Effect Of Ginger Supplement On Chemotherapy Induced Nausea And Vomiting Among Patients Receiving Cisplatin Attending Chemotherapy Unit Of Aims, Kochi

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Abstract: The present study design used was Quasi experimental non equivalent control group after only design by selecting the 40 subjects by convenience sampling technique. Socio-demographic data and clinical data were collected by semi-structured interview method. Acute and delayed nausea and vomiting occurrence and the frequency of nausea and vomiting were collected by standardized tool (MAT). Data analysis was done using descriptive and inferential statistics involving frequency, percentage, Chi square and independent 't' test. Considering the level and occurrence of nausea and vomiting, majority of the subjects 16(80%) in the experimental group had no nausea and vomiting at 24hrs of chemotherapy whereas 10(50%) subjects in the control group had moderate to severe nausea and vomiting. It indicates that the ginger supplement is worth in reducing chemotherapy induced nausea and vomiting. On comparison of the mean post test scores of frequency of nausea and vomiting between experimental and control group, subjects in the experimental group had only mild 13 (65%) to moderate 7 (35%) nausea and vomiting whereas the control group experienced moderate 7 (35%) to severe 13 (65%) experience of nausea and vomiting. \( t_{(38)}= 10.272, 9.454, 14.139 \) respectively for 24hrs, day4, and day 10; \( p< 0.001 \) After providing ginger supplement, the subjects exhibited a transition from a higher 4(20%) to lower level (100%) of nausea and vomiting. There was a statistically significant association between smoking, alcohol, surgical history, income and feeding route with the nausea and vomiting. The study findings showed that majority of patients receiving chemotherapy experience nausea and vomiting. Ginger supplement was a very effective intervention in reducing the occurrence of nausea and vomiting among patients receiving chemotherapy.

I. INTRODUCTION

Cancer is a class of diseases characterized by out of control cell growth. Cancer is the leading cause of death in economically developed countries and the second leading cause of death in the developing countries.¹

Chemotherapy has evolved to become a therapeutic option for certain cancers. For millions of people, chemotherapy helps treat their cancer effectively, enabling them to enjoy full, productive lives. The goal of chemotherapy is to eliminate or reduce the number of malignant cells. An undesirable consequence of chemotherapy not related to the cancer is a side effect. Nausea and vomiting are one of the common side effects of the drugs like cisplatin, which can be immediate or delayed after. Despite the use of antiemetics, nausea and vomiting are not controlled effectively.

It is during this scenario that alternative therapies gained attention of the health care providers as well as the public. Various alternative therapies are being used widely to combat the side effects of chemotherapy. Ginger is already used in traditional folk medicine to treat nausea and vomiting. Additionally, ginger's ability to block 5-HT3 receptors and its free-radical scavenging action in the gut suggests that it may be beneficial for reducing both the prevalence and severity of chemotherapy induced nausea and vomiting.
II. LITERATURE REVIEW

A double-blind, multicenter study conducted by Charls B in 644 patients IN 2002 for identifying the effects of ginger supplement in reducing nausea and vomiting. It found that all doses of ginger significantly (p = 0.003) reduced nausea compared with placebo. All patients took ginger or placebo for 6 days starting 3 days before initiating chemotherapy. Patients were randomly assigned to one of four arms: placebo, 0.5-, 1.0-, or 1.5-gram doses of a purified, dried ginger extract in 250-mg capsules. Patients reported their level of nausea four times each day on a scale of 1 to 7, with 1 representing no nausea and 7 as an indicator of extreme nausea. In addition to the ginger supplement or placebo, all patients received a standard 5-hydroxytryptamine type 3 receptor antagonist drug (ondansetron or granisetron) on day 1 of the chemotherapy cycle. Most patients report the most severe nausea on the first day of chemotherapy and examined the change in nausea in the four study arms on day 1. The largest reduction in nausea approximately 40% occurred with 0.5- and 1.0- doses of ginger also observed a statistically linear decrease (p < 0.001) in nausea over 24 hours. Patients enrolled in the trial had a mean age of 53; 90% were female and 92% were white. Represented cancer types included breast cancer (66%), alimentary cancer (6.6%), and lung cancer (6.1%).

