

Research Article

## Electroacustimulation is as Effective as B6 for Reducing Nausea and Vomiting in the First Trimester of Pregnancy

### *Elektroakustimulasi memiliki Efektivitas yang Sama dengan B6 untuk Mengatasi Keluhan Mual-Muntah pada Trimester Pertama Kehamilan*

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#### Abstract

**Objective:** To determine the benefit of electroacustimulation in reducing nausea and vomiting in the first trimester of pregnancy.

**Methods:** This study is an experimental study. The subject were 40 pregnant women divided into 2 groups randomly. The control group was given vitamin B6 3x30 mg per day and the case given the electroacustimulation device. The degree of severity of nausea and vomiting of patients assessed before and 3 days after treatment using Pregnancy Unique Quantification of Emesis and Nausea (PUQE) questionnaire.

**Result:** There were no differences between groups in gestational age at entry and PUQE score pre-treatment. After 3 days therapy, there were significant decrease in PUQE score in group receiving B6 ( $p=0.004$ ) and also in electroacustimulation group ( $p=0.000$ ). However, the change in PUQE score was not significantly different between the two groups ( $p=0.286$ ).

**Conclusion:** From the results of this study concluded that electroacustimulation is effective for reducing nausea and vomiting in the first trimester of pregnancy. There is no difference in effectiveness between electroacustimulation and vitamin B6 to treat nausea and vomiting in the first trimester of pregnancy.

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**Keywords:** electroacustimulation, nausea and vomiting in pregnancy, P6 or neiguan point, pregnancy unique quantification of emesis and nausea (PUQE)

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#### Abstrak

**Tujuan:** Untuk mengetahui manfaat elektroakustimulasi dalam mengatasi keluhan mual dan muntah pada trimester pertama kehamilan.

**Metode:** Merupakan uji eksperimental yang diikuti oleh 40 ibu hamil yang dibagi ke dalam 2 kelompok secara acak. Kelompok kontrol diberikan vitamin B6 3x30 mg per hari dan kelompok kasus diberikan alat elektroakustimulasi. Derajat keparahan mual dan muntah pasien dinilai pra dan 3 hari pasca perlakuan dengan menggunakan kuesioner Pregnancy Unique Quantification of Emesis and Nausea (PUQE).

**Hasil:** Tidak didapatkan adanya perbedaan usia kehamilan dan skor PUQE pra perlakuan pada kedua kelompok. 3 hari pasca perlakuan didapatkan pengurangan skor PUQE yang bermakna secara statistik baik pada kelompok vitamin B6 ( $p=0,004$ ) maupun pada kelompok elektroakustimulasi ( $p=0,000$ ). Namun, perubahan skor PUQE pada kedua kelompok tersebut tidak berbeda bermakna secara statistik ( $p=0,286$ ).

**Kesimpulan:** Didapatkan kesimpulan bahwa elektroakustimulasi efektif untuk mengatasi mual dan muntah pada trimester pertama kehamilan. Tidak terdapat perbedaan efektivitas antara elektroakustimulasi dan vitamin B6 dalam mengatasi mual dan muntah pada trimester pertama kehamilan.

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**Kata kunci:** elektroakustimulasi, mual-muntah pada kehamilan, P6 atau titik neiguan, pregnancy unique quantification of emesis and nausea (PUQE)

## INTRODUCTION

Nausea and vomiting are common symptoms in pregnancy. Incidence rate reached 70% in pregnant women and a quarter of the women complained that they were unable to work because of complaints of nausea, vomiting.<sup>1</sup>

Pharmacological interventions have proven effective in reducing complaints of nausea and vomiting in pregnant women. But because almost all women feel the complaint most severe during the

first trimester of pregnancy, while embryogenesis happened, there were fear that the drugs interfering the health of the fetus. In addition, most drugs to deal with complaints of nausea and vomiting side effects makes drowsiness. Drowsiness was also one of the side effect of anti emetic drugs which can be a burden for working pregnant women.<sup>2</sup>

Therefore, an alternative therapy is needed to deal with the complaints of nausea and vomiting in pregnancy. Noninvasive electrical stimulation

(electroacustimulation) median nerve at the P6 point can be an alternative therapy to deal with complaints of nausea and vomiting caused by motion sickness, chemotherapy, anesthesia, and pregnancy.<sup>3</sup>

This study is aimed to know the benefits electroacustimulation in reducing nausea and vomiting in the first trimester of pregnancy.

