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To What Extend Aromatherapy with Peppermint Oil Effects on Chemotherapy Induced Nausea and Vomiting in Patient Diagnosed with Breast Cancer? A Randomized Controlled Trial

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Abstract

Background: Breast cancer is one of the most common malignancies in the world and in Iran. Prevalence of this disease in Iran 21.4% was reported. One of the main alternatives for treating breast cancer is chemotherapy which causes complications such as acute and delayed nausea and vomiting. The aim of this study was to determine the effect of aromatherapy with peppermint oil on nausea and vomiting induced by chemotherapy among breast cancer patients.

Methods: This study was a randomized controlled trial on 100 women who suffering from Breast Cancer and receiving chemotherapy as outpatient's hospital care in Imam Khomeini. Before chemotherapy and after obtaining informed consent the patients with random sampling block were randomly allocated into intervention and control group. Intervention group received routine medications for controlling nausea and vomiting as well as aroma therapy with peppermint for five days. Meanwhile, the control group received only the routine medications. The data were gathered by using demographic and Rhodes Standard Questionnaire (about severity and number of nausea and vomiting). The results obtained from both groups were compared by using the SPSS version 11.5 software and descriptive and analytic statistics.

Results: The results showed there were no statistical differences between two groups in some variables such as age, duration of cancer, history of alcohol use, history of nausea and vomiting ($p>0.05$). Use of aromatherapy with peppermint in acute phase lead to decreased of nausea and vomiting without any complications ($p<.0.5$). The use of aromatherapy with peppermint oil leads to a reduction in frequency and duration of nausea and vomiting in the delayed phase but not statistical significance ($p>0.05$). Indeed more than half of samples stated that they are satisfied with aromatherapy and recommend it to others.

Conclusions: Aromatherapy with peppermint in breast cancer patients could decrease nausea and vomiting in acute phase after chemotherapy. It is suggested that nurses use this aroma therapy as a complementary treatment, inexpensive and without complications for relieving the nausea and vomiting caused by chemotherapy.

Keywords: Aromatherapy; Nausea; Vomiting; Breast cancer; Peppermint oil

Introduction

Breast cancer (BC) is one of the most prevalent malignancy affecting women in the worldwide and also in Iran [1,2]. It is reported that in Iran the prevalence of BC is 24.2% [3]. Despite all the advances in medical science, BC is still one of the most fatal diseases [2]. Breast cancer is a complicated and multi-factorial disease affected by genetic and environmental factors. Risk factors involved in BC are: age, sex, family history, obesity, diet, race, alcohol and cigarette use. Despite there are a lot of factor leading to this disease it is difficult to determine the main cause of BC [4]. Early treatments for BC are complex and may include surgery, chemotherapy, biotherapy, radiotherapy and plastic surgery [1]. The treatment strategies are determined based on tumor level, hormone receptors' condition, the possibility of metastasis and the patient's condition. One of the main treatment options for BC is chemotherapy which is already used pervasively [5]. The treatments side effects can have detrimental effects on the patients. Although gastrointestinal (GI) symptoms due to chemotherapy such as nausea, vomiting and diarrhea are not fatal yet they can influence patients' quality of life [6]. Despite taking anti-emetic drugs 32.6% to 59.2% of the patient's undergone chemotherapy show moderate emetic risks and about 35.3% to 66% of the patients used high emetic risk drugs experience nausea and vomiting in a critical as well as delayed manner [7]. Recent studies showed that in order to adapt with medical problems the patients constantly seek interventions which are available

