



## INVESTIGATING THE EFFECT OF CHAMOMILE EXTRACT ON INTENSITY OF NAUSEA AND VOMITING RESULTED FROM CHEMOTHERAPY

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### ABSTRACT

**Introduction:** Uncontrollable nausea and vomiting can cause delay in chemotherapy period and a general decrease in patient's quality of life. Since matricaria chamomilla is believed to be effective in reducing nausea and vomiting, the present study was aimed at determining the effect of its extract on the severity of nausea and vomiting caused by chemotherapy in Zahedan's Social Security Hospital. **Materials and methods:** The present single-blind clinical trial was carried out on the patients receiving chemotherapy in Chemotherapy Wards of Zahedan's Hospitals in 2015. In doing so, 60 patients were selected through convenience sampling and assigned into an intervention group and a control one. Two hours before chemotherapy, the intervention group was given matricaria chamomilla extract while the control patients were given distilled water as placebo. Nausea rate was measured using Visual Analogue Scale (VAS) 0, 2, 6, and 12 hours after chemotherapy. **Results:** In the beginning of the study, there was no significant difference between the two groups in terms of their mean scores of nausea ( $P=0.4$ ); however, 2 hour after chemotherapy had been carried out, nausea score increased in both groups, such that it was significantly higher in the control group than the intervention group ( $P=0.034$ ). After 6 and 12 hours, the mean scores of nausea in both groups declined; however, the control patients' mean score was constantly and significantly higher than that of the intervention group. There was no significant difference between the two groups in regard to vomiting ( $P>0.05$ ). **Conclusion:** The results of the study indicated that consuming matricaria chamomilla extract can reduce nausea caused by chemotherapy while it has no effect on vomiting.

**Keywords:** Chemotherapy, Matricaria Chamomilla Extract, Nausea and Vomiting

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### Introduction

Cancer is a developing and common disease. Now, cancer diseases are not limited to some developed societies and have become as a considerable health problem all over the world.

Almost 1596670 people are annually diagnosed with cancer in US and 571950 of them lead to their deaths [1]. Cancer will be an important increasing factor of death in the upcoming decades in the universe and it is expected that it will reach to 15 million new cases in 2020 [2, 3].

Nowadays, there have been considerable progresses for curing cancer. The main aim of neoplasm treatment is the complete annihilation of cancer cells and if possible at least the control or palliative treatment of cancer for decreasing symptoms, improving survival level and life quality. One of the treatment methods to achieve this goal is chemotherapy [4]. A successful period of chemotherapy can be along with different side effects [5].

Nausea and vomiting are considered as the most common and annoying side effects resulted from chemotherapy in the patients with cancer [6] such that 48-70% of the patients will suffer pain despite receiving industrial anti-nausea and anti-vomiting drugs such as serotonin receptor antagonists [4].

Non-controllable nausea and vomiting can cause delay in chemotherapy periods and generally decreasing life quality of the patients [7]. There is a broad spectrum of anti-nausea and anti-vomiting to prevent and cure nausea and vomiting resulted from chemotherapy [1].

Using non-pharmacological methods together with pharmacological methods is suggested in order to decrease nausea and vomiting from chemotherapy. The suggested non-pharmacological methods include listening to music, relaxation techniques, hypnotism, Yoga, acupressure and acupuncture which are widely used for reduce nausea and vomiting preventive and curative methods.

Since, the wide use of industrial anti-vomiting drugs have adverse effects like extra pyramidal complications, drop in blood pressure and head ache etc. therefore, the tendency to use medicinal plant is increased [8]. Among the herbal medicines, chamomile has anti-vomiting and anti-nausea properties [9].

Chamomile is from medicinal plants of Asteraceae which has several types and grows in different locations. Chamomile extract contains some chemical compositions including Chamazulene and flavonoids. In pharmaceutical science, different types of this plant and existing compositions of its essence are recognized and are used in treatment. Among the cases in which this plant is used, the treatments for fever, migraines, headaches, rheumatoid arthritis, stomach pain, toothache, insect bites, infertility can be mentioned [8].

