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RESEARCH ARTICLE

EFFECT OF GINGER ON CHEMOTHERAPY INDUCED NAUSEA AND VOMITING (CINV) AMONG BREAST CANCER PATIENTS- RANDOMIZED CONTROL TRIAL

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ABSTRACT

Background: Nausea and vomiting are among the most prevalent and disturbing side effects of chemotherapy. Therefore, there is a need for additional antiemetic agents that could effectively reduce chemotherapy-induced nausea and vomiting (CINV), whether alone or in combination with current standard therapies. Since clinical data on the effectiveness of ginger in patients with breast cancer is lacking, the present study aimed to evaluate the effects of ginger against both acute and delayed forms of CINV in a population with breast cancer as the main malignancy. **Methods:** In this double blind randomized clinical trial, 60 women with breast cancer who were initially assigned to standard Anthracycline based chemotherapy protocol with the C.A.F regimen were randomly assigned to receive ginger extract (1.0 gm/day in 2 divided doses every 12 hours) plus standard antiemetic regimen or placebo containing glucose with standard antiemetic regimen to control group. The duration of treatment with ginger was specified to 4 days from the initiation of chemotherapy. Chemotherapy induced nausea & vomiting were assessed using MASCC Antiemesis Tool. **Result**: Significantly low number of subjects had chemotherapy induced nausea and vomiting in the experimental group during acute and delayed period after chemotherapy. In cycle 2 and 3 of chemotherapy significantly less number of subjects suffered from nausea and vomiting in experimental group as compare to control group in acute and delayed period. **Conclusion:**-Addition of ginger (1 gm/day) to standard antiemetic therapy in patients with breast cancer effectively reduces the chemotherapy induced nausea and vomiting. However, there is no side effects observed with use of ginger. **Recommendations**: Ginger should be given to breast cancer patients receiving Anthracycline based chemotherapy to decrease CINV.

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INTRODUCTION

The topic of nausea and vomiting is all too familiar to most nurses. Nausea and vomiting are unpleasant complications or indications of many medical conditions and are adverse effects of hundreds of medications. Nausea and vomiting occur so frequently that they are almost considered "acceptable," usually referred to as "minor" and considered more of an inconvenience or a nuisance than a medical problem. This duo, however, is not only unpleasant but can be debilitating and can cause unnecessarily prolonged recovery times and increased costs. Although nausea and emesis (vomiting and/or retching) can result from surgery, opiates, or radiotherapy, chemotherapy-induced nausea and vomiting (CINV) is potentially the most severe and most distressing. Although significant progress has been made, CINV remains an important adverse effect of treatment. Nausea and vomiting are two of the most feared cancer treatment-related side effects for cancer patients and their families. In 1983, Coates *et al*. found that patients receiving chemotherapy ranked nausea and vomiting as the first and second most severe side effects, respectively.

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Up to 20% of patients receiving highly emetogenic agents in this era postponed, or even refused, potentially curable treatments. Despite the availability of more than 20 different antiemetics, nausea and vomiting in cancer patients remain problematic and continue to pose tremendous challenges to practicing oncologists (Paula Gill, 2006). Many chemotherapeutic agents are associated with significant nausea and vomiting, which represent a challenge to effective therapy. These adverse effects can negatively impact patient quality of life, performance status, and daily functioning. Poor compliance with scheduled chemotherapy due to nausea and vomiting can result in treatment interruptions or discontinuation, leading to poor outcomes (O'Brien, 1993; Osoba, 1997 and Richardson, 1988). The incidence of acute and delayed Nausea &Vomiting was investigated in highly and moderately emetogenic chemotherapy treatment regimens. More than 35% of patients experienced acute nausea, and 13% experienced acute emesis. In patients receiving highly emetogenic chemotherapy, 60% experienced delayed nausea, and 50% experienced delayed emesis. In patients receiving moderately emetogenic chemotherapy, 52% experienced delayed nausea, and 28% experienced delayed emesis (Grunberg, 2004). Controlling chemotherapy-induced nausea

and vomiting (CINV) is substantial in improving a cancer patient's life. Studies show that between 70% and 80% of patients who receive cancer chemotherapy experience nausea and/or vomiting (National Comprehensive Cancer Network [NCCN], 1997) (www.cancer.org). What's worse is that this also interferes with the overall quality of life of patients. CINV that occurs during the 3-day period after chemotherapy, when the patient is at home, has a negative effect on a patient's ability to care for him/herself (Grunberg, 2004).