A randomized, open-label clinical trial by Panahi Y, Saadat A, Sahebkar A, Hashemian F, Taghikhani M, Abothasani E in 2005 on effect of ginger on acute and delayed chemotherapy-induced nausea and vomiting on 100 women (mean age = 51.83 ± 9.18 years) with advanced breast cancer who were initially assigned to standard chemotherapy protocol with docetaxel, epirubicin, and cyclophosphamide were randomized to receive ginger (1.5 g/d in 3 divided doses every 8 hours) plus standard antiemetic regimen (granisetron plus dexamethasone; the ginger group) or standard antiemetic regimen alone (control group). The duration of treatment with ginger was specified to 4 days from the initiation of chemotherapy. Prevalence, score, and severity of nausea, vomiting, and retching were assessed using a simplified form of Rhodes index in the first 6 hours, between 6 to 24 hours, and days 2, 3, and 4 post chemotherapy. The result is a significantly lower prevalence of nausea was observed in the ginger group during 6 to 24 hours post chemotherapy. Despite this effect, no other significant additional benefit from ginger (1.5 g/d) was observed against prevalence or severity of nausea, vomiting, and retching in any of the assessed periods. Addition of ginger (1.5 g/d) to standard antiemetic therapy (granisetron plus dexamethasone) in patients with advanced breast cancer effectively reduces the prevalence of nausea 6 to 24 hours post chemotherapy.

A randomized, double-blind, placebo-controlled study conducted by Zick S, Ruffin T, Mack T, Lee J, Normolle P, D, Siden R, et al in 2006 on effectiveness of encapsulated ginger as a treatment for chemotherapy-induced nausea and vomiting (CINV) in 162 patients with cancer who were receiving chemotherapy and had experienced CINV during at least one previous round of chemotherapy. All participants were receiving a 5-HT3 receptor antagonists or aprepitant. Participants were randomized to receive either 1.0 g ginger, 2.0 g ginger daily, or matching placebo for 3 days the results shows there were no differences between groups in the prevalence of delayed nausea or vomiting, prevalence of acute CINV, or severity of delayed vomiting or acute nausea and vomiting. Participants who took both ginger and aprepitant had more severe acute nausea than participants who took only aprepitant. Ginger appeared well tolerated, with no difference in all adverse events (AEs) and significantly less fatigue and miscellaneous in the ginger group.

A study was conducted by Balci C, Ayse O, Nurun E, Songul Y, Meltem A, AciKgoz, et al to investigate the effects of ginger on chemotherapy-induced nausea and vomiting in cancer patients in the haematology clinic of a training hospital, Alahabad in 2011. The study group was composed of intervention (n=15) and control (n=30) patients. Control patients received antiemetic drugs for ethical reasons and intervention patients received ginger tablets (800 mg). Statistical analysis revealed no differences in the characteristics of the intervention and control groups (p>0.05). A significant difference was found between the groups receiving ginger and antiemetic, suggesting that ginger is effective for treatment of nausea and vomiting (p<0.05). Results of the present study suggest that ginger is effective for reducing chemotherapy-induced nausea and/or vomiting and they should be confirmed in future studies that include more patients with a hematological cancer.

A study conducted by Pillai AK, Sharma KK, Gupta YK, Bakhshi S. On Anti-emetic effect of ginger powder versus placebo as an add-on therapy in children and young adults receiving high emetogenic chemotherapy in 2010. Delhi. Sixty chemotherapy cycles of cisplatin/doxorubicin in bone sarcoma patients were randomized to ginger root powder capsules or placebo capsules as an additional antiemetic to ondansetron and dexamethasone in a double-blind design. Acute moderate to severe nausea was observed in 28/30 (93.3%) cycles in control group as compared to 15/27 (55.6%) cycles in experimental group (P = 0.003). Acute moderate to severe vomiting was significantly more in the control group compared to the experimental group [23/30 (76.7%) vs. 9/27 (33.33%) respectively (P= 0.002)]. Delayed moderate to severe nausea was observed in 22/30 (73.3%) cycles in control group as compared to 7/27 (25.9%) in the experimental group (P < 0.001). Delayed moderate to severe vomiting was significantly more in the control group compared to the experimental group [14/30 (46.67%) vs. 4/27 (14.81%) (P = 0.022)]. It is evident that ginger root powder was effective in reducing severity of acute and delayed CINV as additional therapy to ondansetron and dexamethasone in patients receiving high emetogenic chemotherapy.