With regard to the medical feature of chamomile and its possible influence on controlling and curing nausea and vomiting from chemotherapy and in the other hand lack of sufficient studies in this area, this study was performed with the aim of investigating the effects of chamomile plant's extract in controlling nausea and vomiting related to chemotherapy.

## **Materials and Methods**

### **Research method**

This is a semi-experimental study and is implemented by clinical trial method. In this study, totally 60 cancer patients under chemotherapy were investigated in chemotherapy sectors of Zahedan hospitals in two groups of case (30 persons receiving chamomile extract) and control (30 persons receiving placebo). The aim of this research is to investigate the effect of chamomile plant's extract on nausea and vomiting related to chemotherapy in the patients with cancer at Tamin Ejtamae hospital in Zahedan.

Sampling was performed easily and by cancer patients under chemotherapy. The mentioned people were located by alternation in control and intervention groups. Sample volume in each group was equal to 30 people and was calculated using the following formula.

N: number of intended sample 30

Z: standard normal distribution 1.96

A: accepted error 0.05

L: preferred trust 0.010

P: the possibility for first event 0.5

P2: the possibility for second event 0.25

p-p2: maximum acceptable error 20.2

### **The criteria to enter the study**

1. Having a kind of cancer
  2. Having age above 15 and informed consent
  3. Using chemotherapy as the only method for cancer treatment
  4. Having at least one previous chemotherapy period and experiencing nausea and vomiting complications
  5. Being conscious and without psychotic and vestibular symptoms before the beginning of chemotherapy
  6. Not to use any drug 3 days before and 12 hours after chemotherapy
  7. Having normal test values for blood Haematological and biochemical results
  8. Having no symptoms of pregnancy
- 3-10- The criteria for exiting from the study
- 1- Patient request for exiting from the study before questionnaire fulfillment
  - 2- Lack of full access to the patient up to 12 hours before chemotherapy beginning

### **Data collection tools and implementation method**

Eligible patients of chemotherapy sector of Zahedan hospital in 2015 were entered to this study after the explanation of design steps and obtaining written conscious consent. Demographic information and the clinical and therapeutic conditions of the patients were obtained through clinical document and interview. With regard to the importance of observing food diet during the research, all patients were instructed orally by researcher in order to control nausea and vomiting. Then, the patients were divided into two groups of receiving German chamomile extract and receiving placebo which is distilled water. The used dosage of chamomile was 25 mg per kg and saline were used to make the solution.

Chemotherapy of all participants was beginning in a certain time and the environmental conditions including light, voice, smell and temperature were similar for all participants during chemotherapy.

Investigation of nausea and vomiting was performed before chemotherapy, two hours, 6 hours and 12 hours after chemotherapy. Visual Analog Scale (VAS) was used in order to evaluate nausea and vomiting. All patients were trained to score their nausea level based on VAS criterion. This tool was constituted of a 10 cm line (domain between 0 and 10) which 0 is the mean for lack of nausea and 10 is severe nausea. In determining the intensity of nausea, the classification was in a way that 0 represented lacking nausea, 1-3 for mild nausea, 4-6 for moderate nausea, 7-9 for severe nausea and 10 for very severe nausea. Vomiting was defined as severe mobility of digestive system which causes the exhaust of digestive system contents from mouth.

**Data analysis**

Statistical analysis was performed using the software SPSS version 20. In order to analyze data, the required statistical tests including T test (for comparing age and nausea score based on VAS criterion between the two groups), Mann Whitney test (to compare nausea intensity between the two groups) and Square test (to compare the frequency of vomiting between the two groups) were used.

**Results**

Accordinging the results (table 1 and 2), the average age in intervention group is equal to 50.26±11.83 years and in control group is equal to 49.60±10.01 years. Sexual distribution in intervention group was as 17 (56.7%) men and 13 (43.3%) women and in control group as 14 (46.7%) men and 16 (53.3%) women. In terms of marital statuses of the patients, 27 (90%) in intervention group and 24 (28%) in control group were married.

