the pregnant women with NVP (home visit)	
No	Tools	Orientation & Tool Application Stage	Description of Stages
1	  	Orientation & Tool application Stage	<ol style="list-style-type: none"> 1. Confirm the patient's identity using the observation sheet or sociodemographic data 2. Explain to the patient or family about the intervention to be taken 3. Position the patient as comfortably as possible, for example in a sitting position, half sitting, lying down 4. Use the following: <ol style="list-style-type: none"> a. Massage oil (Vegetable oil complex) b. Acupressure sea band (golf tees) c. Small towel
2	Anatomy Position	Work Stage	<ol style="list-style-type: none"> 1. Determine the P6 acupressure point 2. Then press the P6 acupressure point
	.		1. The patient is to be educated regarding the

		<p>identification of the P6</p> <p>Location: 2 Cun (According World Health Organization a cun is the traditional Chinese unit of length. The traditional measure is the width of a person's thumb at the knuckle, while the width of the two index fingers indicates 1.5 cun, the size of the 2 knuckle lines on the index finger is 2 cun and the width of the four fingers side by side is 3 cun) below the wrist:</p> <ol style="list-style-type: none"> 2. Acupressure band is placed at the P6. This band is to be placed at the acupressure point for duration of 30 minutes/day. 3. Patient will be thought on how massage at the identified P6 4. The pressure is done for about 10-15 minutes, and can be repeated at least 3 times for 1 week
3	Termination	<ol style="list-style-type: none"> 1. Explain to the patient that the therapy has been completed 2. Provide positive reinforcement to patients
4	Result	<ol style="list-style-type: none"> 1. Evaluate the results of the activities and the patient's response after the intervention 2. Make a contract to the next therapy 3. End the activity in a good way <p>Hand wash</p>

Objectives

This study examined the effectiveness, safety, and satisfaction of the P6 acupressure method to reduce nausea and vomiting during the first 16 weeks of pregnancy.

Methods

The mixed-methods sequential explanatory design consists of two phases: quantitative followed by qualitative. Quantitative data will be collected and analyzed, then the next sequence will cover the qualitative data part and elaborate on the quantitative results obtained in the first phase (Creswell et al. 2003). Non-equivalent (pre-test and post-test) control group design in this design, a popular approach to quasi-experiments, the experimental group A and the control group B are selected without random assignment. Both groups take a pre-test and post-test, and only the experimental group received the treatment. In this design, participants will be made of the intervention group (pregnant women with NVP + P6 acupressure on both arms using pressure and acupressure bands) and the comparison group (pregnant women with NPV without P6 acupressure and pharmacological intervention). Interventions: In the first stage of the intervention group, P6 acupressure was applied together with acupressure bands for 3 consecutive days, with 10 minutes of pressure on the left arm and acupressure band on the right arm for 30 minutes per day for 7 weeks, while the control group did not get any intervention.

The population in this study consisted of all first trimester pregnant women who experienced nausea and vomiting at 4 selected maternity clinics in Samarinda, Indonesia. Sample size calculation was done using G Power Software version 3.1.9.7, and parameters for calculation was based on study by Mobarakadi et al, 2021, including the effect of using p6 acupressure for nausea score, mean (Sd) intervention group= 6.24(4.1), mean (Sd) control group= 9.23(3.7), with alpha error= 0.05, power 0.80, allocation= 1. This resulted in sample size per group as 24, attrition rate was set at 20%, thus, the total minimum sample size for this study is 58 respondents.

The effectiveness of P6 acupressure will be measured in terms of the nausea and vomiting frequency score as a continuous variable. Then the score for the frequency of nausea and vomiting will be classified into 4 symptom categories (normal, mild, moderate, and severe). The score was measured using PUQE. The safety of P6 acupressure will be measured in terms of safety score using a validated questionnaire. The score of at least 50% is categorized as safe if the patient answers Yes from a total of 9 question items.

In the qualitative part, this study applied a phenomenological approach to explore the perception of pregnant women in the first trimester after doing P6 acupressure to reduce nausea and vomiting. This type of design was chosen to explore the effectiveness of the P6 acupressure intervention as a reliever of nausea and vomiting. This design was chosen because the participants had been given the intervention. Bracketing is a process in phenomenological studies, participants must be independent from their views without the researcher's point

of view, about the experiences experienced after doing P6 acupressure (Creswell, 2007).

