Original article

Effects of an integrated yoga programme on chemotherapy-induced nausea and emesis in breast cancer patients

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RAGHAVENDRA R.M., NAGARATHNA R., NAGENDRA H.R., GOPINATH K.S., SRINATH B.S., RAVI B.D., PATIL S., RAMESH B.S. & NALINI R. (2007) *European Journal of Cancer Care* **16**, 462–474
Effects of an integrated yoga programme on chemotherapy-induced nausea and emesis in breast cancer patients

This study examined the effect of an integrated yoga programme on chemotherapy-related nausea and emesis in early operable breast cancer outpatients. Sixty-two subjects were randomly allocated to receive yoga ($n = 28$) or supportive therapy intervention ($n = 34$) during the course of their chemotherapy. Both groups had similar socio-demographic and medical characteristics. Intervention consisted of both supervised and home practice of yoga sessions lasting for 60 min daily, while the control group received supportive therapy and coping preparation during their hospital visits over a complete course of chemotherapy. The primary outcome measure was the Morrow Assessment of Nausea and Emesis (MANE) assessed after the fourth cycle of chemotherapy. Secondary outcomes included measures for anxiety, depression, quality of life, distressful symptoms and treatment-related toxicity assessed before and during the course of chemotherapy. Following yoga, there was a significant decrease in post-chemotherapy-induced nausea frequency ($P = 0.01$) and nausea intensity ($P = 0.01$), and intensity of anticipatory nausea ($P = 0.01$) and anticipatory vomiting ($P = 0.05$) as compared with the control group. There was a significant positive correlation between MANE scores and anxiety, depression and distressful symptoms. In conclusion, the results suggest a possible use for stress reduction interventions such as yoga in complementing conventional antiemetics to manage chemotherapy-related nausea and emesis.

Keywords: yoga, meditation, nausea, vomiting, complementary therapies, supportive care, stress.

INTRODUCTION

Nausea and emesis are two of the most distressing side effects of chemotherapy and are experienced by as many as 66–91% of patients receiving chemotherapy (Rhodes & McDaniel 2001). Complete control of emesis (i.e. no vomiting with currently available antiemetic agents) is achievable in a majority of patients in the first 24 h and in only

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Accepted 18 September 2006
DOI: 10.1111/j.1365-2354.2006.00739.x

European Journal of Cancer Care, 2007, **16**, 462–474

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45% of patients during the first 5–7 days of chemotherapy (Gralla *et al*. 1999; Roila *et al*. 2005). However, chemotherapy-induced nausea occurs at a greater frequency than vomiting and, despite the use of new-generation antiemetics, complete control rates for nausea remain low as compared with those for emesis (Perez *et al*. 1998). Another significant problem is that a substantial gap remains between antiemetic guidelines and practice and that most of these guidelines may not be widely implemented even in developed countries (De Angelis *et al*. 2003). This is even more so for developing countries such as India and other countries where nausea and emesis following chemotherapy are not adequately managed because of low affordability of new-generation antiemetic medications. However, various psychological techniques, such as cognitive behaviour therapy, biofeedback, relaxation, supportive therapy and coping preparation interventions, have been shown to complement antiemetics in managing chemotherapy-related nausea and emesis (Burish *et al*. 1991; Burish & Tope 1992). We therefore evaluated the benefits of using traditional intervention strategies such as yoga and meditation in comparison with standard supportive care and coping preparation in managing chemotherapy-related nausea and emesis.

There is a high prevalence of nausea and emesis following chemotherapy. This is attributed to high doses of emetogenic antineoplastic agents and anticipatory nausea and emesis (King 1997). Distressing symptoms (such as nausea, vomiting, retching, anorexia, motion sickness, headaches, etc.) commonly occur after chemotherapy and antiemetogenic administration. These distressing symptoms can impede the ability of patients to perform normal household tasks, enjoy meals, and maintain daily function and recreation, thereby reducing their quality of life (Osoba *et al*. 1997). Some patients may even see the treatment and resulting distress worse than the disease itself (Rimer *et al*. 1983), while some may even discontinue the prescribed course of chemotherapy (Burish & Tope 1992), thereby reducing hope of recovery and life expectancy (Gilbar 1991).