Table 1 shows frequency distribution (number-percent) of participating patients in the study in terms of the group type and cancer type. Breast cancer with the frequency of 7 people (23.3%) and thereafter colorectal cancer with the frequency of 6 people (20%) were the most common types of cancer among the patients in intervention group. Also colorectal cancer with the frequency of 7 people (23.3%) and then breast cancer with the frequency of 6 people (20%) had the highest frequency among the people in control group.

Accordinging the obtained results, no significant difference was demonstrated in the mentioned factors between intervention and control group at the significance level of 0.05.

**Table 1.** Frequency distribution (number-percent) of participating patients in the study in terms of the study group and cancer group

Group Cancer type	Case (%)	Control (%)	Total (%)	P-value*
Breast cancer	7 (23.3%)	6 (20%)	13 (21.7%)	0.96
Colorectal cancer	6 (20%)	7 (23.3%)	13 (21.7%)	
Lung cancer	3 (10%)	5 (16.7%)	8 (13.3%)	
Leukemia cancer	5 (16.7%)	5 (16.7%)	10 (16.7%)	
Testicular Cancer	3 (10%)	2 (6.7%)	5 (8.3%)	
Others	6 (20%)	5 (16.7%)	11 (18.3%)	
Total	30 (100%)	30 (100%)	60 (100%)	

\* Chi-square test

**Table 2.** The mean and standard deviation of nausea score

Time Group	Before chemotherapy (mean ± standard deviation)	2 hours later (Mean± SD)	6 hours later (Mean± SD)	12 hours later (Mean± SD)
Case	1.31± 0.7	2.21± 2.8	1.56 ±1.43	1.13± 0.56
Control	1.33± 0.53	2.54± 4.13	1.7± 2.33	1.83± 1.43
P-value	0.4*	0.034*	0.038**	0.03*

\* Independent samples t-test

Table 2 shows mean nausea score of control group in different times before and after chemotherapy. Mean nausea score before chemotherapy, two hours after chemotherapy, 6 hours after chemotherapy and 12 hours after chemotherapy are 1.33± 0.53, 2.52± 4.13, 1.7 ±2.33 and 1.83± 1.43 respectively. The above mentioned results show that highest mean nausea score is related to control group which is higher than intervention group significantly.

**Table 3.** frequency (number-percent) of vomiting from chemotherapy between the study groups in terms of evaluation time

Time Group		Before chemotherapy Frequency (percent)	2 hours later Frequency (percent)	6 hours later Frequency (percent)	12 hours later Frequency (percent)
Intervention	Yes	29 (96.7%)	25 (83.3%)	28 (93.3%)	29 (96.7%)
	No	1 (3.3%)	5 (16.7%)	2 (6.7%)	1 (3.3%)
	Total	30 (93.3%)	21 (70%)	25 (83.3%)	27 (90%)
Control	Yes	28 (93.3%)	21 (70%)	25 (83.3%)	27 (90%)
	No	2 (6.7%)	9 (30%)	5 (16.7%)	3 (10%)
	Total	30 (100%)	30 (100%)	30 (100%)	30 (100%)
P-value*		0.55	0.22	0.22	0.30

\* Chi-square test

Table 3 shows frequency (number-percent) of vomiting from chemotherapy among the study groups in terms of evaluation time. In both groups, the frequency of the patients with vomiting was increased by chemotherapy, but over time, the level of this frequency was decreased in both groups. At all evaluation times before and after chemotherapy, no significant difference was observed in terms of vomiting frequency between the two groups.

### Discussion and conclusion

A successful period of chemotherapy can be along with different types of side effects [1, 7]. Nausea and vomiting causes the complications such as dehydration, liquids and electrolytes imbalance, malnutrition, thinning of the mucosa of digestive system and intolerance to treatment and even causes their refusal of continuing treatment [8].

