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Effect of Transcutaneous Electrical Nerve Stimulation Versus Capsicum Plaster on Emesis Gravidarum

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ABSTRACT

Objectives: To determine the difference between the effects of transcutaneous electrical nerve stimulation and capsicum plaster on emesis gravidarum. Design: Randomized clinical trial.

Location: This study was conducted at Kasr El Ainy University Hospital, Cairo, Egypt.

Subjects: Fifty pregnant women with emesis gravidarum were split into two equal groups. They were between the ages of 20 and 35 years, with gestational age less than 20 weeks. Intervention: Group (A) received transcutaneous electrical nerve stimulation (TENS) at p6 with the following parameters: Frequency: 80–120 Hz, Pulse width: 150 ms, Duration: 15 minutes for 30 consecutive days. Group (B) received capsicum plaster on p6 point for 12 hours per day for 30 consecutive days.

Outcome measures: a Rhodes index for nausea, vomiting, and retching. The assessment was performed pre- and post-treatment.

Results: Within the group comparison in groups (A) and (B), there was a significant difference in both groups between pre- and post-results. In between-group comparisons, there was no significant change across groups (A) and (B) in decreasing the intensity of distress due to retching, the intensity of distress due to vomiting, the volume of vomiting, or the amount and intensity of distress due to nausea per 24 hours. but there was significance difference between group (A) and (B) in favor of group (B) in decreasing the frequency of vomiting, frequency of retching, frequency and duration of nausea per 24 hours and in the total score of the questionnaire

Conclusion: Transcutaneous electrical nerve stimulation and capsicum plaster are both effective in the treatment of emesis gravidarum. Capsicum plaster is more beneficial than transcutaneous electrical nerve stimulation in decreasing the frequency of nausea, retching, and vomiting and reducing the duration of nausea.

Keywords: *TENS, capsicum plaster, emesis gravidarum, nausea, vomiting, retching, Rhodes index, pregnancy*

1. INTRODUCTION

Morning sickness is a common and natural symptom of emesis gravidarum, which occurs in pregnant women nearly every morning and evening (1).

It lasts for around ten weeks and starts about six weeks after the initial day of the previous menstrual cycle. During the first trimester, nausea and vomiting affect between 50 and 90 percent of pregnant women. About 60% to 80% of primigravida and 40% to 60% of multigravida suffer from nausea and vomiting. In one out of every 1000 pregnancies, these symptoms will worsen (2).

Symptom severity can range from mild nausea to persistent nausea that can happen day or night and frequently persists throughout the day, whether it involves retching and/or vomiting (3).

Nausea and vomiting of pregnancy (NVP) often manifest between weeks four and six, peaking between weeks eight and twelve. Hyperemesis gravidarum (HG), a more serious form of NVP, is also found in 0.5 to 3% of pregnancies and may result in hospitalization (4).

Pregnancy-related morning sickness has a major impact on the body, leading to the women becoming pale and weak and less likely to urinate, which lowers bodily fluid levels and thickens the blood (hemoconcentration). Because such a condition decreases blood circulation, the tissue receives less oxygen and nourishment. Consequently, it may result in tissue damage that exposes the mother and fetus to danger (5).

If emesis gravidarum is not addressed quickly, the fetus may develop congenital defects, die in the womb, or have stunted growth. Dehydration, alkaline acid balance problems, and deficient potassium are possible consequences for moms (6) .

No particular laboratory tests are advised for the diagnosis of NVP, with the exception of a pregnancy test. However, further tests might help rule out other causes of nausea and vomiting (7).

Treatments for NVP include vitamin supplements, antiemetic medication, hospitalization, and dietary and lifestyle modifications. Non-pharmacologic therapies are typically used as the first line of treatment; if NVP does not improve, medication therapy is added (8).

Pharmaceutical therapies include corticosteroids, metoclopramide, vitamins B6 and B12, dopamine antagonists, anticholinergics, antihistamines, and H3 antagonists (9) .

Concerns over the usage of pharmaceutical interventions to manage or alleviate pregnancy symptoms have existed since the thalidomide catastrophe in the 1960s, which affected both gravid women and their caregivers. The lack of effectiveness of previous pharmacological medications has created a therapeutic gap in managing NVP, along with potential teratogenic effects and adverse consequences such as sleepiness, heartburn, or arrhythmia (9).