III. STATEMENT OF THE PROBLEM

“Effect of Ginger Supplement on Chemotherapy Induced Nausea and Vomiting Among Patients Receiving Cisplatin Attending Chemotherapy Unit of AIMS, Kochi”.

IV. OBJECTIVES OF THE STUDY

The objectives of the study were to
✓ assess the level of nausea and vomiting among experimental and control group at after 24 hours, 4th day, 10th day,
✓ compare the level of nausea and vomiting between the experimental group and the control group
✓ associate selected demographic and clinical variables with level of nausea and vomiting in the experimental and control group

V. OPERATIONAL DEFINITIONS

EFFECT

It refers to the outcome of ginger supplement in reducing nausea and vomiting by comparing the level of nausea and vomiting between experimental and control group.

GINGER SUPPLEMENT

It is the purified encapsulated powered dry ginger

CHEMOTHERAPY

In this study, it refers to treatment of malignancies with cytotoxic drugs in the first cycle

NAUSEA

It is a sensation of unease and discomfort in the upper stomach with an involuntary urge to vomit as reported by the patient and measured with Multinational Association of Supportive care in Cancer Antiemesis Tool (MAT)

VOMITING

It is the forceful expelling of the contents of the stomach and intestines through the mouth as reported by the patient and measured with Multinational Association of Supportive care in Cancer Antiemesis Tool (MAT).

PATIENTS

In this study patients refers to those individuals diagnosed to have cancer and is receiving first cycle of chemotherapy with cisplatin and antiemetics attending the chemotherapy unit.

CISPLATIN

In this study, it refers to the chemotherapeutic drug used for the treatment for various cancers during the first cycle of chemotherapy

ASSUMPTIONS

✓ Nausea and vomiting is a common problem in patients receiving chemotherapy
✓ Ginger capsules is effective in minimizing the severity of nausea and vomiting

HYPOTHESES

H₁: There will be a significant difference in the occurrence of nausea and vomiting among patients receiving ginger capsules compared to patients not receiving ginger capsules.
H₂: There will be a significant difference in the post test mean score of nausea and vomiting between the experimental and control group.
H₃: There will be a significant association between the mean post test score nausea and vomiting and selected variables

VARIABLES

Dependent variable - Chemotherapy induced nausea and vomiting among patients receiving Cisplatin
Independent variable - Effect of ginger supplement
Extraneous variables – Antiemetics taken by the patient
- Other systemic drugs taken by the patient
- Stage of the disease
- Emetogenic potential of the chemotherapeutic drug

VI. METHODOLOGY

RESEARCH DESIGN

The research design used for the study was Quasi experimental nonequivalent control group after only design. This can be represented as.

<table>
<thead>
<tr>
<th>Group</th>
<th>Intervention</th>
<th>Measurement</th>
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<tbody>
<tr>
<td>E</td>
<td>X</td>
<td>O₁</td>
</tr>
<tr>
<td>C</td>
<td></td>
<td>O₂</td>
</tr>
</tbody>
</table>

Schematic representation of the research design

KEY

E- Experimental group (Patients receiving Cisplatin); C- Control group (Patients receiving Cisplatin); X- Intervention (Administration of ginger supplement); O₁- Post intervention – Measurement of nausea and vomiting experience in the experimental group; O₂- Post intervention - Measurement of nausea and vomiting experience in the control group.

The study involved two independent groups, an Experimental group(E) and a control group(C). Subjects in the experimental and control group were matched purposively with respect to their clinical diagnosis; hence there was no randomization in allocating the subjects to experimental and control group. The intervention (ginger supplement) was administered only for the subjects in the experimental group.

RESEARCH SETTING

The present study was done at the Oncology Day Care Chemotherapy Unit (T3F0), Oncology Day Care
Chemotherapy unit is a 25 bedded unit with an intake of 70-75 patients/day. AIMS is a 1200 bedded super specialty hospital, which is a fast growing metropolis of Kerala established in 1998. The Oncology wing of AIMS was organized as The Amrita Cancer Centre incorporating a full fledged Medical Oncology division, Radiation Oncology facility, dedicated Surgical Oncology department and a pain and palliative care centre with hospital based and community based outreach service programs.