## METHOD

The study was an experimental study. The research was conducted at the obstetrics clinic of the Dr. Cipto Mangunkusumo General Hospital, Rahiem Maternity Clinic, and Bunda Aliyah Women and Children's Hospital in patients who experienced emesis gravidarum. The study was conducted from July 2012 to September 2012.

Nerve stimulation therapy done by using Retetex™ model that has been approved by the U.S Food and Drug Administration (FDA).

The inclusion criteria were pregnant women with emesis gravidarum below 16 weeks of gestation who were willing to follow this study. The exclusion criteria were patient having other conditions that have similar symptoms or using a pacemaker or had previously used acupuncture.

To calculate of the sample size, we use formula of statistical software EPICALC 2000, which defines a total sample size was 20 respondents fatherly each group.

Patients who have been selected according to inclusion and exclusion criteria were given informed consent of the research to be conducted. Once it is done random sampling, the first group will receive treatment stimulation while the second group will get a tablet of vitamin B6. Respondents will receive treatment for 3x24 hours. During the study patient fills PUQE scoring system to assess complaints of nausea and vomiting respondents efore and 3-days after treatment. Respondents are entitled to withdraw from the study when she felt worsening symptoms of nausea and vomiting during treatment and respondents remain included in the data analysis. Respondents also asked to wrote perceived side effects when getting treatment. All data from the study sample are recorded on a form of research. Then do the tabulation of data and then the data were statistically processed using SPSS 17.0

## RESULT

Of the 40 samples obtained, 18 samples obtained from RSCM, 10 samples obtained from RB Rahiem, and 12 samples of RSIA Bunda Aliyah. Sampling was done by random sampling. Of the 40 patients, 20 patients were included in the control group (vitamin B6 therapy) and 20 patients included in the treatment group (electroacustimulation).

Age of subjects ranged from 19 to 37 years with a mean age of 26 years. Subject gestational age ranged from 6 to 15 weeks with a mean gestational age of 9 weeks. Of the 40 subjects studied, 15 patients is primigravida and 25 patients is multigravida.

Shapiro-Wilk normality test shows the data distribution is not normal in both groups ( $p < 0.05$ ). Data distribution is not normal in this study due to the small sample size. Further analysis using the median, minimum and maximum values of the two groups.

**Table 1.** Characteristics of Study Subjects.

Variable	(n = 40)
<b>Age (years)</b>	
• Max	37
• Median	27
• Min	19
<b>Gestational Age (weeks)</b>	
• Max	15
• Median	9.5
• Min	6
<b>Parity</b>	
• Primigravid	15
• Multigravid	25

Based on the Mann-Whitney test, found no statistically significant difference in PUQE total score between the vitamin B6 and electroacustimulation groups before treatment. So it can be concluded there is no significant difference in the severity of nausea and vomiting between the two groups before treatment.

Most pregnant women in the control group suffered from moderate degree of nausea and vomiting before treatment (n = 16). Only one person suffering severe degree from nausea and vomiting. On the 3<sup>rd</sup> day of treatment, there is a decrease in the number of pregnant women who suffer from mo-

derate degree of nausea and vomiting from 16 people to just 10 people. However, we note that actually one pregnant women experience worsening of nausea and vomiting after administration of vitamin B6 therapy.

Based on Wilcoxon test, there is a significant difference ( $p < 0.05$ ) before and after therapy with vitamin B6.

In the treatment group, there is a decrease in the number of pregnant women with moderate degree nausea and vomiting from 19 to only 8 people. There were no patients with severe degrees of nausea and vomiting in this group.

**Table 2.** PUQE Score on Case Group (Electroacustimulation).

	n	≤6	7-12	≥13	p*
PUQE score pre-treatment	20	1	19	0	0.00
PUQE score after 3-days treatment	20	12	8	0	0

\* Wilcoxon test

Based on Wilcoxon test, there is a significant difference in the degree of nausea and vomiting before and after electroacustimulation therapy ( $p < 0.05$ ).

In this study, we also tried to compare the effectiveness of vitamin B6 with electroacustimulation by taking into account the change in total score PUQE before and after treatment in both groups of patients.

Based on the Mann-Whitney test, the results obtained were not statistically significant ( $p > 0.05$ ). It can be concluded that there were no difference in effectivity between vitamin B6 and electroacustimulation to treat nausea and vomiting in pregnancy.