outside medical clinics. These interventions are called complementary or alternative medicine [8]. Even though using complementary or alternative medicine by patients diagnosed with cancer is not an alleviating option in medical clinics in some countries according to World Health Organization (WHO) but about 80% of such patients use complementary medicine [5]. The patients diagnosed with BC are reported to use complementary medicine the most with an average of 76%-83% [9]. Aromatherapy is one of the most common complementary therapies. It is derived from odor (aroma) and it refers to the act of controlled use of aromatic oils to protect and promote physical and mental health. Aromatherapy, as a part of nursing practice is used in many countries like Swiss, Germany, England, Canada and the US. The use of herbal aromatic oils in medicine is a prominent tradition. Egyptians, Sumerians and the Greek have put a lot of effort in developing aromatherapy around thousands years ago [3,10]. Aromatherapy is used as a treatment for a variety of diseases and problems [3,11]. Aromatherapy using peppermint oil is considered an herbal treatment. Inhalation of the oil through nasal mucus and lungs leads to the systemic absorption of the odor which enters blood stream a few minutes after inhalation. As these substances are lipophilic they are absorbed by olfactory nerve and transferred to the brain afterwards [12,13]. Aromatherapy is favored by many as an effective, economical complementary treatment for cancer complications, sleeping disorders and vomiting after the surgeries [14,15]. Potential advantages of aromatherapy using peppermint oil are quick responses, ease of use, no side effects and the fact that it is a cost-effective treatment. Therefore, it can be used as an anti-emetic treatment [16]. Peppermint oil has a couple of benefits including anti-spasm effects, relief of pain, anti-inflammation, decongestant and anti-oxidant features [3,17,18]. Aromatherapy is a cost-benefit treatment, non-invasive and generally with few side effects, especially in comparison to standard drugs. What is yet to be known is the fact that whether the clinical effectiveness justifies the use of aromatherapy or not [19]. Some studies have examined the effect of peppermint oil on nausea and vomiting they reported opposite results though. In addition, there is no study in the literature examining the effect of peppermint oil on chemotherapy-induced nausea and vomiting. For instance, there was a study conducted in Saudi Arabia (KSA) concerning the effect of inhaling aromatherapy on nausea and vomiting during pregnancy the results showed that aromatherapy was more effective on vomiting compared to nausea and the participants reported to have been more energetic after aromatherapy [11]. Another study aimed at determining the effect of peppermint oil on vomiting and nausea during pregnancy. The results showed that, the severity of vomiting decreased in both groups after 7 days of interventions. Although vomiting reduced more in the group presented with peppermint oil the difference was not statistically significant [20]. Moreover, in a more recent systematic review study it was found that there is no reliable evidence available proving the effectiveness of peppermint odor on vomiting and nausea after surgery [19]. Nurses, as a key member of a treatment team are responsible for controlling the chemical drugs use and the following care and support. In case it is proved effective they can apply this treatment procedure as a strategy to reduce the side effects of chemotherapy on the patients. It will also help improving the quality of care and support and alleviating the patients' pain therefore, improving the patients' satisfaction with the treatment procedure. Considering the myriad of the problems patients encounter caused by the chemotherapy side effects and the available information regarding this treatment procedure; the researcher decided to conduct the present study in order to determine the effectiveness of aromatherapy using peppermint oil on chemotherapy-induced nausea and vomiting in patients diagnosed with breast cancer.

Materials and Methods

Design and participants

The present study is a randomized clinical trial which aims at determining the effect of aromatherapy using peppermint oil on vomiting and nausea caused by chemotherapy in patients diagnosed with breast cancer. The protocol of this study was registered in Iranian registry for clinical trials (www.irct.ir). Registration number is IRCT2014050215649N2 the population of the study is consisted of the patients diagnosed with breast cancer undergone chemotherapy and qualify for the study based on the inclusion criteria. The study was conducted in the chemotherapy ward of the cancer institute in Imam Khomeini hospital, Tehran. The inclusion criteria for the present study include the confirmation of being diagnosed with breast cancer, chemotherapy using drugs with moderate to severe emetogenic, literacy, having a healthy sense of smell, having no record of physical, emotional and mental diseases, showing no allergy for plants (medical plants), having no record of respiratory diseases like asthma, allergic diseases, chronic obstructive pulmonary diseases, not using anti-emetic drugs except those prescribed by the doctor, no record of being diagnosed with diseases leading to vomiting such as hepatic and renal failure, gastrointestinal disorders, type B hepatitis acute phase, gastrointestinal obstruction and brain tumors. In case, the participants show no interest of continuing with the procedure, show inconsistency in receiving aroma (not using it for two consecutive days) and feeling uncomfortable with the aroma smell they will be omitted from the population.