Studies have shown that some of these side effects that develop after chemotherapy may be partly psychological rather than purely pharmacological in nature (Burish & Tope 1992). Nearly 70% of patients who experience anticipatory nausea and emesis attribute these side effects to a psychological aetiology (Morrow 1982). This may be because the information from the vomiting centre in the brain to higher brain centres is involved in the perception of nausea and vice versa (Hawthorn 1995). Various studies have shown risk factors such as motion sickness, vomiting related to particular foods, and pre-treatment anxiety and expectations (Jacobsen *et al*. 1988; Morrow *et al*. 1991) to have a strong predisposition for post-chemotherapy and anticipatory nausea and vomiting, and these can further exacerbate the responses to conditioned stimuli in these subjects (Mattes *et al*. 1987). Therefore, these strong relationships between psychosocial variables, nausea and emesis justify the need for integrating mind/body therapies with pharmacological interventions in managing treatment-related nausea and emesis (Schwartz *et al*. 1996).

Studies show that complementary and alternative medicine (CAM) and mind/body approaches such as hypnosis, progressive muscle relaxation training with guided imagery, music therapy, acupuncture, acupressure, systematic desensitization, biofeedback and distraction are useful in reducing nausea and emesis either alone or in combination with antiemetics and anxiolytic medications (Redd *et al*. 2001; Mundy *et al*. 2003). Of these, relaxation with guided imageries has been studied extensively, and has been shown to reduce the duration and frequency of both acute and delayed nausea and emesis following chemotherapy in subjects with poor control of nausea and vomiting (Burish & Tope 1992; Arakawa 1997; Molassiotis *et al*. 2002). Most of these techniques reduce anxiety, physiological arousal and psychological distress in cancer patients through stress reduction (Morrow & Rosenthal 1996). A growing interest in the use of these therapies reflects a need for a more holistic approach to cancer treatment (Cassileth 1999).

Yoga as a complementary modality is being practised increasingly in both Indian and western population. Yoga practices have been used for therapeutic benefits in numerous health-care concerns, such as asthma (Nagarathna & Nagendra 1985), diabetes (Sahay & Sahay 2002), hypertension (Sainani 2003), heart disease (Jayasinghe 2004), musculoskeletal disorders (Raub 2002), cancer (Cohen *et al*. 2004) and others in which mental stress (Gimbel 1998; Bijlani 2004) was believed to play a role. These practices include several techniques, such as *asanas* (postures done with awareness), *pranayama* (voluntarily regulated nostril breathing), *yoga nidra* (guided relaxation with imagery) and meditation, which promote physical well-being and mental calmness. These practices are known to build inner awareness and attention of mental phenomena. This is thought to alter the perceptions and mental responses to both external and internal stimuli, slow down reactivity and responses to such stimuli, and instill a greater control over stressful situations. This could be particularly useful in cancer patients who perceive cancer as a threat. Recent randomized waitlist controlled studies using meditation and mindfulness yoga

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components (Mindfulness-Based Stress Reduction programme) have found beneficial effects in terms of improved affective states; decrease in mood disturbance, stress symptoms and disturbed sleep; improved quality of life; and benefits in terms of improved immune responses in early breast (Speca *et al*. 2000; Targ & Levine 2002) and prostate cancer patients (Carlson *et al*. 2003). However, most of these studies involve heterogeneous cancer populations at varying stages of their disease and treatment, and evaluate quality of life and psychosocial outcomes.

However, studies reviewed using yoga/meditation components do not address issues pertaining to conventional treatment toxicity and chemotherapy-related nausea and vomiting.