POPULATION

TARGET POPULATION

Patients who are receiving first cycle chemotherapy in AIMS.

ACCESSIBLE POPULATION

Patients who are receiving first cycle of chemotherapy (Cisplatin) day care unit, who meet designated criteria.

SAMPLE AND SAMPLING TECHNIQUE

SAMPLE

Patients who are receiving first cycle of chemotherapy (Cisplatin) day care unit, who meet designated criteria.

SAMPLING TECHNIQUE

Convenience sampling technique was used to select subjects in the experimental and control group. Subjects in either group were conveniently selected with respect to their inclusion criteria.

SAMPLE SIZE

Total 40 subjects were included in the study within 20 were in the control group and 20 in the experimental group. Sample size was calculated using the formulae used in computing the minimum sample size requirement for comparing the means of a quantitative variable between experimental and control group. Minimum sample size estimated for the present study was 24 with 12 subjects in the experimental group and 12 in the control group.

SAMPLE SELECTION CRITERIA

INCLUSION CRITERIA

✓ Clients who were willing to participate.
✓ Clients who were receiving first cycles of chemotherapy (Cisplatin).
✓ Clients who were able to read and write English and Malayalam.
✓ Clients in the age group of 18-60 years.

EXCLUSION CRITERIA

✓ Clients who have impaired cognition.
✓ Clients who were critically ill.
✓ Clients with metastasis.
✓ Clients undergoing more than 1 cycle of chemotherapy.
✓ Clients with brain tumor.
✓ Clients with GI disorders.
✓ Clients who currently receiving radiation.
✓ Clients with other than Cisplatin.

DATA COLLECTION INSTRUMENTS AND TECHNIQUES

Instruments used for the study were
✓ Semi structured Interview Schedule
✓ Multinational Association of Supportive Care in Cancer Antiemesis Tool (MAT) in 2004

DATA COLLECTION PROCEDURE

Before starting data collection ethical clearance from Thesis Review Committee and permission from the head of the institution was obtained. Nursing supervisor and sister in charge was also informed. Data collection was from 29th October 2011 till 14th November 2011. Ginger dry powder from Govt. Ayurveda Medical College has standardized in Govt. Analytical lab situated in Kakkanad, Kochi. Then the researcher herself has prepared the ginger capsules from the Amrita Pharmacy College under the guidance and supervision of the faculty. First the researcher established a rapport with the client, explained the importance of the study and procedures involved in data collection. Further, obtained a written informed consent from the client and collected the demographic data and clinical data using a semi structured interview schedule. Few items in the clinical data were collected through reviewing the patient file and the remaining through the direct interaction with the patient. Semi-structured interview schedule was completed within 15 minutes. Capsules were administered by the investigator on chemotherapy days and rest of the days clients were instructed to take it by themselves which were packed in a sterile container and handed over to the clients with clear instructions. After the completion of chemotherapy, the condition of nausea and vomiting were assessed by checking MAT tool through self report on 10th day.

VII. ANALYSIS AND INTERPRETATION OF DATA

Frequency and percentage distribution of subjects in the experimental and control group was done using descriptive statistics. The occurrence of nausea and vomiting and frequency of nausea and vomiting were also assessed in the experimental and control group. Association between level of nausea and vomiting and selected socio-demographic variables were done using ‘chi-square’ test. Comparison of the experience of nausea and vomiting in the experimental and control group was done using independent’s test and chi-square test.
The data thus obtained were analyzed and presented under the following sections.

SECTION I: SOCIO-DEMOGRAPHIC AND CLINICAL CHARACTERISTICS OF THE SUBJECTS

The data shows that 9(45%) of the subjects in the control group were in the age group 18-39 and 13(65%) of the subjects in the experimental group were in the age group 50-59. 13(65%) of the subjects in the control group and 12(60%) of the subjects in the experimental group were females. 16(80%) and 15(75%) of subjects in the control group and experimental group were married. With regard to religion 9(45%), 5(25%), 6(30%) of subjects in the control group and 10(50%), 3(15%), 7(35%) in the experimental group were Hindus, Muslims and Christians respectively. Data on education shows that 40% and 30% of the subjects in the control group having higher secondary level of education and are graduate/Post graduates and 70% subjects in the experimental group are graduates/post graduates. As far as occupation is concerned 30% and 25% of the subjects in the control group are Government employees, business and private employees, and 35% subjects in the experimental group were private employed and only 20% of them were unemployed. 40% of the subjects in the control group have an income 10000-15000 and 35% of the subjects in the experimental group have an income 15000-20000.

