

Journal of Medicinal and Chemical Sciences

Journal homepage: http://www.jmchemsci.com/

Original Article

Impact of Pharmacological and Non-Pharmacological Intervention among Pregnant Women Complaining of Nausea and Vomiting

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ARTICLE INFO

Article history

Receive: 2023-01-14

Received in revised: 2023-03-20

Accepted: 2022-03-22

Manuscript ID: JMCS-2302-1958 Checked for Plagiarism: **Yes**

Language Editor: Dr. Fatimah Ramezani

Editor who approved publication:

Dr. Azahar Ali

DOI:10.26655/JMCHEMSCI.2023.9.11

KEYWORDS

Intervention Nausea Non-pharmacology Pregnant woman Vomiting

ABSTRACT

This study was conducted with the aim of investigating the effect of pharmaceutical and non-pharmacological interventions in pregnant women complaining of nausea and vomiting because identifying safe and effective ways to manage these symptoms is important to improve health outcomes for both mother and fetus.

This semi-experimental research was performed on (n=123) pregnant women referred to Erbil's main healthcare centre from December 2021 to September 2022. People were divided into three groups and the PUQE criterion was used to evaluate the severity of muscle cramps, vomiting, and nausea.

In the ginger group, acupressure group, peppermint oil group, and B6 group, a statistically significant decrease was observed in the mean and the mean number of hours of nausea (p<0.001). Vomiting frequency (in the previous 24 hours) dropped considerably from day zero to day four (p<0.001). The variations between day zero and all subsequent days were statistically significant (p<0.001).

Likewise in the B6 group, a significant decrease in the number of throwing times per day (p<0.001) and a significant reduction in periods of retardation or dryness (p<0.001) were observed.

The results revealed that the ginger group had the greatest change in puqe score, followed by the acupressure with oil group, and the B6 group had the least improvement (p<0.001).

According to the findings, administering vitamin B6, ginger, and acupressure with peppermint oil can reduce the intensity of nausea, vomiting, and dry retching during pregnancy from moderate to minor.

GRAPHICALABSTRACT



Introduction

Pregnancy is a physiological and joyful phenomenon, and at the same time, it is accompanied by many changes in different systems of the pregnant mother's body. One of the systems that undergo changes is the gastrointestinal tract [**1**]. Multiple gastrointestinal complaints may occur during pregnancy. One of these complaints is nausea and vomiting which can range from mild to moderate and severe [2]. Many pregnant women (70-80%) may experience these symptoms [3]. Several studies have shown that pregnant women are usually hospitalized due to nausea and vomiting. Accordingly, the World Health Organization (WHO) emphasizes the treatment of nausea and vomiting during pregnancy [4]. Although this condition is not life-threatening, it can cause significant concern for pregnant women and their families. Therefore, the stress caused by it can threaten the fetus and the mother. Therefore, the maximum measures should be taken to help pregnant mothers cope with these conditions [5]. The results have shown that about a quarter of pregnant women who suffer from nausea need to take time off from work. Hence, nausea and vomiting caused by pregnancy can limit working pregnant women [6]. Nausea typically starts 4 to 8 weeks following menstruation. Although it decreases and improves by weeks 14 to 20, it is experienced by 2% of pregnant women throughout their pregnancy [7-10]. Although most cases experience mild to moderate nausea, it is an unpleasant discomfort. Today, this cause rarely leads to maternal mortality. In pregnant women with nausea and vomiting, adverse pregnancy outcomes, miscarriage, and low birth weight occur less often [11]. Nausea and vomiting during pregnancy are usually symptomatic, of unknown cause, and their treatment process is long in a large number of women [12]. Based on the severity of symptoms, management course of gestational nausea and vomiting can differ from simply changing the diet to hospitalizing the patient and even prescribing a totally parenteral nutrition [11]. There are various treatment methods to treat nausea and vomiting. One of them is giving vitamin B6 according to the