Alternative and complementary treatments have gained popularity in many nations in recent years. These include acupressure, acustimulation bands, acupuncture, moxibustion, homeopathic treatments (Nux vomica, Pulsatilla), and herbal products (ginger, chamomile, peppermint, and raspberry leaf). These may be accepted by expectant mothers as "natural" and safe. Acupuncture has been utilized in China for thousands of years to alleviate morning sickness (9).

For many years, acupuncture has been promoted as a helpful antiemetic. Based on traditional Chinese medicine (TCM), point 6 on the pericardium channel is the ac point most frequently employed for antiemetic effect (10).

P6 is situated between the tendons of the Palmaris longus and the flexor carpi radialis, near the median nerve on the front of the wrist. P6 is typically measured as the distance between the patient's flexor crease and three fingerbreadths; its location is 3 to 5 cm in front of the flexor crease. Despite the existence of other acupuncture points with antiemetic properties, P6 has received the most extensive examination (11).

Various physiological processes have explained the antiemetic action of P6 activation. These include reflexes that affect the lower esophagus and help the stomach relax, the release of serotonin, increased control by the vagus nerve, direct stimulation of the smooth muscle in the intestines, and adjustments to the body's natural pain relief system (12) .

Pericardium 6 (P6) Neiguan, which is an acupoint on the wrist, may help control stomach function, rectify an undesirable qi flow, and avoid nausea and vomiting (13).

Transcutaneous acupoint electrical stimulation (TAES) at the Nei–Guan P6 acupoint can be an effective substitute for antiemetic medications. Motion sickness, NVP, and chemotherapy-related emesis can all be effectively treated with it (14).

Acupressure and acupuncture are closely associated to transcutaneous electrical nerve stimulation (TENS) since some TENS devices are made to trigger the wrist region that correlates to the predicted acupoint, which may help avoid nausea and vomiting. Another name for this type of TENS is acustimulation or electroacupoint stimulation (15).

An alternate to acupuncture, capsicum plaster was initially created and explained by Namsan, a Korean Buddhist priest. Controlling postoperative nausea and vomiting (PONV), and postoperative pain has been found to be effective with the application of capsicum plaster to the acupuncture points (16).

Capsicum plaster applied to the acupoints, an alternate form of pain management, is well-known for its efficacy in preventing and treating PONV (17).

2. Patients and Methods

Design: It was a pre-post test, randomized controlled clinical trial.

Participant: The study was carried out at Kars El Ainy University Hospital in Cairo, Egypt. Following examination, patients were referred by the outpatient obstetrician and gynecologist, who was blinded to the intervention groups, to exclude patients who met the exclusion criteria (the exclusion criteria were supplied to the obstetrical and gynecological clinic).

Regarding the power analysis, the minimum proper sample size is 44 subjects. Despite evaluating 100 primary participants for eligibility, not all patients finished the research. The final sample size was 50 pregnant women. Subjects who participated in this study had the following criteria: pregnant women suffering from emesis gravidarum throughout pregnancy. Their ages ranged from twenty to thirty-five years, and their body mass indices did not exceed thirty-five kg/m². Their gestational ages were less than 20 weeks. All of the women experienced mild to moderate vomiting and/or nausea. Every woman had a singleton pregnancy. If a subject possessed any of the following, they were excluded:

1) Previous carpal tunnel syndrome.
2) Skin abnormalities
3) Acute viral disease
4) Receiving any antiemetic drugs during the study period.

5) Hyperemesis gravidarum.
6) Previous history of nausea or vomiting before pregnancy.

After being chosen after consulting with an obstetrician and gynecologist, the patients introduced their written agreement and could express any questions they might have had about the procedure. The research has been accepted by Research Ethical Committee of the Faculty of Physical Therapy, Cairo University, Egypt (No: P.T.REC/012/004494) and also has been registered on Clinical Trials.gov Identifier (No: NCT06427434). Another clinician who was blind to the study utilized a sealed envelope to assign patients to the two groups. The main researcher, who was unaware of the assignment groups, applied the pre-treatment measurements.