Data regarding the clinical variables shows that 3(85%) and none of the subjects in the control group and experimental group have no family history of cancer. 5(80%) and 4(75%) of the subjects in the control group and experimental group has no habit of smoking. 3(85%) and none of the subjects in the control group and experimental group have no habit of using illicit drugs. 15(75%) of the subjects in both the groups has no habit of use of alcohol. 18(90%) and none of the subjects in the control group and experimental group are not using tobacco. 14(75%) and 15(70%) of the subjects in the control group and experimental group are non-vegetarian. 12(60%) and all the subjects in the control group and experimental group are taking orally as feeding route. 14(70%) of the subjects in the control group having BMI <24 and 17(85%) subjects in the experimental group having BMI between 25-29. 15(75%) of the subjects in the control group have no co-morbidity and 16(80%) subjects in the experimental group have co-morbidity. 16(80%) and 15(75%) of the subjects in the control group and experimental group have no history of surgical therapy for cancer. 19(95%) and 18(90%) of the subjects in the control group and experimental group have no history of radiation therapy for cancer.

SECTION II: FREQUENCY OF NAUSEA AND VOMITING

Data presented in fig 1 shows that mild nausea and vomiting was present only in four (20%) subjects in the experimental and control group at 24 hours. 16 (80%) subjects in the experimental group have no nausea and vomiting in 24 hours. Ten (50%) subjects in the control group have moderate to severe nausea and vomiting during 24 hours.
Figure 5 shows that three (15%), ten (50%) and seven (35%) subjects in the control group have mild, moderate and severe nausea frequency and none of the subjects in the experimental group having no nausea frequency respectively on day 10.

SECTION III: OCCURRENCE OF NAUSEA AND VOMITING

Figure 6: Cone diagram shows Occurrence of nausea and vomiting in 24 hour

Figure 6 shows that 16(80%) of subjects in the control group have nausea and vomiting and four (20%) of subjects in the control group have nausea and vomiting at 24 hours.

Figure 7: Bar diagram of occurrence of nausea and vomiting in day 4

Figure 7 shows that 18(90%) of subjects in the control group have nausea and vomiting and three (15%) of subjects have nausea and vomiting at day 4.

Figure 8: Cylindrical diagram of occurrence of nausea and vomiting in day 10

Figure 8 shows that all subjects in the experimental group have no nausea and vomiting and 20 (80%) of subjects in the control group has nausea and vomiting at day 10.

Hence the findings of section II reveals that the null hypothesis, H₀₁-“There is no significant difference in the occurrence of nausea and vomiting among patients receiving ginger capsules compared to patients not receiving ginger capsules” can be rejected indicting that there is a significant difference in the occurrence of nausea and vomiting between experimental and control group

SECTION IV- ASSOCIATION BETWEEN EXPERIENCE OF NAUSEA AND VOMITING AND SELECTED VARIABLES FOR THE SUBJECTS IN THE CONTROL GROUP

Table 3: Association between surgical history and occurrence of nausea and vomiting at 24 hour

<table>
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<th>Surgical History</th>
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<th>χ²</th>
<th>p value</th>
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Table 4: Association between occurrence of nausea and vomiting at day 10 and selected variables in control group

<table>
<thead>
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<td>10000-15000</td>
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<td>Alcohol</td>
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<td>6.64</td>
<td>&lt;0.01</td>
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<tr>
<td>No</td>
<td>40</td>
<td>93</td>
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Table 5: Association between feeding route and level of nausea and vomiting frequency at day 4

<table>
<thead>
<tr>
<th>Feeding Route</th>
<th>Mild</th>
<th>Moderate</th>
<th>Severe</th>
<th>χ²</th>
<th>p value</th>
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<td>Oral</td>
<td>3</td>
<td>11</td>
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<td>PEG</td>
<td>5</td>
<td>25</td>
<td>30</td>
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</tr>
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</table>

Table 6: Association between feeding route and level of nausea and vomiting frequency at day 4
Table 5 indicates that mild nausea and vomiting was present in five (41.7%) subjects taking oral feeding route, moderate nausea and vomiting in six (50%) subjects taking oral feeding route and severe nausea and vomiting in 5 (62.5%) subjects taking PEG feeding route.