doctor's prescription for symptoms treatment during pregnancy [13]. It is quite necessary to use drugs rationally in many cases. Therefore, vitamin B6 limitations should seriously be taken consideration while into using pharmacological treatment during pregnancy [14]. In addition, alternative therapy and changing lifestyles are among the nonpharmacological strategies used to alleviate nausea and vomiting [15]. As a therapeutic approach, herbal medicine has lately drawn much attention. Ginger and peppermint have been utilized to treat gestational vomiting and nausea. Ginger (Zingiber officinale) has been used for a long time as a spice in food and traditional medicine, particularly in Iran, India, Japan, and China to treat different diseases, especially gestational nausea, and vomiting [16, 17]. As shown by various studies, gestational nausea, and vomiting can be treated with ginger. It has been reported that administering ginger during pregnancy does not lead to abortion or a rise in maternal complications and birth deficit [18]. Ginger exists in different forms, including ginger capsules, biscuits, and tea. Ginger capsules are easier to consume; moreover, they contain a dry form of ginger which is more effective compared to its fresh root. Pregnant lifestyles, especially dietary regimes, are associated with the severity of nausea and vomiting. As a result of an increase in their nausea severity, pregnant women start consuming fewer fruit juices, citrus fruits, beans, breakfast cereals, pasta, rice, coffee, tea, and vegetables but more soft drinks and white bread [19]. Pregnant women consider mild nausea and vomiting quite typical during their pregnancy. However, the unrelenting nature of this condition has a strong effect on women. In a study conducted in North Carolina, the participating nurse-midwives recommended that over 10% of their patients should utilize alternative therapies for their gestational nausea and vomiting [15]. No previous studies have been carried out in Erbil to examine the impact of interventions for treating nausea and vomiting during early pregnancy. Therefore, we conducted an interventions study to treat nausea and vomiting in pregnant women. For this purpose, the mothers were assessed, and pharmacology and non-pharmacology intervention methods were used for them, and then they compared to recommend the most effective method for treating the symptoms of gestational nausea and vomiting.

Martials and Methods

The present study was a quasi-experimental one carried out from December 2021 to September 2022 to assess the impact of pharmacological and non-pharmacological intervention on pregnant women complaining of nausea and vomiting in primary health care centres in the Kurdistan Region of Iraq. Before performing the project, a pilot study was carried out. A study sample of (n=123) pregnant women who experienced mild and moderate nausea and vomiting during their first trimester were selected by a purposive sampling method. The participating women were chosen based on some inclusion criteria like the capability of attending an interventional program, attendance in the data collection session, age between 18 to 40 years old, healthy pregnant woman, singleton pregnancy, and communicating ability. However, women who had previously taken part in education programs, had a history of infertility, become pregnant after infertility, had any medical and surgical history, missed over 2 educational sessions, or faced any issues causing them to abandon the study were excluded. The participating women were divided into three intervention groups. The questionnaire consists of the patient's demographic data including age, educational level, and occupation. The dietary consumption consists of a 16itemscale in which the responses to the items are scored based on an ordinal scale of three points that varies from "always" 2," sometimes" 1, to "never" 0 [19]. Visual analog scale is a cm line divided from no nausea to severe. It consists of 8 questions asking about the daily frequency of vomiting episodes, the vomiting volume, nausea and retching length and degree, and nauseaassociated distress. The questions on the initial day (before the intervention) were asked at the end of each day every twenty-four hours [20]. In addition, a five-point Likert scale was used to assess the response to the intervention used to treat nausea, vomiting, and retching. The reliability was done and the validity of this scale has been calculated through Cronbach's alpha 0.8. The instrument was translated into Kurdish, the participants' native language, and then translated back into English. All patients underwent education sessions, provided written consent forms, and were informed about the aims of the study. The study was approved by the Ethics Committee at Hawler Medical University and the authorities of hospital NO.123 and dated 7.10.2022.