Sample size

The sample size for the control and experimental groups was determined to compare the prevalence of chemotherapy-induced nausea and vomiting. In order to consider a 25% difference between the two groups as clinically significant provided that confidence coefficient is 95% and the statistical power is 80% there should be 47 participants in each group which means a total of 94 participants for the study. Due to the possibility of the participants' attrition the researchers decided to consider the sample size 100. The sampling was of convenience and the participants were assigned to the two groups of control and experimental according to the randomized block design. The protocol of this study was approved by ethical committee of Tehran University of Medical Sciences (TUMS) after obtaining informed consent, randomized block design used for randomly assigning patients to one of the two groups.

Instruments

A two-part questionnaire was used in the present study. The first part was concerned with the demographic information of the participants. The second part was the Rhodes standard questionnaire for nausea and vomiting.

The Rhodes' nausea and vomiting index questionnaire encompass eight questions in a form of a 5-point Likert scale which needs to be completed in a 24-hour basis. This instrument completed by the patients could measure the severity of vomiting, the frequency of vomiting, the feelings after vomiting, the number of nausea, the

amount of nausea, the feelings after nausea, the number of retching and the feelings after each retching.

This questionnaire measures objective and subjective issues regarding nausea and vomiting. The participants need to choose an option ranging from the least or none indicator (0) to the worst situation (4). Therefore, the sum of the points will range from 0 to 32. This questionnaire has also been translated into Farsi and enjoys high indexes of reliability and validity [21].

The patients were taught how to complete the questionnaire at home. To ensure they follow the aromatherapy procedure, a checklist was given to the patients. The researcher reminded the patients to do the intervention by making phone calls. The participants had access to the researcher as well.

Intervention

The procedure applied in the intervention group was that beside routine prescribed medicine; the patients were asked to instill 2 drops of peppermint oil (produced in Barij Essence company, Kashan, Iran) on a piece of tissue (20 cm × 20 cm) and attach it to their collar [17]. Then, they were asked to breathe normally and naturally for about 20 minutes and it was done three times (in the morning, at noon and at night) each day.

In case the patients feel nausea they were allowed to repeat the procedure. In the control group, instead of inhaling peppermint oil, the patients used placebo (normal Saline) during the same time intervals. The CONSORT flow diagram is showed below (Figure 1).