The purpose of this trial was to study whether a support intervention based on mind/body and psycho-spiritual interventions such as yoga might be a viable alternative to standard supportive therapy and coping preparation in reducing the frequency and intensity of nausea and emesis in chemotherapy-naïve stage II and III breast cancer patients receiving adjuvant chemotherapy.

METHODS

Subjects

This study is a part and continuation of the original randomized control study that recruited 98 recently diagnosed women with stage II and III operable breast cancer to assess the effect of a yoga programme on mood, quality of life, distressful symptoms, toxicity and immune responses in early breast cancer patients undergoing conventional treatment. These patients were recruited from Bangalore Institute of Oncology, a comprehensive cancer care centre in Bangalore, India, over a 2.5-year period from January 2000 to June 2002. Only subjects who were on adjuvant chemotherapy were included for analysis in this study. Patients were eligible to participate in this study if they met the following selection criteria at the start of the study: (1) recently diagnosed operable breast cancer; (2) aged between 30 and 70 years; (3) Zubrod's performance status 0–2 (ambulatory >50% of time); (4) high-school education; (5) having a treatment plan with surgery followed by adjuvant chemotherapy or by both adjuvant radiotherapy and chemotherapy; and (6) consenting to participate in the study. Subjects were excluded if they had any concurrent medical condition that was likely to interfere with the treatment, major psychiatric, neurological illness or autoimmune disorders, and any known metastases. Subjects were excluded from analyses in the current study if they had a history of intestinal obstruction and any known sensitivity to any class of antiemetics (such as $5HT_3$ receptor antagonists or dopamine receptor antagonists) and corticosteroids (such as dexamethasone). Of the 98 subjects who were randomized to yoga and supportive therapy initially at the start of the study, 62 subjects (yoga $n = 28$; control $n = 34$) completed their prescribed chemotherapy cycles. There were 29 dropouts immediately following surgery, and seven subjects did not receive chemotherapy (see trial profile, Fig. 1). The reasons for dropouts were migration to other hospitals, use of other complementary therapies (e.g. homeopathy or ayurveda), lack of interest, time constraints and other concurrent illness.

Randomization

Subjects consenting to participate in this study to compare two interventions, 'yoga versus supportive therapy and coping preparation', were randomly allocated to receive either one of these interventions prior to their primary treatment or surgery, using random numbers generated by a random number table. These subjects were then followed up with interventions and assessments during their adjuvant treatment (radiotherapy and chemotherapy). Randomization was performed using opaque envelopes with group assignments. The envelopes were opened sequentially in the order of assignment during recruitment, with the names and registration numbers of the participants written on the covers. The order of randomization was verified with the hospital date of admission records for surgery at study intervals to make sure that field personnel had not altered the sequence of randomization to suit the allocation of consenting participants into two study arms.

Procedure

This study evaluated the effects of yoga intervention versus supportive therapy and coping preparation in chemotherapy-naïve early stage II and III breast cancer patients undergoing adjuvant chemotherapy. The subjects in the study were prescribed four to eight cycles of FAC or CMF or both as adjuvant chemotherapy protocols following surgery, which was the standard care in the hospital during the study period. The FAC protocol consisted of 5-fluorouracil (600 mg/m^2), adriamycin (60 mg/m^2) and cyclophosphamide (600 mg/m^2), and the CMF protocol consisted of cyclophosphamide (600 mg/m^2), methotrexate (50 mg/m^2) and 5-fluorouracil (600 mg/m^2). The standard approach to chemotherapy-related nausea and emesis in the hospital when the study was conducted was 8-mg

