

Prospective randomized trial of standard antiemetic therapy with yoga versus standard antiemetic therapy alone for highly emetogenic chemotherapy-induced nausea and vomiting in South Asian population

ABSTRACT

Aim/Background: Chemotherapy-induced nausea and vomiting (CINV) is one of the most distressing side effects of highly emetogenic chemotherapy regimens. There have been continuous efforts in the direction to control CINV by many investigators.

Materials and Methods: Randomly selected patients were those receiving highly emetogenic chemotherapy regimen grouped into yoga and standard antiemetic therapy ($n = 50$) just before receiving chemotherapy and continued for the following days and other group ($n = 50$) received only the standard antiemetic agent. Both the groups were assessed, followed for acute and delayed onset of chemotherapy-induced and anticipatory nausea and vomiting using radiation therapy oncology group grading for the same. We also assessed the quality of life of the patient using the Functional Assessment of Cancer Therapy-General questionnaire.

Results: The median age group of the patients was 51 years with male:female ratio 2:1, The Eastern Cooperative Oncology Group (ECOG) performance status was 0/1 in 38% of the selected population, while ECOG 2 in 62% of the patients. In yoga arm, insignificant reduction in chemotherapy-induced nausea (90% vs. 78%, $P = 0.35$) and but significant reduction in vomiting (42% vs. 22%, $P = 0.01$) was observed as compared to the standard antiemetics only arm. There was a significant reduction in Grade 2 and 3 nausea (84% vs. 38% $P < 0.01$) and vomiting (14% vs. 0% $P < 0.01$). Quality of life is also significantly improved in the yoga arm, especially in the ECOG 2 performance status.

Conclusions: This study concludes that yoga along with standard antiemetic medication should be a part of the management plan for the cancer patients receiving highly emetogenic chemotherapy.

KEY WORDS: Antiemetics, chemotherapy-induced nausea and vomiting, yoga and pranayama

INTRODUCTION

Nausea and vomiting have been one of the most common and distressing side effects that patients face while getting treated for malignancy. Chemotherapy-induced nausea and vomiting (CINV) in particular remains one of the most feared side effects from the patient's point of view.^[1] CINV affects all the aspects of the quality of life, negatively.^[2] In preantimetic era, nearly 80% of the patients receiving moderate to highly emetogenic chemotherapy agents would experience nausea and vomiting in the first postchemotherapy days.^[3]

CINV also constitutes of another form of nausea and vomiting, i.e., intuitive or anticipatory nausea and vomiting, which is one of the important causes of nausea and vomiting in patients receiving chemotherapy. This is more common in patients getting second or subsequent chemotherapy. Nausea might be experienced even before

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Table 1: Characteristics

Characteristic	Values (%)
Age (median)	51 years
Sex ratio (male:female)	2:1
Diagnosis	Genitourinary=19 Breast=14 Head and neck=37 Lung=14 Others=16
ECOG performance status ^[13]	0/1 in 38 2 in 62
Smoking history	Smoker: 51 Nonsmoker: 49

ECOG=Eastern Cooperative Oncology Group

Table 2: Grades of nausea and vomiting characteristics (incidence and prevalence: Study and control group)

	Study group (yoga arm) (%)	Control group (without yoga) (%)
Nausea		
Day 1		
Grade 1	32	32
Grade 2	24	42
Grade 3	4	8
Day 2		
Grade 1	30	50
Grade 2	16	35
Grade 3	8	9
Day 3		
Grade 1	24	36
Grade 2	6	8
Grade 3	2	2
Vomiting		
Day 1		
Grade 1	18	22
Grade 2	0	4
Grade 3	0	0
Day 2		
Grade 1	12	24
Grade 2	0	12
Grade 3	0	1
Day 3		
Grade 1	4	24
Grade 2	0	3
Grade 3	0	0

Table 3: Comparison between yoga + standard antiemetics and standard antiemetics only

	Control group (%)	Study group (%)	P
Nausea	90	78	0.35
Vomiting	42	22	0.01
Grade 2 and 3 nausea	84	38	<0.01
Grade 2 and 3 vomiting	14	0	<0.01
Grade 2 nausea and vomiting	42	20	<0.01
Grade 3 nausea and vomiting	14	12	0.39

administration of the chemotherapy drugs in approximately 20% of patients at any one of chemotherapy cycles and by 25%–30% of patients by their fourth chemotherapy cycle.^[4] It is also referred to as conditioned, learned, or psychological nausea and vomiting^[5,6] as this is due to the state of the mind of the patient. This psychological disturbance may aggravate

the problem of nausea and vomiting to such an extent that patient may refuse to go for any further treatment.

The age-old practice of yoga (“union”) as mentioned in the Patanjali Yoga Sutras is a spiritual practice that helps and strengthens in union of mind with body.^[7] The word yoga is derived from the Sanskrit word “Yuj” which means to bind, join, attach, or yoke to direct and concentrate the attention in order to use it for betterment. Thus, yoga is an art which brings an incoherent and scattered mind to a reflective and coherent state.

Patanjali evolved eight stages on path of realization to bring the mind from due state to active state and stability. In short, we can say that yoga leads to health, strength, and congruence of body and leads the performer to a state of peace and joy. It systematically teaches the performer to discover the strength within himself.^[8]

These are primarily concerned with the health of body at the same time improving the mental health. Pranayama, which is a sort of breathing exercise, works both as a physical exercise and a type of meditation.