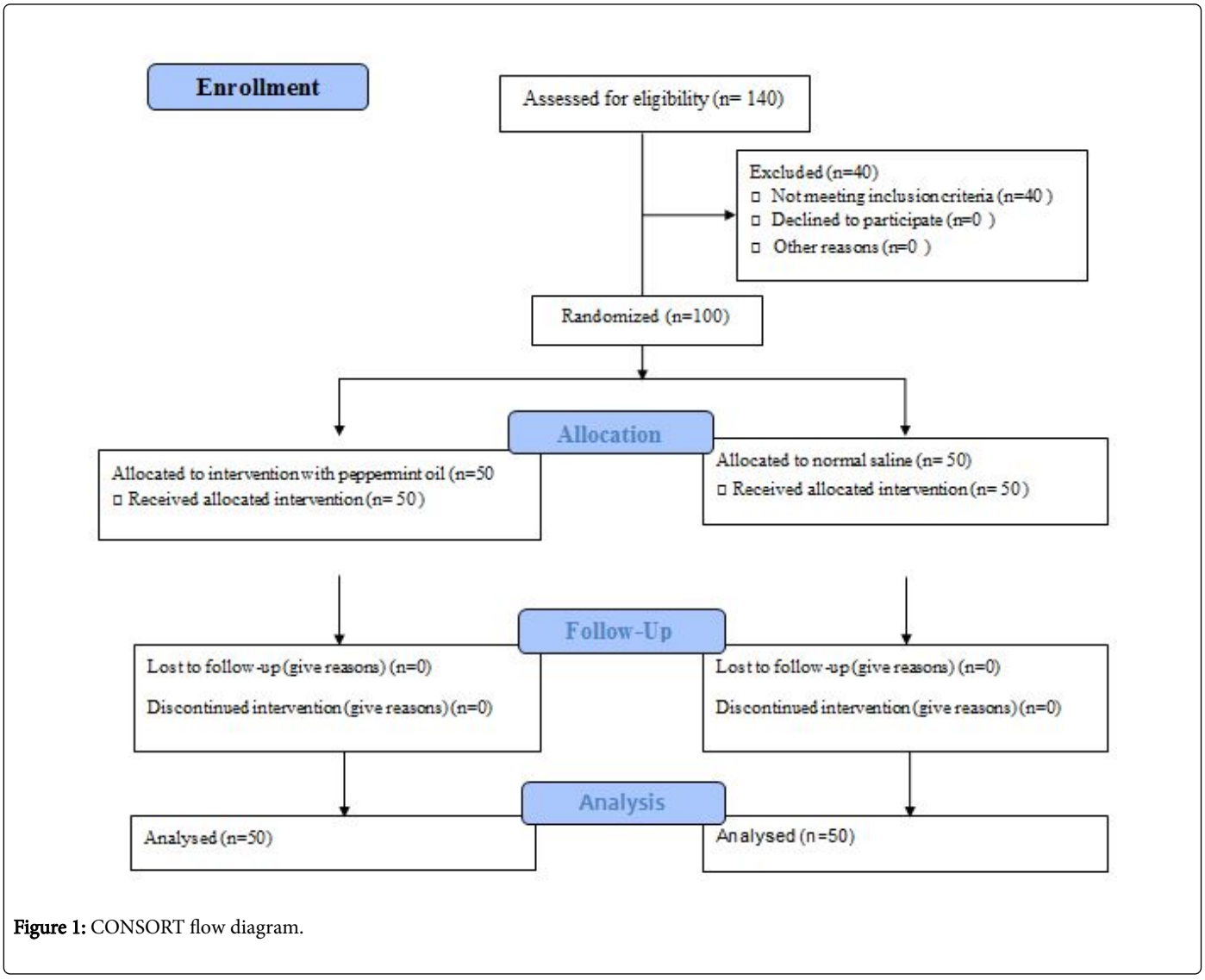

Figure 1: CONSORT flow diagram.

Statistical analysis

Numerical data were represented with mean and standard error and grouping variables with frequency and percentage. Analysis of covariance (ANCOVA) was used for comparing changes in outcome variables in treatment groups.

Ethical consideration

Having received the confirmation from ethics committee of Tehran University of Medical Sciences and after registering the study in Iranian Registry of Clinical Trial; the researcher asked the participants for a written informed consent as they were about to participate in the present study.

Results

Demographic characteristics

Having met the inclusion criteria 100 women diagnosed with breast cancer undergone chemotherapy participated in the present study. The individual information and clinical characteristics such as age, marital status, educational level, the duration of cancer, cigarette and alcohol use and motion sickness for both groups are presented in Table 1. The statistical tests revealed that the two groups are homogenous regarding these factors (p>0.05) (Table 1).