In addition, all three groups were provided with a printed copy of the education materials, and they were required to participate in and complete the intervention program. During the first session, general information on nausea and vomiting (definition, signs, symptoms if getting severe, causes, also benefit, indication, side effect about each of vitamin b6, ginger, peppermint oil, and acupressure) was given to the participant. The pregnant women who were present in the second session were helped to recall the information from the session before. During that session, they were provided with information about avoiding empty stomach at all time, avoiding fried food, and foods cooked with grease, oil, or fatty meats, avoiding spicy food and eating bland foods like apple sauce, tofu, eggs, broth, plain baked potato, dry toast, rice, or bananas, eating toast or a few crackers in bed before arising, taking in more liquid than solid, eating high protein snacks between meals like milk, cheese, apple slices, peanut, yogurt, nuts, and beans, eating several small meals throughout the day instead of large meals, opening a window to inhale fresh air, keeping the room well ventilated, getting outside from time to time, drinking fluids between meals rather than with meals, getting out of bed in the morning very slowly, minimizing stress, getting plenty of rest and sleep, wearing loose clothes, avoiding strong smells, smelling fresh and pleasant scents like lemon, avoiding brushing teeth immediately after eating, and rinsing mouth with water after vomiting to protect the teeth. In the third session, the understanding of pregnant women from the previous sessions was checked and important points were mentioned to remember the contents. The necessary training was further given about the value and method of each treatment (ginger acupressure, peppermint oil, and vitamin B6).

The first group of pregnant women used vitamin B6 orally. The pyridoxine dosage was 100 mg every 24 hours a day. Every pregnant woman in this group was provided with four tablets in a sachet. The second group of pregnant women used ginger capsules containing 500 mg of ginger powder. The capsules were weighed and enveloped. Each pack contained eight capsules. They were taken twice a day after meals for four days. The third group of pregnant women were required to use peppermint oil, and acupressure peppermint oil, and apply the solution twice per day prior to their afternoon rest and night sleep for four days. The women were also asked to put 4 drops of pure peppermint oil on cotton and inhale the scent for 20 minutes while keeping the cotton at a distance of 20 cm from their noses. The pressure point P-6 (PC6), also called Neiguan, is located on the wrist volar side about 3 cm above the wrist crease, between two easily palpated tendons. Fingers or thumbs can be used to apply acupressure PC6, which provides steady

pressure from a small button or disc on the site with no message of the area. It was performed three to four times daily and 10 minutes each time

The women in all three groups were followed up every twenty-four hours for four days to monitor their adherence to the dietary recommendation, complementary method, and pyridoxine. During the follow-up, the researcher kept telephoning the participants to assess the method implementation for each pregnant woman, responded to their questions, and motivated them to be active. Moreover, they were provided with the researcher's phone number.

SPSS version 25 was employed to analyse the collected data. In this regard, inferential and descriptive statistics were utilized to calculate frequency, percentage, mean, and standard deviation. In addition, post-hoc (Bonferroni) Kruskal-Wallis, two-way ANOVA, Friedman test, Fisher's exact test, and Chi-square test were utilized. A p-value of less than 0.05 was considered as statistically significant.

Table 1: Basic characteristics of the study groups

	В6	Ginger	Ginger Acupressure		P-value
	No. (%)	No. (%)	No. (%)	No. (%)	
Age (years)					
< 25	12 (29.3)	17 (41.5)	15 (36.6)	44 (35.8)	
25-34	23 (56.1)	15 (36.6)	19 (46.3)	57 (46.3)	
≥ 35	6 (14.6)	9 (22.0)	7 (17.1)	22 (17.9)	0.527*
Mean (SD)	28.1 (5.8)	28.0 (6.8)	28.1 (6.7)	28.1 (6.4)	0.996†
Educational Level					
Illiterate	1 (2.4)	1 (2.4)	1 (2.4)	3 (2.4)	
Read/Write - Primary School	13 (31.7)	13 (31.7)	12 (29.3)	38 (30.9)	
Secondary School	8 (19.5)	9 (22.0)	9 (22.0)	26 (21.1)	
Institute	9 (22.0)	5 (12.2)	6 (14.6)	20 (16.3)	
College or Higher	10 (24.4)	13 (31.7)	13 (31.7)	36 (29.3)	0.983*
Occupation					
Student	3 (7.3)	3 (7.3)	2 (4.9)	8 (6.5)	
Housewife	32 (78.0)	31 (75.6)	32 (78.0)	95 (77.2)	
Skilled Manual worker	6 (14.6)	7 (17.1)	7 (17.1)	20 (16.3)	1.000**
BMI (Kg/m ²)					
< 25	17 (41.5)	18 (43.9)	17 (41.5)	52 (42.3)	
25-29	20 (48.8)	16 (39.0)	18 (43.9)	54 (43.9)	
≥ 30	4 (9.8)	7 (17.1)	6 (14.6)	17 (13.8)	0.860*
Total	41 (100.0)	41 (100.0)	41 (100.0)	123 (100.0)	

^{*}By Chi square test. **By Fisher's exact test. †By ANOVA.