Studies have suggested that practicing pranayama can create a relaxed state by enhancing parasympathetic tone,^[9-11] thus decreasing the chances of anticipatory nausea and vomiting.

MATERIALS AND METHODS

The study was conducted in Acharya Tulsi Regional Cancer Treatment and Research Center with due approval from the Institutional Ethics Committee. One hundred cancer patients receiving moderate to highly emetogenic chemotherapy were selected and randomized.

Study design

The consenting patients were recruited and randomized into two groups comprising fifty patients each. Those in the study group started doing yoga and pranayama 2 days before the scheduled chemotherapy and continued it throughout the cycle if it was spread over days and through the post-Chemotherapy (CT) days as well. Yoga and pranayama were done by these patients under supervision of a yoga master. Yogasanas practiced were mainly seated and lying poses such as The accomplished Pose(Siddhasana), the lotus pose (Padmasana), forward bends also dog pose (Adho mukh Shavasana). Guided meditation was also included in the practice. These patients also received standard antiemetic agents. Instructions were given to the patients to continue yoga at home in the period between the two cycles of chemotherapy [Figure 1].

~~The control group received chemotherapy cycles along with standard antiemetic agents.~~

Both the groups were followed for 3 days post-CT for incidences and grades of nausea and vomiting according to the radiation therapy oncology group grading for the same.^[12]

RESULTS

The average age of the patients enrolled in the study was 48.9 years $\pm$ 12.94 (standard deviation). Male-to-female ratio was 1.43:1 [Table 1].

Maximum patients, i.e., 37% were of head and neck malignancies receiving cisplatin-based chemotherapeutic regimen. Genitourinary cancer patients were 19% of the total while breast and lung comprised 14% each [Table 1].

In the study arm, insignificant reduction in the incidence of chemotherapy-induced nausea (90% vs. 78%, $P = 0.35$) was observed, but significant reduction in the incidence vomiting (42% vs. 22%, $P = 0.01$) was found when compared with the control arm.

There was a significant reduction in Grade 2 and 3 nausea (84% vs. 38% $P < 0.01$) and vomiting (14% vs. 0% $P < 0.01$) [Table 3].

In addition to this, we got the data for Grade 2 and Grade 3 nausea and vomiting separately and we found that there was a greater impact on Grade 2 nausea and vomiting as compared to Grade 3 (14% vs. 12% Grade 3 nausea and vomiting, $P = 0.39$; 42% vs. 20% Grade 2 nausea and vomiting, $P < 0.01$) [Tables 2 and 3].

Chi-square test was used to find the level of significance. Other statistics were derived using Microsoft Excel 2007 and SPSS version 20 (IBM, Armonk, NY, United States of America).

Although the beneficial effects of yoga are seen on the management of side effects, it is worth noting that participants enrolled in this study had varied diagnosis and were in various stages of treatment contributing to generalizability of the results.

DISCUSSION

Cancer patients receiving chemotherapy treatment frequently experience the disagreeable side effects including nausea and vomiting which may meddle with the patient's appetite and also capability to perform activities of daily living, thus causing malnutrition leading to proneness to infections and metabolic imbalances. When CINV is very severe, psychological distress, depression, and physiological impairment occur. Different nonpharmacological interventions have been tried in many forms previously and are still being studied to be helpful in improving the life of the cancer patients and also to tackle the side effects of the cancer treatment.^[14-17]

With our study, we found that there was a significant decrease in the number of patients experiencing nausea and vomiting

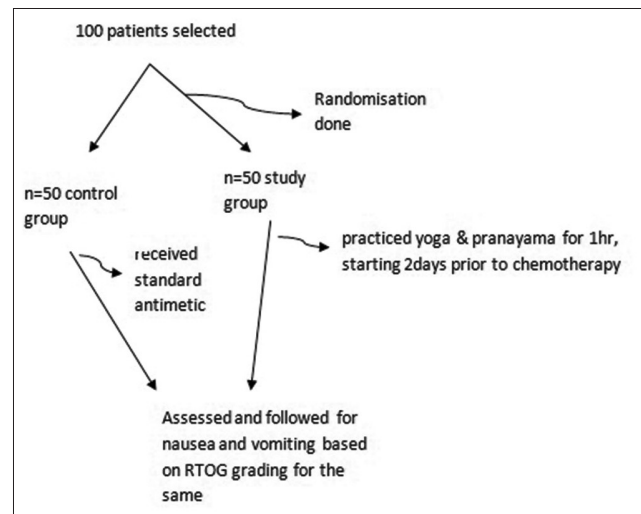


Figure 1: Study design

in the study group of yoga as compared to the control group. Not just the incidence but also grade of nausea and vomiting were affected, with low-grade CINV seen in the patients in the study arm.

As a result, the quality of life of the patients was better in the study group as compared to that in the control group (measured using the Functional Assessment of Cancer Therapy-General criteria).

The poor health conditions were not a hindrance since the yogasanas included were very basic postures and breathing techniques including meditation.

CONCLUSIONS

This study including yoga and pranayama with meditation successfully demonstrated that these interventions can be utilized along with the standard antiemetic measures and are very safe and effective in reducing this debilitating side effect of chemotherapy.

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Conflicts of interest

There are no conflicts of interest.

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