Parameters		Experimental group	Control group	Statistical test	p- value
		N=50	N=50		
Age (Y)		47.86 ± 9.52	45.74 ± 9.92	Independent T-test	0.27
Diagnosed with breast cancer(M)		8.14 ± 5.16	17.72 ± 7.96	Independent T-test	0.31
Marital status	Single	1 (2%)	2 (4%)	Chi-square	0.83
	Married	49 (98%)	48 (96%)		
Alcohol use	Never	49 (98%)	49 (98%)	Chi-square	>0.9
	In the past	1 (2%)	1 (2%)		
	Currently	0	0		
Cigarette smoking	Never	46 (92%)	47 (94%)	Chi-square	0.33
	In the past	2 (4%)	3 (6%)		
	Currently	2 (4%)	0		
Motion sickness	Never	35 (70%)	34 (68%)	Chi-square	0.21
	In the past	9 (18%)	14 (28%)		
	Currently	6 (12%)	2 (4%)		
Educational level	Illiterate	5 (10%)	4 (8%)	Chi-square	0.55
	Elementary	8 (16%)	10 (20%)		
	High school	33 (66%)	28 (56%)		
	Academic	4 (8%)	8 (16%)		

Table 1: Demographic characteristics in patient diagnosed with breast cancer.

Acute phase

The results indicated that the patients in the intervention group showed fewer nausea experiences and the difference was proved to be statistically significant (p<0.05). It was also found that the frequency and the duration of vomiting in the acute phase were statistically fewer and the uncomfortable feeling followed by nausea was statistically less in the group exposed to aromatherapy with peppermint (p<0.05).

It was also observed that, in the acute phase, the average frequency of vomiting was fewer and the uncomfortable feeling followed by vomiting was less in the experimental group. However, the difference was only statistically significant regarding the uncomfortable feeling followed by vomiting.

In case of retching in the acute phase the results indicated that the frequency of retching was fewer in the experimental group compared to that of the control group yet the difference was not statistically significant (p>0.05).

It was also found that the patients in the experimental group experiencing aromatherapy showed less uncomfortable feelings and the difference were found to be statistically significant. Indeed the data showed that 76% of the participants were satisfied with aromatherapy and about 54% argued that they have suggested aromatherapy to the others, too (Table 2).

Variable		Experimental group		Control group		P-value
		Mean	SE	Mean	SE	
Nausea	Duration	1.3	0.18	2.16	0.22	0.003
	Distress	1.14	0.19	1.72	0.18	0.016
	Frequency	0.88	0.16	1.58	0.21	0.013
	Total	1.1	0.14	1.82	0.19	0.004
Vomiting	Frequency	0.2	0.07	0.46	0.16	0.15
	Distress	0.64	0.16	1.26	0.2	0.02
	Amount	0.18	0.07	0.26	0.1	0.53
	Total	0.34	0.09	0.66	0.13	0.05

	Distress	0.76	0.14	1.36	0.2	0.02
	Frequency	0.74	0.16	1.1	0.19	0.16
Retching	Total	0.75	0.14	1.33	0.19	0.04

Table 2: Comparing mean and standard error for nausea, vomiting and retching after chemotherapy in patient diagnosed with breast cancer in the acute phase.

Delayed phase

The results of the independent t-test showed that there was no statistically significant difference observed between the two groups regarding nausea in the delayed phase. Besides, it was found that there was no statistically significant difference between the two groups as concerns vomiting and retching in the delayed phase ($p>0.05$) (Table 3).

Variable		**Experimental group**		**Control group**		**P-value**
		Mean	SE	Mean	SE	
	Day 2	3.06	0.27	4.07	0.27	0.01
	Day 3	3.56	0.45	4.48	0.42	0.53
	Day 4	3.58	0.41	3.74	0.46	0.22
	Day 5	2.35	0.34	3.44	0.49	0.01
Nausea	Total	10.89	1.24	13.05	1.21	0.82
	Day 2	0.9	0.23	1.8	0.35	0.02
	Day 3	0.8	0.21	1.63	0.31	0.01
	Day 4	0.97	0.27	1.47	0.3	0.01
	Day 5	0.56	0.18	0.76	0.26	0.92
Vomiting	Total	3.32	0.69	4.6	0.51	0.48
	Day 2	1.13	0.22	1.91	0.28	0.03
	Day 3	1.58	0.29	2.36	0.24	0.07
	Day 4	1.57	0.21	1.66	0.29	0.42
	Day 5	0.89	0.18	1.45	0.25	0.02
Retching	Total	4.73	0.79	6.06	0.69	0.38

Table 3: Comparing mean and standard error for nausea, vomiting and retching after chemotherapy in patient diagnosed with breast cancer in the delayed phase.