**Table 3.** PUQE Score on Both Group.

	-3 - 0	1 - 3	4 - 6	p*
Vitamin B6	5	13	2	0.286
Electroacustimulation	4	10	6	

\* Pearson Chi-Square

## DISCUSSION

This study is the first study in Indonesia which try to figure out the effect of electroacustimulation in reducing complaints of nausea and vomiting in the

first trimester of pregnancy. In this study electroacustimulation prove useful in overcoming nausea and vomiting in the first trimester of pregnancy. Electroacustimulation is as effective as vitamin B6 in dealing with nausea and vomiting in the first trimester of pregnancy. Almost all patients experience improvement of symptoms and signs of nausea and vomiting during the treatment period.

Nausea and vomiting is both a complain that is often felt in the first trimester of pregnancy. Most of the patients complained of mild to moderate symptoms, only 1% who experienced hyperemesis gravidarum.<sup>1,4</sup> Exact etiology is unknown to date. Increased chemical substances due to pregnancy, such as hormone chorionic gonadotropin (hCG) is estimated to have a role in the pathogenesis of emesis gravidarum. Increased progesterone is also thought to cause symptoms of nausea and vomiting through the mechanism of gastroesophageal sphincter relaxation.<sup>5,6</sup> Social and psychological factors also play a role in the symptoms.<sup>7</sup>

There have been many studies that examine both pharmacological and non-pharmacological management of nausea and vomiting in pregnancy. Vitamin B6 is the first-line drug for nausea and vomiting in pregnancy which has been proven to be effective and safe when used according the recommended dosage.<sup>8</sup>

Sahakian<sup>9</sup> conducts research in 59 pregnant women with complaints of nausea and vomiting. A total of 31 patients were asked to consume vitamin B6 3 x 25 mg orally and 28 patients taking placebo in the manner and dosage forms of the same. Patients were then followed for 72 hours. At the end of the observation period, only 8 of the 31 patients in the vitamin B6 group who experienced vomiting compared with 15 of 28 patients in the placebo group ( $p < 0.05$ ). In these studies proved that the consumption of vitamin B6 25 mg per 8 hours is more effective than placebo in mild to moderate nausea and vomiting of pregnancy, but not to the severe nausea and vomiting (hyperemesis gravidarum).

Research with a similar result was also done by Vutyavanich.<sup>10</sup> A total of 342 pregnant women with gestational age less than 17 weeks participated in this study. Patients were divided into 2 groups, vitamin B6 and placebo by double-blind random sampling. Patients were followed for 5 days. The severity of nausea measured using VAS (Visual Analogue Scale) and frequency of vomiting

calculated for 24 hours before and after 5 days of treatment. The result is nausea in the vitamin B6 significantly reduced compared to the placebo group. Although the average number of vomiting was decreased in the vitamin B6 group, but the statistical test is somehow show not significant result. The conclusion that can be drawn from this study is vitamin B6 is effective to reduce complaints of nausea in early pregnancy.

Although many studies have suggested the efficacy of vitamin B6 for nausea and vomiting in pregnancy, but the mechanism of action of vitamin B6 to treat nausea and vomiting in pregnancy has not yet been clearly established. A new note is vitamin B6 plays an important role in the homeostasis of the body because it is water soluble and its role as a coenzyme in the metabolism of fats, carbohydrates, and amino acids. Previous studies have noted that vitamin B6 may reduce mild to moderate nausea, but not vomiting complaints. In addition, in a study by Magee's<sup>8</sup>, vitamin B6 proven to be safer than other antiemetic drugs. Therefore, vitamin B6 can be recommended as first-line treatment for patients with mild-moderate nausea and vomiting, but not for patients with hyperemesis gravidarum.

Electroacustimulation is a noninvasive procedure that allegedly effective way to overcome or reduce nausea and vomiting in pregnancy. This tool can also be used as an alternative therapy for some patients who have a fear of its own to take medicine. Electroacustimulation so far have not proven to give adverse effects on pregnancy. Recent research shows that acustimulation not associated with increased perinatal morbidity and mortality.<sup>11,12</sup>

Basically, electroacustimulation working mechanism is as the same as regular acupressure used to stimulate acupuncture point P6 (Neiguan). Disadvantages of regular acupressure tools is they are often not correctly stimulate P6 point. In electroacustimulation, stimulation of the P6 point is done by an electric wave. When the point of stimulation is right, it will give the sensation of tickling down to the fingertips. The sensation is not found in ordinary acupressure tool. While electroacustimulation advantages compared with acustimulation is on the adjustable intensity of the impulse in electroacustimulation.