Results and Discussion

The total number of women were 123, who were divided into three equal groups (41 women in each group). The mean age of the participants were 28.1 (6.4), and there was a non-significant difference between the three groups in the mean age (p = 0.996 and p = 0.527, respectively). The largest proportion (46.3%) of the participants were in the age group 25-34 years. Around onethird (29.3%) of the participants were college graduates, and 30.9% were either graduates of primary schools or can just read and write. No significant difference was detected between the groups. The majority (77.2%) of the women were housewives, but there were no significant differences between the groups in the occupation categories. The prevalence of obesity was 13.8%, but there were no significant differences between the groups (Table 1).

In the B6 group, there was a significant decrease (from day zero to day 4) in the mean rank of the

number of hours, the women remain nauseated per day (p < 0.001), but the adjusted p-values did not show significant differences between each two days. The number of times of vomiting (of the past 24 hours) decreased significantly from day zero to day 4 (p < 0.001). The differences between day zero and all the following days were significant (p < 0.001). The same pattern can be applied for periods of retching or dry heaves (Table 2).

In the ginger group, there was a significant decrease in the mean and median of the number of hours the patients remain nauseated per day (p < 0.001), as the median decreased from 1 hour on day zero to zero hours on day 2, 3, and 4. In addition, there was a significant decrease in the number of times of throwing up per day (p < 0.001), and a significant decrease in the periods of retching or dry heaves (p < 0.001) (Table 3).

Table 2: Pregnancy unique quantification of emesis (PUQE score), at baseline, and the days after the intervention in the B6 group

Day	Mean rank	Median	P-value	Groups	P*	Groups	P**		
In the p	In the past 24 hours, how many hours did you remain nauseated or were sick to your stomach?								
D0	3.38	1.0		D0XD1	1.000	D1XD3	1.000		
D1	3.26	1.0		D0XD2	1.000	D1XD4	0.232		
D2	3.13	1.0	< 0.001	D0XD3	0.808	D2XD3	1.000		
D3	2.77	1.0		D0XD4	0.088	D2XD4	0.548		
D4	2.46	1.0		D1XD2	1.000	D3XD4	1.000		
	In the past 24 hours, how many times did you throw up?								
D0	4.82	1.0		D0XD1	< 0.001	D1XD3	0.332		
D1	3.06	0.0		D0XD2	< 0.001	D1XD4	0.332		
D2	2.49	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.32	0.0		D0XD4	< 0.001	D2XD4	1.000		
D4	2.32	0.0		D1XD2	1.000	D3XD4	1.000		
In	In the past 24 hours, how many times did you have periods of retching or dry heaves?								
D0	4.73	3.0		D0XD1	< 0.001	D1XD3	0.694		
D1	3.11	1.0		D0XD2	< 0.001	D1XD4	0.003		
D2	2.83	1.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.48	1.0		D0XD4	< 0.001	D2XD4	0.052		
D4	1.85	0.0		D1XD2	1.000	D3XD4	0.749		

^{*}By Friedman two-way ANOVA by ranks. **By a post-hoc test (Bonferroni).

Table 3: Pregnancy unique quantification of emesis (PUQE score), at baseline, and the days after the intervention in the ginger group