Discussion and Conclusion

As far as we know, the present study is the very first randomized clinical trial concerning the effect of aromatherapy with peppermint oil on nausea and vomiting followed by chemotherapy on the patients diagnosed with breast cancer in Iran. The results showed that while aromatherapy using peppermint oil can lead to significant decline in nausea in the acute phase among the patients; it didn't have any significant impacts in the delayed phase. In this regard, Ghani et al. conducted a pilot study to examine the effect of inhaling aromatherapy on nausea and vomiting during pregnancy among Saudi Arabia women experiencing their first pregnancy. They reported similar results as that aromatherapy using peppermint and lavender oil along with teaching the patients the appropriate eating diets have led to a decrease in the frequency and the severity of nausea during pregnancy [11].

Seale et al. carried out a research examining the effect of using peppermint oil on the reduction of nausea among 15 patients undergone alleviative and clinical care. They concluded that aromatherapy with peppermint led to a decline in nausea [8]. In contrast, Ferruggiari et al. aimed at observing the effect of aromatherapy on nausea after surgery among women in USA. They reported that using aromatherapy with peppermint oil cannot reduce the frequency and severity of nausea and vomiting after surgery hence, they proposed that there is a need for further studies [16]. The justification behind this contradiction can be the difference between the diseases and also the difference in the aromatherapy procedure.

The results of the present study indicate that the frequency and the extent of vomiting in the acute phase have been fewer in the experimental group as compared with the control group. Nevertheless, this difference was not statistically significant. It was in line with the findings of Lusia Ferruggiari and Pasha's study as they concluded that aromatherapy with peppermint oil is effective in reduction although statistically insignificant for vomiting among the patients [16,20]. Other studies though showed that aromatherapy can lead to a statistically significant decline in vomiting [12].

The reason for such inconsistencies can be the low amount of vomiting in the present study. According to the findings of the present study aromatherapy using peppermint oil led to a significant decrease in retching among the patients and this was in line with the results of the study conducted by Ghani et al. With respect to the delayed phase it was found that aromatherapy with peppermint oil was effective in reduction of nausea, vomiting and retching yet statistically insignificant. It is consistent with the results of a similar study by Pei Lin Lua who investigated the effect of aromatherapy on the treatment of nausea and vomiting followed by chemotherapy [11,22].

Based on the findings of the present study it is believed that using aromatherapy with peppermint oil (in a prescribed amount) has no side effects and can have its alleviating effects along with medical treatments used as anti-emetics following chemotherapy. Hence, providing the nurses with cheap and available equipment concerning aromatherapy will allow them to use it beside the routine medical interventions.

This will lead to the improvement of the situation and decline of the side effects of chemotherapy among the patients. Since the present study was conducted only on women diagnosed with breast cancer who underwent a one-day chemotherapy treatment, it is recommended to conduct further studies considering the patients diagnosed with other types of cancer and also other treatment intervals. The nausea and vomiting followed by chemotherapy appears after the treatment yet as we had no basic information about this problem among the patients the study was conducted after the intervention-based on the data comparison approach. This can be considered as one of the limitations of the present study.

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Conflict of Interest

No conflict of interest has been declared by the authors.

Mohammad Eghbali: Study design, Data collection and analysis, Manuscript writing.

Shokoh Varaei: Study design, Data collection and analysis, Manuscript writing.

Mir Saeed Yekaninejad: Data analysis, Technical and material support.

Faezeh mohammadzadeh: Data collection, Manuscript writing

Farhad shahi: Study design, Technical and material support.

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