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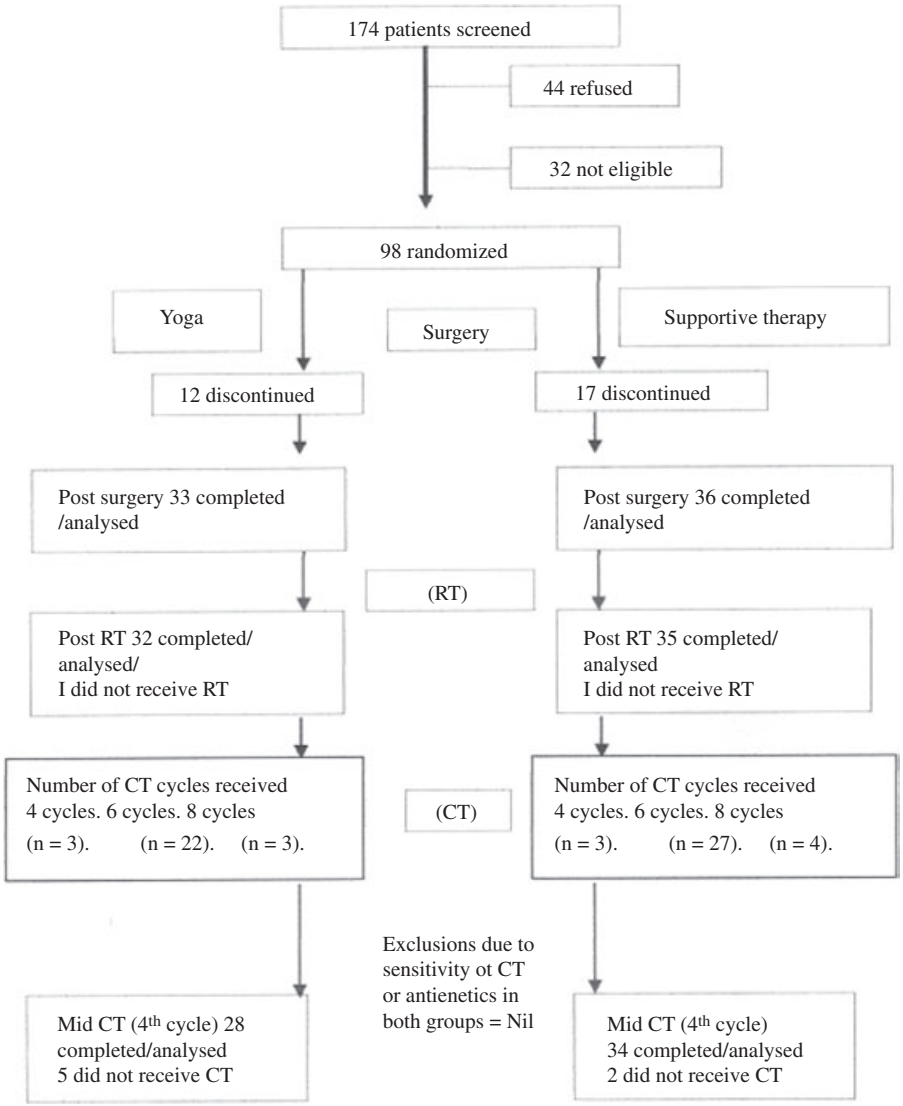

Figure 1. Patient flow chart. CT, chemotherapy; RT, radiotherapy.

intravenous odansetron, with 8-mg dexamethasone given as a bolus injection 30 min before chemotherapy. This was followed by per-oral administration of either 8-mg odansetron (Emeses) bid for the next 3 days after chemotherapy or 10-mg domperidone (Doomster) qid for 2 days to control delayed nausea and vomiting. Some subjects in the study were also prescribed anxiolytic medication, such as lorazepam (Aprazolam 0.5 mg o.d.), by the medical oncologists, who were blinded to the intervention.