MATERIAL AND METHODS

Double blind, Randomized control trial, Experimental study design with pre test post test design was chosen for the study where research implies with manipulation of independent variable to see its effect on dependant variable. The data was collected for 3 consecutive cycle of chemotherapy after every 21 days interval and intervention was given at 2nd and 3rd cycle of chemotherapy in the day care of radiation department of Guru Gobind Singh medical college and hospital faridkot. Patients, who were able to understand Punjabi/ English, willing to participate and relatives nominated by breast cancer patients receiving anthracycline based chemotherapy to provides significant care at home were included in the study. Family caregivers were not eligible for the participation if the family caregiver was unable to cooperate due to physical, psychological or emotional reasons. Sixty breast cancer patients receiving anthracycline based chemotherapy were conveniently recruited for study. The tools used for the study were Demographic profile of the patient and MASCC Antiemesis Tool (MAT) which are as follows:

Tool no. 1- Demographic profile of the patient: This tool was used for recording socio demographic details and selected variables of the subjects, developed by the researcher under the guidance of guide and co-guide. It has total fourteen items which were Number of Chemotherapy cycle, Age, Gender, Marital status, Educational status, Occupation, Life style pattern, Caregiver at home, Educational status of care giver, Cooccurance of cancer diagnosis along with breast cancer, Any other illness present, History of recent surgery, Intake of ginger in routine. Appropriate content validity of the tool was established by experts. The reliability was established through test retest method (r =1).

Tool no. 2- MASCC Antiemesis Tool (MAT: The Multinational Association of Supportive Care in Cancer (MASCC) has developed such a tool, which is an eight-item scale for the assessment of acute and delayed nausea and vomiting, and is completed once per cycle of chemotherapy. Questions from one to four assess the nausea and vomiting in acute period and from five to eight number assess the nausea and vomiting in delayed period. The internal consistency reliability of the MAT was high, both when completed by patients, with a Cronbach's alpha coefficient of 0.77 (n=87), and when completed by carers, with a Cronbach's alpha coefficient of 0.82 (n=22). This is further supported by high MAT item-to-total correlations, ranging from r=0.60 to r= 0.91 (all P<0.001) The tools were translated into local Punjabi language. Try out of the tool and pilot study was conducted and the study was found to be feasible.

Ethical considerations: Prior to administration to tools, an informed written consent form was signed by the each subject before data collection. All the subjects were ensured that confidentiality and anonymity will be maintained throughout the study. Permission was obtained from Institutional Ethical Committee to carry out the study. Written permission was also obtained from Medical Superintendent of selected hospital.

STATISTICAL METHODS

The data was analyzed by SPSS- 16. In descriptive statics mean, percentages and standard deviation were used for analyzing the distribution of subjects according to their socio-demographic characteristics. In inferential statistics, chi-square was computed by SPSS 16.0 statistical package. Results of the study were presented in the form of tables and figures. The p value at <0.05 was considered is as statistically significant.

RESULTS

Study results found that more than half 34(56.6%) subjects were from age group 41-60 years followed by 10(16.6%) subjects in 20-40 years. Majority of the subjects 51(85%) were illiterate with 4(6.6%) having primary level of education, nearly one third of the subjects were ambulatory and capable of self care. No co occurrence of other cancer was found in 47(78.8%) of subjects. One third of the subjects were not using ginger in routine diet with 8(13.3%) using ginger in tea and 7(11.7%) in form of pickle. Experimental and control group were found to be comparable with regard to these socio-demographic variables. Hence no significant difference was found in two groups. Table 1 shows comparison of acute nausea in experimental and control group at Cycle 1(baseline), at Cycle 2(after intervention 1), at Cycle 3(after intervention 2).

C1 cycle of chemotherapy: At C1 cycle, chemotherapy induced acute nausea was present in 13(21.7%) subjects in experimental and 12(20%) subjects in control group. Chemotherapy induced acute nausea was not present in 17(28.3%) subjects in experimental and 18(30%) subjects in control group. As per chi square test, the relationship between experimental and control group was found non significant at baseline. (χ^2=.069 and p=0.793) at level p<0.05. Thus it can be concluded that both experimental and control group were similar with regards to chemotherapy induced acute nausea at baseline.