Day	Mean rank	Median	P-value	Groups	P*	Groups	P**		
In the past 24 hours, how many hours did you remain nauseated or were sick to your stomach?									
D0	4.22	1.0		D0XD1	0.548	D1XD3	0.021		
D1	3.55	1.0		D0XD2	0.001	D1XD4	< 0.001		
D2	2.89	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.48	0.0		D0XD4	< 0.001	D2XD4	0.034		
D4	1.87	0.0		D1XD2	0.593	D3XD4	0.808		
	In the past 24 hours, how many times did you throw up?								
D0	4.87	1.0		D0XD1	< 0.001	D1XD3	1.000		
D1	2.78	0.0		D0XD2	< 0.001	D1XD4	1.000		
D2	2.70	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.38	0.0		D0XD4	< 0.001	D2XD4	1.000		
D4	2.28	0.0		D1XD2	1.000	D3XD4	1.000		
I	In the past 24 hours, how many times did you have period of retching or dry heaves?								
D0	4.91	3.0		D0XD1	< 0.001	D1XD3	0.254		
D1	3.0	0.0		D0XD2	< 0.001	D1XD4	0.212		
D2	2.67	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.22	0.0		D0XD4	< 0.001	D2XD4	1.000		
D4	2.20	0.0		D1XD2	1.000	D3XD4	1.000		

Table 4: Pregnancy unique quantification of emesis (PUQE score), at baseline, and the days after the intervention in the acupressure and peppermint oil group

intervention in the acupressure and pepper inint on group									
Dav	Mean	Median	P-value	Groups	P*	Groups	P**		
- 5	rank			Groups	-	агоцро	•		
In the past 24 hours, how many hours did you remain nauseated or were sick at your stomach?									
D0	3.80	1.0		D0XD1	1.000	D1XD3	0.642		
D1	3.32	1.0		D0XD2	0.098	D1XD4	0.037		
D2	2.90	1.0	< 0.001	D0XD3	0.012	D2XD3	1.000		
D3	2.67	1.0		D0XD4	< 0.001	D2XD4	0.871		
D4	2.30	0.0		D1XD2	1.000	D3XD4	1.000		
	In the past 24 hours, how many times did you throw up?								
D0	4.67	1.0		D0XD1	< 0.001	D1XD3	1.000		
D1	3.05	0.0		D0XD2	< 0.001	D1XD4	0.145		
D2	2.55	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.54	0.0		D0XD4	< 0.001	D2XD4	1.000		
D4	2.20	0.0		D1XD2	1.000	D3XD4	1.000		
In th	In the past 24 hours, how many times did you have period of retching or dry heaves?								
D0	4.83	3.0		D0XD1	< 0.001	D1XD3	0.108		
D1	3.20	1.0		D0XD2	< 0.001	D1XD4	0.058		
D2	2.44	0.0	< 0.001	D0XD3	< 0.001	D2XD3	1.000		
D3	2.30	0.0		D0XD4	< 0.001	D2XD4	1.000		
D4	2.23	0.0		D1XD2	0.304	D3XD4	1.000		

^{*}By Friedman two-way ANOVA by ranks. **By a post-hoc test (Bonferroni).

P* P** Mean (SD) Mean rank B6 X Acupressure, oil B6 2.83 (1.09)48.73 1.000 Ginger 3.95 (1.05)82.66 < 0.001 B6 X Ginger < 0.001 Acupressure, oil Acupressure 3.00 (1.05)54.61 0.001 Ginger

Table 5: Mean of difference between day 0 and day 4 PUQE score by the type of intervention

The results of the mean and median number of hours that patients have nausea show that there is a significant decrease in the acupressure and peppermint oil group (p<0.001) because the median decreased from 1 hour on day zero to zero hours in day 3 and 4. Likewise, there was a significant decrease in the number of times of throwing up per day (p < 0.001), and a significant decrease in the periods of retching or dry heaves (p < 0.001) (Table 4).

The result of the study shows that the means and mean ranks of difference between the three groups were compared. The maximum improvement in PUQE score was in the ginger group, and then in the acupressure and peppermint oil group, and the least was in the B6 group (p < 0.001) (Table 5).

As indicated by the results of the present study, implementing the intervention methods, i.e. vitamin B6, ginger, and acupressure with peppermint oil, for 4 days led to a significant decrease in the pregnant women's gestational nausea and vomiting. However, the three groups were different in terms of their mean scores. Based on the results of this study, if the intervention programs are designed implemented according to the pregnant women's needs, and sufficient follow-ups are considered, they can lead to a remarkable decrease in the pregnant women's complaints about gestational and vomiting. Implementing interventions for 4 days in the present study resulted in significant changes among the women. Another important point in the present study was the effect of follow-ups and the participating women's trust in the researcher's availability to respond to their questions. In spite of its limited data, a Cochrane systematic review revealed that vitamin B6 monotherapy can be beneficial for gestational nausea and vomiting [13]. However, the effectiveness of vitamin B6 at higher doses

needs to be investigated based on more evidence [21].