Intervention: The trial lasted nine months, and each patient in the two groups received treatment for thirty days consecutively. Data was entered into a prepared card after the patients were assessed. The number of primary participants assessed for eligibility was 100, yet 30 did not meet inclusion criteria or refused to participate and were excluded. Following the start of the study, 20 participants left and did not complete the entire program, whereas 50 patients completed the entire study.

The participants were randomly split into two equal groups by using closed envelopes and included.

- **Group (A):** This group consisted of 25 pregnant women with emesis gravidarum. They were treated by transcutaneous electrical nerve stimulation (TENS) on the p6 point with the following parameters: frequency of 80–120 Hz, pulse width of 150 ms, and duration of 15 minutes for 30 consecutive days.

- **Group (B):** This group consisted of 25 pregnant women with emesis gravidarum. They were treated with capsicum plaster on p6 point for 12 hours per day for 30 consecutive days.

Outcome measures:

The Rhodes index for nausea, vomiting, and retching was utilized to determine the severity and frequency of emesis gravidarum before and after the procedures.

Data analysis:

The arithmetic mean and standard deviation (SD) were employed to summarize all of the gathered data. Flexion, extension, and lateral side bending findings were compared pre- and post-treatment via the paired T-tests and across the two groups using unpaired T-tests. Every statistically significant difference was set at a P value of 0.05, with a 95% confidence interval.

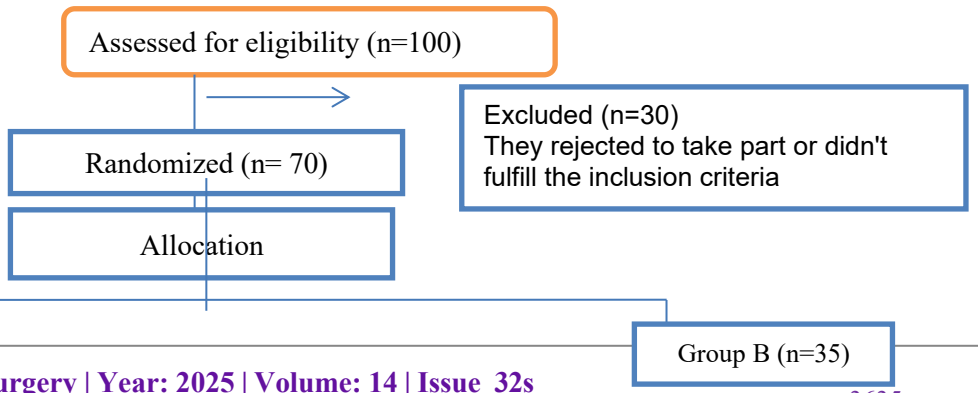
Data analysis and statistical design

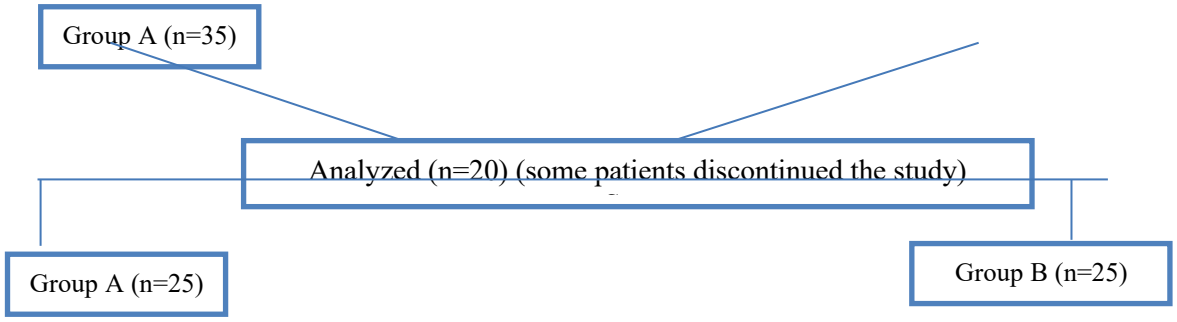
The mean ± SD was used to express the data. The unpaired t-test was applied to compare the participant's characteristics of the two groups. The normality of the data distribution was checked utilizing the Shapiro-Wilk test. The effects of the Rhodes index for nausea, vomiting, and retching variables were compared within and across groups using the Wilcoxon and Mann-Whitney tests. Data analysis was conducted using the statistical package for the social sciences computer program (SPSS Inc., Chicago, Illinois, USA; version 20 for Windows). A P-value of 0.05 or less was regarded as significant.