C2 cycle of chemotherapy: At C2 cycle (post intervention 1) of chemotherapy 6(10%) subjects in experimental and 14(23.3%) in control group were having acute nausea, whereas 24(40%) subjects in experimental and 16(26.7%) in control group were not having acute nausea. As per chi square test, the relationship between experimental and control group was found significant at C2 cycle (post intervention 1). (χ^2=4.80 and p=0.028) at level p<0.05. Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced acute nausea at C2 cycle of chemotherapy.

C3 cycle of chemotherapy: At C3 cycle of chemotherapy 5(8.3%) subjects in experimental and 16(26.7%) subjects in control group were having acute nausea, 25(41.7%) subjects in experimental and 14(23.4%) in control group were not having nausea in acute period. As per chi square test, the relationship between experimental and control group was found significant at C3 cycle (post intervention 2). (χ^2=8.86 and p=0.003) at level p<0.05.

Table 1. Comparison of acute nausea at baseline, after intervention 1 and after intervention 2 in experimental and control group

N=60

Variable		Experimental f(%)	Control f(%)	χ^2	P Value	Df
Acute nausea at Cycle=1(Baseline)	Yes	13(21.7)	12(20)			
	No	17(28.3)	18(30)	.069	0.793^{NS}	1
Acute nausea at Cycle=2 (After intervention 1)	Yes	6(10)	14(23.3)			
	No	24(40)	16(26.7)	4.80	0.028^{*}	1
Acute nausea at Cycle=3 (After intervention 2)	Yes	5(8.3)	16(26.7)			
	No	25(41.7)	14(23.4)	8.86	0.003^{*}	1

NS=non significant at p<0.05*=significant at p<0.05

Table 2. Comparison of delayed nausea at baseline, after intervention 1 and after intervention 2 in experimental and control group

N=60

Variable		Experimental f(%)	Control f(%)	χ^2	P Value	Df
Delayed nausea at Cycle=1(Baseline)	Yes	15(25)	14(23.3)	.067	0.796^{NS}	1
	No	15(25)	16(26.7)			
Delayed nausea at Cycle=2 (After intervention 1)	Yes	6(10)	17(28.3)			
	No	24(40)	13(21.7)	8.53	0.003^{*}	1
Delayed nausea at Cycle=3 (After intervention 2)	Yes	6(10)	18(30)			
	No	24(40)	12(20)	10.0	0.002^{*}	1

NS=non significant at p<0.05*=significant at p<0.05

Table 3. Comparison of acute vomiting at baseline, after intervention 1 and after intervention 2 in experimental and control group

Variable		Experimental f(%)	Control f(%)	χ^2	P Value	Df
Acute vomiting at Cycle=1(Baseline)	Yes	6(10)	6(10)			
	No	24(40)	24(40)	0	1^{NS}	1
Acute vomiting at Cycle=2	Yes	2(3.3)	8(13.3)			
(After intervention 1)	No	28(46.7)	22(36.7)	4.320	$.038^{*}$	1
Acute vomiting at Cycle=3	Yes	2(3.3)	9(15)			
(After intervention 2)	No	28(46.7)	21(35)	5.455	$.02^{*}$	1

NS=non significant at p<0.05*=significant at p<0.05

Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced acute nausea at C3 cycle of chemotherapy and ginger is effective in reducing nausea in acute and delayed period in experimental group. Table 2 shows comparison of delayed nausea in experimental and control group at Cycle 1(baseline), at Cycle 2(after intervention 1), at Cycle 3(after intervention 2).

C1 cycle of chemotherapy: At C1 cycle of chemotherapy, delayed nausea was present in 15(25%) subjects in experimental and 14(23.3%) subjects in control group. Chemotherapy induced delayed nausea was not present in 15(25%) subjects in experimental and 16(26.7%) subjects in control group. As per chi square test, the relationship between experimental and control group was found non significant at baseline.(χ^2=.067 and p=0.796) at level p<0.05.Thus it can be concluded that both experimental and control group were similar with regards to chemotherapy induced delayed nausea at baseline.

C2 cycle of chemotherapy: At C2 cycle (post intervention 1) of chemotherapy, 6(10%) subjects in experimental and 17(28.3%) in control group were having delayed nausea, 24(40%) subjects in experimental and 13(21.7%) in control group were not having delayed nausea. As per chi square test the relationship between experimental and control group was found significant at C2 cycle (post intervention 1). (χ^2=8.531 and p=0.003) at level p<0.05.Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced delayed nausea at C2 cycle of chemotherapy. It means ginger is effective in reducing the chemotherapy induced delayed nausea at C2 cycle of chemotherapy.