With regard to the first aim of this research i.e. comparing nausea level before chemotherapy and at 2, 6 and 12 hours after chemotherapy in the patients of intervention and control groups, the results in the tables 4-6 show that the two groups have no significant difference in terms of mean nausea score ( $P=0.4$ ), but two hours after chemotherapy, nausea score was increased in both groups. The increase in control group was significantly more than case group ( $P=0.034$ ). After two hours of chemotherapy, mean nausea score was decreased in both group over time, but mean nausea score in control group was higher at all these times. The results for table 4-7 showed that in both groups, the frequency of the patients who had vomiting was increased by performing chemotherapy, but the level of this frequency was decreased over time for both groups. At all evaluating times, before and after chemotherapy, no significant difference was observed in terms of vomiting frequency between the two groups.

Since there is no research similar to this one, the accurate comparison and anticipation of the results is difficult. [9] by comparing the effect of ginger and chamomile in the decrease of nausea and vomiting of pregnancy period reported that chamomile edible capsules are effective on decreasing nausea and vomiting symptoms from pregnancy compared to ginger or placebo. These findings are in line with this study and emphasize on the effect of chamomile in decreasing nausea feeling. In order to confirm these results, [1] in the investigation of the effectiveness of the treatment with prophylactic chamomile for migraine reported that nausea and vomiting was decreased in the patients who used this medic plant.

Also [7] studied the effect of chamomile oily Extract in migraine treatment. The patient who received placebo had significantly higher frequency and intensity of headache, nausea and vomiting. These findings suggest that this treatment causes the decrease of nausea and vomiting in addition to decreasing frequency and migraine attack intensity whether along with other symptoms or separately.

[10] by performing a review study investigated different interventions about nausea and vomiting in the early stages of pregnancy. In this study, 37 clinical trials were studied which totally were implemented on 5049 women in their early stages of pregnancy. These studies have announced the consumption of the cases such as ginger and B6 vitamin effective in nausea decrease. Also the consumption of chamomile was stated as one of these interventions, but with regard to the shortage of accurate controls they couldn't suggest any of these interventions; their studies are in line with this study.

With regard to the findings of mentioned studies including our study, it seems that chamomile is effective in decreasing nausea state. Among the previous studies, there are some cases that with regard to their findings the mechanism of the effect of this plant in decreasing nausea feeling will be specified. Among these studies, the study of [6] can be mentioned. As there is stated, the existing Parthenolide composition in chamomile plant non-competitively restrains contractile response related to stomach fundus serotonin to indirect agonists HT-5 and is considered as a non-competitive agonist for serotonergic drugs in creating fundus tissue contractions. The mechanism of the effect related to parthenolide includes direct control of HT2-5 receptors and is based on the effect on HT-5 surface saved in nerve vesicles of stomach fundus wall which is consistent with this study.

Also [11] studied the mechanism of anti-pain effect of aqueous extract of chamomile. The obtained results suggested the inclusion of serotonergic system in analgesia from consuming aqueous extract of this plant. Also different studies have

stated the anti-depression effect of this plant via affecting central noradrenaline, dopamine, serotonin and GABA [5]; the findings of their study is consistent with this study.

With regard to the mentioned subjects, it seems that chamomile plant extract has almost similar effect to serotonin antagonists and in this way, causes the decrease of nausea feeling after chemotherapy. Of course, it is possible that central effect of this plant will be involved in the decrease of nausea feeling.

With regard to the high importance of controlling nausea and vomiting from chemotherapy in patients and also along with all mentioned subjects, there is no doubt that this study which can be considered as a first study in this area is not sufficient and needs more studies.

About the hypothesis i.e. between the level of nausea and vomiting of patients in intervention and control group before chemotherapy, 2, 6, 12 hours after chemotherapy in Tamin Ejtemaee hospital of Zahedan, the results of T test showed that there is a significant difference between mean and standard deviation of vomiting for the two groups; therefore by rejecting the hypothesis of H<sub>0</sub>, the research hypothesis will be accepted. Also the results of T test showed that there is no significant difference between mean and standard deviation of vomiting in the patients of intervention and control groups before chemotherapy, 2, 6, 12 hours after chemotherapy in Tamin Ejtemaee hospital of Zahedan; therefore H<sub>0</sub> hypothesis is accepted. Generally, the results show that chamomile plant's extract causes the decrease in nausea feeling from chemotherapy, but has no considerable effect on decreasing the vomiting from chemotherapy.

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