During the chemotherapy protocol, subjects in both groups were given intervention before starting their first adjuvant chemotherapy cycle. Subjects who were on chemotherapy were given a bolus injection of dexamethasone 8 mg, with odansetron 8 mg intravenous 30 min before chemotherapy. Thereafter, subjects in the yoga group were taught bedside yoga relaxation by the instructor for the next 30 min, while the participants and their spouses in the control group were educated about chemotherapy-related nausea and vomiting, food aversions, nutrition, etc., and were counselled by the same yoga instructor, who was trained in counselling cancer patients. Thereafter, subjects in the yoga group were provided with audio and video cassettes of the yoga modules for home practice and were asked to practise them every day for 1 h. Their practice was also supervised once in 10 days by their trainer through house visits. The supportive counselling and coping preparation sessions were of 60-min duration initially and lasted 30 min for the control group, given during their hospital visits for chemotherapy and investigations (once in 10 days). After each chemotherapy infusion, patients were prescribed antiemetic regimens as described above. They were asked to note down the episodes of vomiting and nausea duration after every cycle of chemotherapy and, at the fourth cycle, they were asked to complete the Morrow Assessment of Nausea and Emesis (MANE) questionnaire, State Trait Anxiety Inventory

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(STAI), Beck's Depression Inventory (BDI), Functional Living Index for Cancer (FLIC) and symptom checklist questionnaires.

Sixty-two patients (yoga $n = 28$; control $n = 34$) contributed data for the current analysis during chemotherapy. Signed informed consent was obtained from all participants.

Measures

During the initial visit, demographic information, including age, marital status, education, occupation, obstetric and gynaecological history, medical history and intake of medications, was obtained, and clinical data were abstracted on the history of breast cancer, investigative notes and chemotherapy treatment regimen. The following self-report questionnaires were distributed to the subjects during the study.

The primary outcome measures were frequency and intensity of both post-chemotherapy and anticipatory nausea and vomiting assessed using the MANE scale. The test–retest reliability of this descriptive scale has been reported to range from 0.72 to 0.96 with different cancer patient samples and different chemotherapy protocols (Morrow 1992). Subjects were administered this questionnaire after the fourth chemotherapy cycle as anticipatory nausea and emesis, which are learned responses to chemotherapy, develop by about the fourth cycle in 25% of the patients (Morrow & Rosenthal 1996).

The secondary outcome measures were anxiety state and trait assessed using standard instruments such as Spielberger's STAI (Spielberger *et al*. 1970), depression using BDI (Beck *et al*. 1961) and global quality of life assessed using FLIC (Schipper *et al*. 1984). Subjective symptom checklist was developed during the pilot phase to assess treatment-related side effects, problems with sexuality and image, and relevant psychological and somatic symptoms. The checklist consisted of 31 items, each evaluated on two dimensions: severity, graded from no to very severe (0–4), and distress, graded from not at all to very much (0–4). This scale measured the total number of symptoms experienced, total and mean severity and distress, and was evaluated previously in a similar breast cancer population (Bhaskaran 1996). Finally, treatment-related toxicity and side effects were objectively analysed by the investigators using the World Health Organization (WHO, 1979) Toxicity Criteria during chemotherapy. These secondary outcome measures were used to study relationships between the psychological states, frequency and intensity of post-chemotherapy and anticipatory nausea and vomiting. Assessments were carried out before starting the first cycle of chemotherapy, during the mid-cycle and after chemotherapy, except for MANE and WHO Toxicity Criteria, which was assessed following the fourth cycle of chemotherapy.