C3 cycle of chemotherapy: At C3 cycle of chemotherapy, 6(10%) subjects in experimental and 18(30%) subjects in control group were having delayed nausea, 24(40%)subjects in experimental and 12(20%) in control group were not having nausea in delayed period. As per chi square test, the relationship between experimental and control group was found significant at C3 cycle (post intervention 2). (χ^2=10 and p=0.002) at level p<0.05 .Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced delayed nausea at C3cycle of chemotherapy. It means ginger is effective in reducing the chemotherapy induced delayed nausea at C3 cycle of chemotherapy. Table 3 shows the Comparison of acute vomiting in experimental and control group at Cycle 1(baseline), at Cycle 2(after intervention 1) and at Cycle 3(after intervention 2).

C1 cycle of chemotherapy: At C1 cycle, chemotherapy induced acute vomiting was present in 6(10%) subjects and not present in 24(40%) subjects in both experimental and control group. As per chi square test, the relationship between experimental and control group was found non significant at baseline. (χ^2=0 and p=1) at level p<0.05.Thus it can be concluded that both experimental and control group were similar with regards to chemotherapy induced acute vomiting at baseline.

C2 cycle of chemotherapy: At C2 cycle (post intervention 1) of chemotherapy, 2(3.3%) subjects in experimental and 8(13.3%) in control group were having acute vomiting, 28(46.7%) subjects in experimental and 22(36.7%) in control group were not having acute vomiting. As per chi square test, the relationship between experimental and control group was found significant at C2 cycle (post intervention 1). (χ^2=4.320 and p=0.038) at level p<0.05.

Table 4. Comparison of delayed vomiting at baseline, after intervention 1 and after intervention 2 in experimental and control group

N=60

Variable		Experimental f(%)	Control f(%)	χ^2	P Value	Df
Delayed vomiting at Cycle=1(Baseline)	Yes	5(8.3)	5(8.3)			
	No	25(41.7)	25(41.7)	.000	1^{NS}	1
Delayed vomiting at Cycle=2 (After intervention 1)	Yes	3(5)	8(13.3)			
	No	27(45)	22(36.7)	2.783	$.095^{NS}$	1
Delayed vomiting at Cycle=3 (After intervention 2)	Yes	2(3.3)	9(15)			
	No	28(46.7)	21(35)	5.45	$.02^{*}$	1

NS=non significant at p<0.05*=significant at p<0.05

Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced acute vomiting at C2 cycle of chemotherapy. It means ginger is effective in reducing chemotherapy induced acute vomiting at C2 cycle of chemotherapy.

C3 cycle of chemotherapy: At C3 cycle (post intervention 2) of chemotherapy, 2(3.3%) subjects in experimental and 9(15%) subjects in control group were having acute vomiting, 28(46.7%)subjects in experimental and 21(35%) in control group were not having vomiting in acute period. As per chi square test, the relationship between experimental and control group was found significant at C3 cycle (post intervention 2). (χ^2=5.455 and p=0.02) at level p<0.05.Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced acute vomiting at C3cycle of chemotherapy. It means ginger is effective in reducing chemotherapy induced acute vomiting at C3 cycle of chemotherapy. Table 4 shows the Comparison of delayed vomiting in experimental and control group at Cycle 1(baseline), at Cycle 2(after intervention 1) and at Cycle 3(after intervention 2).

C1 cycle of chemotherapy: At C1 cycle, chemotherapy induced delayed vomiting was present in 5(8.3%) subjects and not present in 25(41.7%) subjects in both experimental and control group. As per chi square test, the relationship between experimental and control group was found non significant at baseline. (χ^2=.000 and p=1) at level p<0.05.Thus it can be concluded that both experimental and control group were similar with regards to chemotherapy induced delayed vomiting at baseline.

C2 cycle of chemotherapy: At C2 cycle (post intervention 1) of chemotherapy, 3(5%) subjects in experimental and 8(13.3%) in control group were having delayed vomiting, 27(45%) subjects in experimental and 22(36.7%) in control group were not having delayed vomiting. As per chi square test, the relationship between experimental and control group was found non significant at C2 cycle (post intervention 1). (χ^2=2.783 and p=0.095) at level p<0.05. Thus it can be concluded that there is a no significant difference in experimental and control group with regards to chemotherapy induced delayed vomiting at C2cycle of chemotherapy.