Using the Rhodes index as reported in the pilot study, the sample size was calculated with 80% power at the $\alpha = 0.05$ level for two groups and an effect size of 0.9 using the Wilcoxon Mann-Whitney test (two groups). The minimum appropriate sample size was 44 subjects. After adding 6 subjects (14%) as dropouts, the overall sample size was 50 people, with 25 subjects in each group. The G*Power software (version 3.0.10) was employed to compute the sample size.

3. Results:

The patient's CONSORT flow chart was made.





Fifty pregnant women with emesis gravidarum that was not secondary to other diseases were distributed into 2 equal groups. As displayed in Table (1), the mean value of women's age in groups A and B was (26.28±4.27) and (27.4±3.66) years, respectively; the mean value of women's weight in groups A and B was (77.52±8.8) and (76.32±7.76) kg, respectively; the mean value of women's height of groups A and B was (160.36±6.38) and (161.16±6.45) cm, respectively; the mean value of women's BMI of groups A and B was (30.26±3.94) and (29.47±3.33) kg/m², respectively; and the mean value of women's gestational age of groups A and B was (15.64±2.1) and (16.2±2.12) weeks, respectively.

No significant change was observed in the mean values of women's age, weight, height, BMI, and gestational age among groups (p=0.324, 0.611, 0.661, 0.447, and 0.353, respectively). The occupations of the patients varied; the majority of the female patients were housewives, but some were employed.

- ***Rhodes index of nausea, vomiting and retching.***

*I– **Intra–group comparison (within group comparison)***

***In group (A)**:*

***There was statistical significant difference in questions*:**

Questions (1): frequency of vomiting per 24 hours; **Questions (2):** intensity of distress due to retching per 24 hours; **Questions (3):** intensity of distress due to vomiting per 24 hours; **Questions (4):** duration of nausea per 24 hours; **Questions (5):** intensity of distress due to nausea per 24 hours; **Questions (6):** volume of vomiting amount per 24 hours; **Questions (7):** frequency of nausea per 24 hours and **Questions (8):** frequency of retching per 24 hours.

In group (B):

There was a statistically significant difference in questions:

Questions (1): frequency of vomiting per 24 hours; **Questions (2):** intensity of distress due to retching per 24 hours; **Questions (3):** intensity of distress due to vomiting per 24 hours; **Questions (4):** duration of nausea per 24 hours; **Questions (5):** intensity of distress due to nausea per 24 hours; **Questions (6):** volume of vomiting amount per 24 hours; **Questions (7):** frequency of nausea per 24 hours and **Questions (8):** frequency of retching per 24 hours.

II– Intergroup comparison (between-groups comparison)

There was no significant difference in the responses to the following questions:

Questions (2): intensity of distress due to retching per 24 hours, **Questions (3):** intensity of distress due to vomiting per 24 hours, **Questions (5):** intensity of distress due to nausea per 24 hours, and **Questions (6):** volume of vomiting amount per 24 hours.

There was a significant difference in questions:

Questions (1): frequency of vomiting per 24 hours; **Questions (4):** duration of nausea per 24 hours; **Questions (7):** frequency of nausea per 24 hours; **Questions (8):** frequency of retching per 24 hours and in the total score of the questionnaire.

Table (1): Demographic data of women of both groups

Demographic data	Group A	Group B	t-value	p-value
Age (years)	26.28±4.27	27.4±3.66	-0.99	0.324
Wight (kg)	77.52±8.8	76.32±7.76	0.51	0.611
Height (cm)	160.36±6.38	161.16±6.45	-0.44	0.661
BMI (kg/m2)	30.26±3.94	29.47±3.33	0.77	0.447
Gestational age (week)	15.64±2.1	16.2±2.12	-0.94	0.353

Data was expressed as mean ± standard deviation, p- value: significance

Table (2): Median (IR) of Rhodes index pre and post treatment of both groups.