Participants

The population in this study consisted of all early trimester pregnant women who experienced nausea and vomiting at the 4 selected maternity clinics in Samarinda, Indonesia. On their first visit, participants will receive a thorough explanation of the study procedure and, if they agree to participate, they need to sign informed consent documents. The eligibility criteria for this study are: i) Inclusion criteria: Pregnant women with nausea and vomiting who has a nausea PUQE score > 6, period of gestation until 16 weeks, Age > 17 years old.; ii) Exclusion criteria: First visit > 8 weeks, Second visit > 10 weeks, Last visit > 16 weeks, pregnant women who consumed anti-nausea medication, mothers with skin problems on the arms such as wounds, eczema, infections, mother with physically disabled.

Interventions

In the first stage of the intervention group, P6 acupressure was applied together with acupressure bands for 3 consecutive days each week, with 10 minutes of pressure on the left arm and acupressure band on the right arm for 30 minutes per day for 7 weeks, while the control group did not get any intervention.

Results and Discussions

Outcome Measures

Data will be collected through compile reports that are from the questionnaires and interviews by the researchers. The intervention outcome measures will be evaluated at the end of therapy (T1) and the follow-up period (T2). The frequency and severity of nausea and vomiting were recorded during 8 weeks period of gestation, interventions began at 8 to 15 weeks gestation (T1), and a post-intervention assessment began at 16 weeks gestation. Phase 2 was then conducted on five participants in the intervention study by conducting a one-to-one interview with the research team.

Primary Outcome Measures

P6 acupressure effectiveness: P6 acupressure intervention will be given to pregnant women who experience nausea and vomiting from 8 weeks of gestation, at the end of therapy and at the end of follow-up to determine the effectiveness of reducing nausea and vomiting with P6 acupressure therapy. The effectiveness of successful P6 acupressure was defined as having decreased nausea and vomiting with acupressure therapy from 8 to 15 weeks of gestation (3 consecutive days of the week for 8 weeks). This will be measured during therapy with reports of observations made by the therapist. Measurements were carried out 2 times, namely with Pre-test measurements at 6 weeks of gestation (T0) and the final results on Post-test measurements carried out at 16 weeks of gestation (T2). Based on the existing literature, P6 acupressure is effective to be given repeatedly

to pregnant women who experience nausea and vomiting in early pregnancy [2]. Assessment of nausea and vomiting using the Pregnancy-Unique Quantification of Emesis (PUQE) Score questionnaire, the total PUQE score was categorized as 0-3 = no nausea and vomiting, 3-6 = mild nausea and vomiting, 7-12 = moderate nausea and vomiting, 13-15 = nausea and vomiting heavy.

Secondary Outcome Measures

The use of acupressure P6: Participants will be massaged or pressured on the outer arm identified at point P6, where the acupressure bracelet will be placed on the left hand at the identified point P6. This band can be used up to 30 minutes per/day until the next follow-up. For the right hand, the patient will be massaged at the identified P6 point and pressure will be applied for 10-15 minutes.

Safety

Patients will report during the study and receive suggestions or advice from therapist. Participants will note any AEs on the CRF and score them on a 3-point scale, 1 = mild (easily tolerated, causes minimal discomfort), 2 = moderate (discomfort significant enough to interfere with daily activities) and 3 = severe (incapacitating). and/or require therapy). The relationship between AE and acupressure P6 point will be assessed as follows: 1 = unsafe, 2 = safe

Satisfaction

Patients will report during the study and receive suggestions or advice from therapist. Participants will record anything on the SERVQUAL satisfaction questionnaire and score them using a 4-point scale, 1 = very dissatisfied, 2 = dissatisfied and 3 = satisfied, 4 = very satisfied. The relationship between satisfaction with the use of the intervention and the measurement of the SERVQUAL questionnaire was assessed based on the patient's perception with objective criteria, categorized as Satisfied: if the total score of respondents' answers > 63 and Dissatisfied: if the total score of respondents' answers < 63.

Discussion

This study examines the effectiveness of P6 acupressure therapy as a stand-alone treatment for all early pregnancy period pregnant women who had nausea and vomiting. The result will help us to identify if the intervention can help pregnant women to reduce nausea and vomiting symptoms. This study will also assess the safety and satisfaction in using P6 acupressure.

Conclusion

The evidence on the effectiveness of P6 acupressure intervention can provide the knowledge to speed up the development of new interventions to treat NVP in early pregnancy, which could be more effective and safer.

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