C3 cycle of chemotherapy: At C3 cycle of chemotherapy 2(3.3%) subjects in experimental and 9(15%) subjects in control group were having delayed vomiting, 28(46.7%) subjects in experimental and 21(35%) in control group were not having vomiting in delayed period. As per chi square test, the relationship between experimental and control group was found significant at C3 cycle (post intervention 2). (χ^2=5.455 and p=0.02) at level p<0.05.

Thus it can be concluded that there is a significant difference in experimental and control group with regards to chemotherapy induced delayed vomiting at C3cycle of chemotherapy. Hence it can be said that ginger is effective in reducing chemotherapy induced nausea and vomiting at C3cycle of chemotherapy.

DISCUSSION

In this section major findings of the study have been discussed with reference to similar findings given by other investigators. The assessment of nausea and vomiting was very important. The findings of the present study revealed that 41.7% subjects were having acute nausea. Related findings according to A Molassiotis *et al*., (2008), estimated that approximately 37.3% patients suffered from acute nausea. Related findings according to Doranne L Hilarius *et al.,* (2011) estimated that 39% patients suffered from acute nausea and similar findings were reported by Booth CM *et al.,* (2007) that 37% subjects having acute nausea. The findings of present study showed 20% subjects suffered from acute vomiting. Similar findings were reported by A Molassiotis *et al* (2008)[7] estimated that approximately 15.7% patients suffered from acute vomiting. Contrary findings according to Doranne L Hilarius *et al* (2011)[8] who conducted a community hospital-based study were revealed 12%subjects suffered acute vomiting.

The present study revealed that 58.3% subjects suffered from delayed nausea. The findings of present study are consistent with findings of a study conducted by S M Grunberg *et al* (2004), who investigated that 60%subjects are having delayed nausea. The findings of present study revealed that 10% subjects suffered from delayed vomiting. The present study findings were consistent with the study conducted by A Molassiotis *et al* (2008)[7], who proved that 14.7% subjects were reported to have delayed vomiting. Findings of present study revealed that ginger is effective in lowering the incidence of chemotherapy induced nausea and vomiting. Related findings were reported by E Ernst *et al* (2010) in his a systematic review of randomized clinical trials in which it was reported that 1gm dose of ginger is collectively favored over placebo in case of sea sickness, morning sickness and chemotherapy induced nausea and vomiting. Similar findings were reported by Levine Max E *et al*. (2007) when ginger is given with high protein diet is effective in reducing delayed nausea. Findings of present study are also supported by Pillai A K *et al.,* (2010) who found that ginger powder is effective than placebo to reduce episodes of chemotherapy induced nausea and vomiting. Findings of present study revealed that there was no significant difference found in experimental and control group for delayed vomiting during 2nd cycle of chemotherapy after the intervention. The possible reason could be that another therapeutic management was done by physician to control

delayed vomiting in control group and the subjects from control group might have started taking some other home remedies for treatment of delayed nausea.

Conclusion

Conclusions were drawn based on the findings of the study. 1 gm of Ginger capsule brought about a significant change at p value <0.05 level of significance in the level of chemotherapy induced nausea and vomiting. There was mean difference in the Pretest and post test chemotherapy induced nausea and vomiting. There was decreased chemotherapy induced nausea and vomiting in the experimental group as compared to control group, thus the research hypothesis was accepted that cancer patients receiving Anthracycline based chemotherapy will have less chemotherapy induced nausea and vomiting (at <0.05 level of significance) than those who are in control group.

Implications and Recommendations

The findings of the study have several implications for the nursing profession i.e. clinical practice, nursing education, nursing administration and nursing research. The statistical significant reduction of nausea and vomiting level among cancer patients receiving Anthracycline based chemotherapy suggests that ginger is a safe and effective complimentary method in nausea and vomiting management, which can be safely added to many other measures used by oncology nurses and physicians. Nursing students should be encouraged to assess the level of nausea and vomiting during the assessment phase of nursing care. Assessment of side effects should be included in the curriculum plan of education. Clinical instructors should arrange the clinical teaching regarding nausea and vomiting among cancer patients for nurses and nursing students. Continuing education should be designed to help nurses to update their knowledge regarding non invasive, complementary and alternative therapies for management of complications arising from chemotherapy.

Limitations

Self report method was used to collect data in current study. It is a small sample-sized study. This study includes patients receiving Anthracycline based regimen only.

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