Currently not many electroacustimulation tools available on the market. In our study, Reletex™

selected as the tool because it is easy to use and the intensity of the electrical stimulation can be adjusted according to the patient's needs.

In this research we divided subjects into 2 groups, the control group and the case group. Our control group asked to take vitamin B6 3 x 30 mg for 3 consecutive days, in accordance with the recommended dosage. As for the case group, we ask the patient to use the electroacustimulation device all day for 3 consecutive days. Patients simply remove the electroacustimulation device when she was about to shower or do an activity that will come into contact with liquid.

Our sampling was done by random sampling so that there is no difference between the two groups. Evidently the two groups in this study remained statistically equivalent reflected in the similarity degree of nausea and vomiting in both groups before treatment.

We followed our patients for 3 days. During that time we found the symptoms of nausea and vomiting was significantly reduced in both groups. In our study none of the patients complained of side effects or discomfort when using the tool electroacustimulation. Our results prove that electroacustimulation is effective to treat nausea and vomiting in the first trimester of pregnancy. This study is also consistent with other studies that mention the positive effects of acustimulation and acupressure to treat nausea and vomiting in pregnancy. In the review study by Roscoe and Matteson<sup>13</sup>, carrying approximately 12 publications that examine the effects of acupressure and acustimulation in overcoming nausea and vomiting in pregnancy. With different research methodology and different ways of working, a study conducted by Hyde, De Aloysio, Evans, Wagner, O'Brien, Miller, and Norheim reached the same conclusion that the stimulation of the P6 point (Neiguan) may reduce nausea-vomiting in pregnancy. No harmful effects were reported with this treatment method.

From all of the reviewed publications, only the study by Evans<sup>14</sup> comparing the effectiveness electroacustimulation with placebo. As a result, 87% (20 of 23) of pregnant women experience nausea and vomiting reduced after they used electroacustimulation, compared with only 43% (10 of 23) pregnant after using the placebo.

The most important part of this research is how to make objective of the subjective symptoms of

nausea and vomiting experienced by patients. Previous gold standard questionnaire to assess the severity of nausea and vomiting is one of Rhodes Index. PUQE (Pregnancy-Unique Quantification of Emesis and Nausea) is a new questionnaire, which is a modification of the Rhodes index. PUQE is more simple and has been proven to be able to assess the degree of severity of nausea and vomiting in pregnancy as accurately as Rhodes Index, as proposed by Koren.<sup>15</sup>

Nausea and vomiting in pregnancy in general will be reduced until it disappears at 14-16 weeks of gestation so that it can be a confounding factor in this study. In our study, the mean gestational age at the commencement of the research is still relatively early (group =  $9:35 \pm 2:18$  electroacustimulation weeks; groups of vitamin B6 =  $9.20 \pm 1852$  weeks), so confounding factor can be eliminated.

There is a study with a similar protocol to our study, which tried to compare the effectiveness of vitamin B6 with acustimulation to treat nausea and vomiting in pregnancy. The study was conducted by Jamigorn and Phupong<sup>16</sup> in 2005 in Bangkok, Thailand. They divided 60 patients into two groups, the group of vitamins B6 and acustimulation group. In the vitamin B6 group, patients were asked to consume vitamin B6 for 2 x 50 mg and using electroacustimulation at a point more lateral than P6 (the radius). In contrast, in the group acustimulation, patients were asked to use the right tool and continuously during the study at the P6 point and were asked to consume a placebo tablet which shape, size, and manner of administration is similar with vitamin B6. Patients were also asked to fill Rhodes Index for 5 days of research time. That study reveal the same result with our study. Both vitamin B6 and electroacustimulation may reduce nausea and vomiting in pregnancy. However, there was no difference in effectiveness between electroacustimulation with vitamin B6 to treat mild to moderate nausea and vomiting in the first trimester of pregnancy.

Our research goal is to examine the effectiveness of new treatment methods to deal with complaints of nausea and vomiting in pregnancy. To that end, we compare it to commonly used drugs and has proven efficacy and safety for the treatment of emesis gravidarum, which is vitamin B6. This study did not escape the limitations. However, small research subjects does not make the results of this

study become invalid. Based on previous studies that have been done with number of subjects that are similar also come to the conclusion that the P6 point stimulation has benefits for nausea and vomiting in pregnancy. Gestational age, educational level, occupation, and number of parity did not we take into account in the statistical analysis as factors affecting nausea and vomiting in pregnancy because it is not in accordance with the literature.