Rhodes index	Group A Median (IR)	Group B Median (IR)	z-value	P-value[1]
Question 1				
Pre-treatment	1 (1.5)	0 (1)	-0.87	0.386
Post-treatment	0 (1)	0 (0)	-2.58	0.010
P-value[2]	0.014	0.010		
Question 2				
Pre-treatment	2 (2)	1 (2.5)	-1.18	0.236
Post-treatment	1 (1)	0 (1)	-1.99	0.046
P-value[2]	0.002	0.002		
Question 3				
Pre-treatment	1 (2)	0 (1)	-1.69	0.092
Post-treatment	0 (1.5)	0 (0)	-2.03	0.042
P-value[2]	0.024	0.020		
Question 4				
Pre-treatment	3 (1.5)	3 (1.5)	-0.86	0.392
Post-treatment	2 (2)	2 (0.5)	-0.5	0.619
P-value[2]	0.001	0.001		
Question 5				
Pre-treatment	2 (1.5)	2 (2)	-1.24	0.213
Post-treatment	2 (1)	1 (2)	-0.26	0.795
P-value[2]	0.002	0.001		
Question 6				
Pre-treatment	1 (1)	0 (0.5)	-1.69	0.090
Post-treatment	0 (1)	0 (0)	-2.3	0.021
P-value[2]	0.035	0.023		
Question 7				
Pre-treatment	3 (1)	3 (2)	-1.02	0.307
Post-treatment	2 (1)	1 (1)	-1.2	0.227
P-value[2]	0.001	0.001		
Question 8				
Pre-treatment	1 (2)	1 (1.5)	-0.87	0.383
Post-treatment	1 (2)	0 (1)	-2.13	0.033
P-value[2]	0.014	0.004		
Total score				
Pre-treatment	12 (10.5)	10 (9)	-0.52	0.606
Post-treatment	8 (8.5)	5 (5)	-2.07	0.039
P-value[2]	0.001	0.001		

(IR): interquartile range, P-value1: significance of comparison between groups, P-value2: significance of comparison within each group.; Data are represented as median (minimum-maximum)

NS= p> 0.05= not significant. S= p< 0.05= significant.

4. Discussion:

The antiemetic action of P6 activation has been explained by a variety of physiological processes. These involve the somatovisceral and somatosympathetic reflexes that influence the lower esophageal sphincter and intestinal relaxation, serotonin release, elevated vagal regulation, direct activation of intestinal smooth muscle, and modulation of the endogenous opioid system (12).

The pericardium 6 (P6) Neiguan, a wrist acupoint, can effectively avoid nausea and vomiting, control gastric function, and correct the improper flow of qi (13) .

For many years, acupuncture has been promoted as a helpful antiemetic. According to TCM, the pericardium P6 point is the acupoint that is most frequently utilized for its antiemetic effect (18).

An effective substitute for antiemetic medications could be transcutaneous acupoint electrical stimulation (TAES) at the Nei–Guan P6 acupoint. Motion sickness, NVP, and chemotherapy-related emesis can all be effectively treated with it (14).

Namsan, a Korean Buddhist priest, was the first to create and explain capsicum plaster as an alternative to acupuncture. Applying capsicum plaster to the acupoints effectively prevents postoperative pain and postoperative nausea and vomiting (PONV) (16).

According to Samad et al. (19), we utilized acupressure on the right hand in our research; however, acupuncture or acupressure has been administered to both hands in the literature. There is evidence to support the claim that using the

dominant hand produced the best acupressure outcomes.

Tantaway and Kamel (20) concurred that TENS considerably lessened the intensity, particularly the length of nausea, retching, and the frequency of vomiting episodes. It is hypothesized that acupressure acts by stimulating skin sensory receptors with low-frequency electrical stimulation, which can trigger A-beta and A-delta fibers. The hypothalamus may release endorphins as a result of these fibers' synapse within the dorsal horn. Following acupuncture stimulation, there have been reports of elevated B-endorphin concentrations in human cerebrospinal fluid. B-endorphins may also have antiemetic effects through their impact on g receptors.

A possible change in serotonin levels could help prevent PONV, just like the activation of serotonergic and norepinephrinergic fibers. It has been demonstrated that acupressure improves stomach motility. Additionally, central dopaminergic receptors may play a part in acupuncture. An action that is opposite to central dopamines may facilitate the P6 point's antiemetic effect. It has been hypothesized that serotonin, substance P, and endogenous opiates are modulated via several routes in the central nervous system by repetitive sensory stimulus. The emetic reflex's serotonin- and substance P-mediated constituents may exhibit certain effects, as may the opiate g receptor's antiemetic properties (20).