Interventions

The intervention group received an 'integrated yoga programme' and the control group received 'supportive counseling and coping preparation'. The yoga intervention consisted of a set of *asanas* (postures done with awareness) breathing exercises, *pranayama* (voluntarily regulated nostril breathing), meditation and yogic relaxation techniques with imagery. These practices were based on principles of attention diversion, mindful awareness and relaxation to cope with day-to-day stressful experiences. The yoga intervention was tailored to the patient's needs during chemotherapy infusion and home practice. The yoga session was conducted 30 min before the start of chemotherapy infusion. This session consisted of yogic relaxation, meditation using breath awareness and impulses of touch emanating from palms and fingers, or chanting a mantra from a Vedic text for 30 min. These sessions were administered by an instructor at the subject's bedside before chemotherapy infusion. Subjects were also provided with audiotapes of these exercises for home practice, using the instructor's voice, so that a familiar voice could be heard on the cassette. The subjects were asked to practise daily for 1 h for 6 days/week as homework during the intervals between chemotherapy cycles. They were required to practise a minimum of 3 h per week, but were told to practise for 6 h per week in their homes. These home sessions started with a few easy yoga postures, breathing exercises and *pranayama* (voluntarily regulated nostril breathing), and yogic relaxation. After this preparatory practice for about 20 min, the subjects were guided through any one of the meditation practices for the next 30 min, which included focusing awareness on sounds and chants from Vedic texts, or breath awareness and impulses of touch emanating from palms and fingers while practising yogic mudras, or a dynamic form of meditation that involved practising with eyes closed of four yoga postures interspersed with relaxation while supine, thus achieving a combination of both 'stimulating' and 'calming' practice. These sessions were followed by informal individual counselling sessions, which focused on problems related to impediments in home practice, clarification of the participant's doubts, motivation, education and supportive interaction with spouses. The participants were also informed about practical day-to-day application of awareness and relaxation to attain a state of equanimity during

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stressful situations, and were given homework in learning to adapt to such situations in their daily life by applying these principles.

The subjects were encouraged to practise one of these meditation techniques daily, were given booklets and instructions on these practices, and were encouraged to pursue relevant themes and gain greater depth through proficiency in practice. Their homework was monitored daily by their instructor, who conducted house visits (once in 10 days), and participants were encouraged to maintain a daily log, listing the yoga practices done, use of audiovisual aids for practice, duration of practice, experience of distressful symptoms, intake of medication and diet history.

The control intervention consisted of a psychodynamic supportive–expressive therapy with coping preparation. Supportive–expressive counselling sessions also included education as an important component. We chose to have this as a control intervention mainly to control for the non-specific effects of the yoga programme that may be associated with adjustment, such as attention, support and a sense of control. We also incorporated coping preparation sessions as a control intervention along with supportive–expressive therapy to enhance patients' knowledge of their disease and treatment options, thereby reducing any apprehensions and anxiety regarding their treatment. This coping preparation consisted of a single 60-min session held at the treatment clinic before the start of the first chemotherapy cycle. Family members were invited to join the patient during the session, which included a tour of the oncology clinic and treatment area, describing the chemotherapy procedure, providing information about a variety of common questions, showing a patient coping successfully with the treatment, and finally, providing dietary advice and taking questions and answers. These didactic educational interventions are known to serve as an effective coping preparation in controlling chemotherapy-related side effects (Burish & Tope 1992).

This counselling was extended over the course of the patients' chemotherapy cycles during their hospital visits (30-min sessions, once in 10 days). Subjects in the supportive therapy group also completed daily logs or diaries on episodes of nausea and vomiting. This therapy mainly involved preparing the patient to adequately cope with chemotherapy side effects, such as nausea and emesis. Similar supportive sessions have been used successfully as a control comparison group to evaluate psychotherapeutic interventions (Jacobs *et al*. 1983; Greer *et al*. 1992), and similar coping preparations have been effective in controlling chemotherapy-related nausea and emesis (Burish *et al*. 1991). All subjects had received either yoga intervention or supportive counselling and coping preparation earlier during their surgery and radiotherapy period, and were followed up with their respective interventions during chemotherapy.

Data analysis

Data were analysed using Statistical Package for Social Sciences version 10.0. Descriptive statistics were used with all questionnaires of the study to summarize the data. Wherever differences between groups were sought, independent samples *t*-tests were used for analysis. Pearson correlation coefficient was used to study the relationship and associations between various primary and secondary outcome measures.