Hence the null hypothesis $H_0$ that there is no significant association between the mean post test score of nausea and vomiting and selected variables is rejected indicating that there is significant association between the mean post test score of nausea and vomiting in terms of income, alcohol, surgical history, smoking and feeding.

SECTION V- COMPARISON OF THE MEAN POST TEST SCORE OF FREQUENCY OF NAUSEA AND VOMITING BETWEEN THE EXPERIMENTAL AND THE CONTROL GROUP

Table 5:

<table>
<thead>
<tr>
<th>Day</th>
<th>Control group n=20</th>
<th>Experimental group n=20</th>
<th>Mean difference</th>
<th>t value</th>
</tr>
</thead>
<tbody>
<tr>
<td>24hrs</td>
<td>Mean 1.9 S.D 0.71</td>
<td>Mean 3.8 S.D 0.41</td>
<td>1.94</td>
<td>10.272***</td>
</tr>
<tr>
<td>4</td>
<td>Mean 2 S.D 0.79</td>
<td>Mean 3.85 S.D 0.36</td>
<td>1.67</td>
<td>9.454***</td>
</tr>
<tr>
<td>10</td>
<td>Mean 1.18 S.D 0.69</td>
<td>Mean 4 S.D 0.0</td>
<td>2.17</td>
<td>14.139***</td>
</tr>
</tbody>
</table>

$t(38) = 3.55$ ***Significant at p<0.001

The above table depicts the t value computed based on the mean difference in the level of nausea and vomiting between the experimental and control group on 24 hours, day 4 and day 10 respectively. On comparison the result was statistically significant at $p<0.001$.

Hence section V indicates that the null hypothesis $H_{02}$: There is no significant difference in the mean score of nausea and vomiting between the experimental and control group is rejected indicating that there is significant difference in the mean post test scores of frequency of nausea and vomiting between the experimental and control group.

SECTION VI- COMPARISON OF THE OCCURRENCE OF NAUSEA AND VOMITING BETWEEN THE EXPERIMENTAL AND THE CONTROL GROUP

Table 6:

<table>
<thead>
<tr>
<th>Day</th>
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<th>control group n=20</th>
<th>$\chi^2$ value</th>
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</tbody>
</table>

$0.00 < 0.001$ ***Significant at $p<0.001$

The table 6 depicts the $\chi^2$ value computed based on the mean difference in the level of nausea and vomiting between the experimental and control group on 24 hours, day 4 and day 10 respectively. On comparison the result was statistically significant at $p<0.001$.

VIII. MAJOR FINDINGS OF THE STUDY

- When considering the level and occurrence of nausea and vomiting majority of the subjects 16(80%) in the experimental group had no nausea and vomiting at 24hrs of chemotherapy whereas 10(50%) subjects in the control group had moderate to severe nausea and vomiting which indicates that the ginger supplement is worth in reducing chemotherapy induced nausea and vomiting.

- On comparison of the mean post test scores of frequency of nausea and vomiting between experimental and control group, subjects in the experimental group had only mild 13 (65%) to moderate 7 (35%) nausea and vomiting whereas the control group experienced moderate 7 (35%) to severe 13 (65%) experience of nausea and vomiting. ($t(38) = 10.272, 9.454, 14.139$ respectively for 24hrs, day4, and day 10; $p< 0.001$)

- After providing ginger supplement, the subjects exhibited a transition from a higher 4(20%) to lower level (100%) of nausea and vomiting.

- There was a statistically significant association between smoking, alcohol, surgical history, income and feeding route with the nausea and vomiting.

IX. CONCLUSION

Based on the study findings it can be concluded that nausea and vomiting remains as a major side effect of chemotherapy inspite of the administration of antiemetics. But ginger supplement had promising effect in reducing the occurrence of nausea and vomiting. Emetogenic potential of
the chemotherapeutic agent was an important extraneous variable affecting the occurrence of nausea and vomiting.

REFERENCES

[8] [http://www.chiro.org/nutrition/ABSTRACTS/Ginger_Effective.shtml](http://www.chiro.org/nutrition/ABSTRACTS/Ginger_Effective.shtml)