As proved by a previous study conducted by Firouzbakht et al. (2014), daily administration of 1000 mg of ginger for a period of 4 days is quite safe and without side effects, and also leads to improvement in the signs of gestational nausea and vomiting [22]. These findings are consistent with studies conducted by Murti et al. (2019), and Kundarti et al. (2015) because the results showed that a two-day treatment led to a significant reduction in the symptoms of nausea and vomiting during pregnancy [23, 24]. The results of the study conducted by Saberi et al. (2013), revealed the ginger effectiveness in reducing gestational nausea and vomiting, such that gestational nausea symptoms were alleviated in the group of pregnant women who received ginger as medicine [25]. In addition, Willetts et al. (2003) conducted a study with the aim of investigating the effectiveness of ginger extract on nausea caused by pregnancy. The results showed that groups of pregnant women who received ginger extract as medicine had a significant decrease in their nausea experience score after the first day of treatment [26].

As indicated by the results of the present study, the ginger group experienced a decrease in their vomiting and nausea. Therefore, ginger was found to be more effective in treating nausea and vomiting than vitamin B6 and peppermint oil with acupressure. The impact of PC6 acupressure stimulation on preventing gestational nausea and vomiting was examined in 14 randomized clinical trials including 6 crossover studies and 8 randomized controlled trials (n=1,655). The results indicated that the incidence of nausea and vomiting decreased up to 15% as a result of this kind of intervention [27]. In addition, the effects of 6 treatments on gestational nausea and vomiting were examined in a meta-analysis that

^{*}By Kruskal-Wallis test. **By Dunn-Bonferroni (post-hoc) test.

consisted of 292 acupressure cases and controls. The results showed that postoperative nausea and vomiting were significantly reduced (about 15%) due to acupressure [28].

The results of another study conducted in 2013 revealed that the puge scores of 101 pregnant women treated with essential oil peppermint inhalation for 3 days significantly decreased. However, the results of another study indicated aromatherapy through peppermint inhalation did not lead to a decrease in gestational nausea and vomiting [29]. The discrepancy between these two studies may be due to the small sample size of the latter study. Seventy pregnant women were studied in a randomized control trial study conducted in Iran, and the results revealed that the severity of gestational nausea was relieved by ginger more than vitamin B6. It was also observed that both ginger and vitamin B6 are equally effective in reducing the number of vomiting episodes in the early stages of pregnancy [30].

One of the limitations of the present study was related to the limited number of pregnant women who attended primary health care centres during their first trimester. As a result, the conduct of longitudinal studies on this subject is recommended.

Conclusion

The severity of nausea, vomiting, and dry retching during pregnancy can be minimized by administering vitamin B6, ginger, and acupressure with peppermint oil mostly from moderate to mild, and also the complaints of gestational nausea and vomiting were decreased among pregnant women for those participated because they are associated with very few adverse events, can be easily applied, and are more accessible and more convenient than other therapies, they can be utilized as suitable therapeutic options for relieving the symptoms of gestational nausea, vomiting, and dry retching.

Acknowledgments

The authors would like to express their sincere appreciation to the women who participated in the current study.

Disclosure Statement

No potential conflict of interest was reported by the authors.

Funding

This research did not receive any specific grant from funding agencies in the public, commercial, or not-for-profit sectors.

Authors' Contributions

All authors contributed to data analysis, drafting, and revising of the paper and agreed to be responsible for all the aspects of this work.

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HOW TO CITE THIS ARTICLE

Shaymaa S. Maqsood, Ibrahim H. Mustafa. Impact of Pharmacological and Non-Pharmacological Intervention among Pregnant Women Complaining of Nausea and Vomiting. J. Med. Chem. Sci., 2023, 6(9) 2028-2037 DOI: https://doi.org/10.26655/JMCHEMSCI.2023.9.11

URL: http://www.jmchemsci.com/article 169012.html