Ezzo et al. (11) suggest some ways that P6 point stimulation lowers the incidence of nausea and vomiting. Another idea is that directly affecting the smooth muscle in the intestines helps slow down fast heart rhythms, which then reduces the stomach's backward movements and, as a result, decreases vomiting.

According to Enest (21), cutaneous stimulation activates the alpha and beta fibers that transfer touch sensations, altering neurotransmitters and so supporting the standardization of gastric function and inhibition of stomach acid production. Vasoactive inhibitory peptide (VIP) and gastric inhibitory peptide (GIP) are two neurotransmitters that may be implicated. While VIP functions as a neurotransmitter in motor neurons, causing those neurons to relax before the peristaltic wave and sphincters, it also prevents parietal cells from releasing gastric acid; in contrast, GIP is a strong inhibitor of gastric acid secretion.

According to Samad et al. (19), the incorrect timing of P6 triggering or the incorrect localization of the P6 meridian point could be the causes of poor outcomes. 25 minutes beyond P6 point activation, which desensitizes the brain's chemoreceptor trigger zone (CTZ), the highest levels of beta-endorphin are produced. However, it is challenging to overcome or desensitize the CTZ once it has become sensitized by the neurochemical substance. This could help to clarify why acupressure needs to be used before the emetic stimulus is started to relieve nausea and vomiting.

Kim et al. (17) demonstrated that Low-frequency stimulation of cutaneous fibers could stimulate the A-beta and A-delta fibers. This might trigger the hypothalamus to release endorphins, which then trigger the serotonergic and norepinephrinergic receptors. According to reports, the continuous low-intensity activation of the P6 acupoint by capsaicin can effectively reduce the frequency of nausea and vomiting. Capsaicin, which triggers vagal modulation and stomach relaxation, also directly suppresses nausea and vomiting.

Murphy et al. (22) postulated that hormonal regulation and the alteration of neurotransmitters linked to nausea and vomiting are related to the stimulation of TRPV1 receptors and capsaicin-sensitive nociceptors. It involves lowering substance P in the chemoreceptor trigger zones, reducing vagal nerve cholinergic transfer, and blocking the proemetic neurotransmitter histamine.

Misra et al. (23) stated that capsaicin, the active component of capsicum plaster, acts on peripheral nerves by a method similar to acupuncture when administered to the skin. Additionally, it might directly affect the gastrointestinal system, which would prevent PONV. Certain neurotransmitters in the pathways connecting the vestibular system to the emetic center may be more strongly affected by acustimulation.

As reported by Koo et al. (23), applying capsicum plaster to the P6 acupoint can result in discomfort, skin irritation, persistent pain, and edema in the wrist. This could make it impossible to continue the treatment.

According to Koo et al. (23), there are numerous advantages of using capsicum plaster as an antiemetic. Initially, compared to capsicum plaster ($1 for 10 sheets), acupressure (about $8.00) or TEAS (Relief Band) ($30) are more costly. Second, compared to acupuncture, capsicum plaster is noninvasive, straightforward, non-painful, and simple to use at the appropriate point. Because of the capsicum element, the convenient 0.95 cm^2 size of capsicum plaster is accessible for 8–12 hours.

Misra et al. (24) also found that the lack of unpleasant sensations linked to invasive acupuncture is one of the evident benefits of using capsicum plaster. Additionally, one sheet of capsicum plaster costs 9 Indian Rupees (INR = $0.20 USD), and it can be utilized on at least twenty-five individuals when cut into 1 x 1 cm squares. Capsicum plaster costs about INR 0.36 per person; it is available over-the-counter as a therapy for musculoskeletal pain and doesn't require any special training to use.

5. Conclusion:

Transcutaneous electrical nerve stimulation and capsicum plaster are both effective in the treatment of emesis gravidarum. Capsicum plaster is more beneficial than transcutaneous electrical nerve stimulation in decreasing the frequency of nausea, retching, and vomiting and reducing the duration of nausea.

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