The most ideal study protocol is to use a placebo in both groups of subjects, as is done by Jamigorn and Phupong<sup>16</sup>. However, due to limitations of time and research tools such protocol we can not do.

Although there are limitations to this study and the exact mechanisms electroacustimulation to treat nausea and vomiting are still uncertain, this tool has advantages in terms of ease of use and no side effects have been proven to date. Therefore, electroacustimulation can be recommended to be given to pregnant women with nausea and vomiting in the first trimester of pregnancy.

## CONCLUSION

Electroacustimulation is effective for nausea and vomiting in the first trimester of pregnancy. There is no difference in effectiveness between electroacustimulation and vitamin B6 to treat nausea and vomiting in the first trimester of pregnancy. So, electroacustimulation can be used as an alternative therapy to treat nausea and vomiting in the first trimester of pregnancy.

## REFERENCES

1. Klebanoff M, Koslowe P, Kaslow R, Rhoads G. Epidemiology of vomiting in early pregnancy. *Obstet Gynecol* 1985; 66: 612-6.
2. Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy (Cochrane Review). In: *The Cochrane Library*, Issue 1, 2003. Oxford: Update Software.
3. Bertolucci LE, DiDario B. Efficacy of portable acustimulation device in controlling seasickness. *Aviat Space Environ Med* 1995; 66: 1155-8.
4. Goodwin TM. Hyperemesis gravidarum. *Clin Obstet Gynecol* 1998; 41: 597.
5. Lagiou P, Tamimi R, Mucci LA. Nausea and vomiting in pregnancy in relation to prolactin, estrogens, and progesterone: a prospective study. *Obstet Gynecol* 2003; 101: 639.
6. Kimura M, Mino N, Tamaki H. Gestational thyrotoxicosis and hyperemesis gravidarum: Possible role of hCG with higher stimulating activity. *Clin Endocrinol* 1993; 38: 345.
7. Buckwalter JG, Simpson SW. Psychological factors in the etiology and treatment of severe nausea and vomiting in pregnancy. *Am J Obstet Gynecol* 2002; 186: 210.

8. Magee LA, Mazzotta P, Koren G. Evidence-based view of safety and effectiveness of pharmacologic therapy for nausea and vomiting of pregnancy (NVP). *Am J Obstet Gynecol* 2002; 186: 256.
9. Sahakian V, Rouse D, Sipes S, Rose N, Niebyl J. Vitamin B6 is effective therapy for nausea and vomiting of pregnancy: a randomized, double-blind placebo-controlled study. *Obstet Gynecol*. 1991; 78: 33-6.
10. Vutyavanich T, Wongtra-ngan S, Ruangsri R. Pyridoxine for nausea and vomiting of pregnancy: a randomized, double-blind, placebo-controlled trial. *Am J Obstet Gynecol*. 1995 Sep; 173 (3 Pt 1): 881-4.
11. Jewell D, Young G. Interventions for nausea and vomiting in early pregnancy. *Cochrane Database Syst Rev* 2003: 145.
12. White PF, Issioui T, Hu J, Jones SB, Coleman JE, Waddle JP. Comparative Efficacy of Acustimulation (Relief Band) versus Ondansetron for preventing Nausea and Vomiting. *Anesthesiology*. 2002; 97: 1073-81.
13. Roscoe JA, Matteson SE. Acupressure and acustimulation bands for control of nausea: A brief review. *Am J Obstet Gynecol* 2002; 186: 244-7.
14. Evans AT, Samuels SN, Marshall C, Berolucci LE. Suppression of pregnancy-induced nausea and vomiting with sensory afferent stimulation. *J Reprod Med* 1993; 38: 603-6.
15. Koren G, Boskovic R, Hard M. Motherisk-PUQE (Pregnancy-Unique Quantification of Emesis and Nausea) scoring system for nausea and vomiting in pregnancy. *Am J Obstet Gynecol* 2002; 186: 228-31.
16. Jamigorn M, Phupong V. Acupressure and vitamin B6 to relieve nausea and vomiting in pregnancy: a randomized study. *Arch Gynecol Obstet*. 2007; 276: 245-9.