RESULTS

Sixty-two subjects (yoga $n = 28$; control $n = 34$) received their prescribed chemotherapy cycles. The age, stages of disease, grade and node status were similar in the yoga and control groups, which received chemotherapy. The mean years of education were 10.4 ± 5 and 13.5 ± 3 years in the yoga and control groups respectively. Subjects were put on a chemotherapy treatment protocol of either FAC, CMF or CMF + FAC, conforming to the standard clinical protocol followed during that time at the hospital. All subjects were ambulatory and had a Zubrod's performance status score of 0–2. All patients had prior mastectomy, 38 subjects had received radiotherapy before chemotherapy, and 24 subjects received chemotherapy as the first adjuvant following mastectomy. A majority of the subjects (90.3%) received six or more cycles of chemotherapy, and six (9.7%) received only four cycles of chemotherapy. The two groups did not differ with respect to age, stage of disease, tumour grade, menopausal status, chemotherapy regimen, number of chemotherapy cycles and antiemetic regimen. Twenty-nine (47%) subjects were on antidopaminergics (domperidone), and 33 (53%) were on odansetron. Medical oncologists who were blinded to the intervention prescribed anxiolytic medication (lorazepam) (Alprazolam) 0.5 mg bid to 22 subjects: 12 (35.3%) in controls and 10 (28%) in the experimental group. A goodness-of-fit test between the socio-demographic and medical characteristics of the study sample revealed no significant differences between the two groups in any of the characteristics examined ($P > 0.05$) (Table 1).

Overall, the administration of anxiolytic medication, chemotherapy treatment regimens (CMF/FAC) and antiemetic regimens (antidopaminergics/5-HT_3 receptor

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Table 1. Medical characteristics of the study population

	Yoga group ($n = 28$) *n* (%)	Control group ($n = 34$) *n* (%)	All subjects ($n = 62$) *n* (%)	*P*-value
Stage of breast cancer				
II	16 (57.1)	14 (41.1)	30 (48.4)	NS
III	12 (42.9)	20 (58.8)	32 (51.6)	
Grade of tumour				
I	1 (3.5)	0 (0)	1 (1.6)	NS
II	5 (17.8)	2 (5.9)	7 (11.2)	
III	22 (78.6)	32 (94.1)	54 (87.1)	
Menopausal status				
Pre-menopausal	18 (64.2)	13 (38.2)	31 (50.0)	NS
Post-menopausal	8 (28.6)	20 (58.8)	28 (45.2)	
Perimenopausal	1(3.5)	0 (0)	1 (1.6)	
Post-hysterectomy	1 (3.5)	1 (2.9)	2 (3.2)	
CT regimen				
FAC	17 (60.7)	18 (52.9)	35 (56.4)	NS
CMF	10 (35.7)	11 (32.4)	21 (33.9)	
FAC + CMF	1 (3.5)	5 (14.7)	6 (9.7)	
Number of CT cycles				
6	22 (78.6)	27 (79.4)	49 (79.0)	NS
8	3 (10.7)	4 (11.8)	7 (11.3)	
4	3 (10.7)	3 (8.8)	6 (9.7)	
Treatment regimen				
S + RT + CT	18 (64.2)	20 (58.8)	38 (61.3)	NS
S + CT + RT	2 (7.1)	2 (5.9)	4 (6.5)	
S + CT3 + RT + CT3	7 (25.0)	10 (29.4)	17 (27.4)	
S + CT	1 (3.5)	2 (5.9)	3 (4.8)	
Antiemetic regimen				
5-HT_3 receptor antagonists	15 (54)	18 (53)	33 (53)	NS
Antidopaminergic	13 (46)	16 (47)	29 (47)	NS
Anxiolytic administration				
Yes	13 (46.4)	17 (50)	30 (48.4)	NS
No	15 (53.6)	17 (50)	32 (51.6)	

NS, not significant for goodness-of-fit test.
CT, chemotherapy; RT, radiotherapy; S, surgery.

antagonists) had no significant influence on measures of nausea and emesis as assessed using the MANE questionnaire. Overall, there was a significant influence only for age group on nausea frequency, with subjects aged less than 50 years having a greater frequency of nausea than those more than 50 years old (Table 2).

Post-chemotherapy-related nausea and vomiting

The severity of post-chemotherapy-related vomiting was mild to moderate in both the groups, and nausea severity was moderate to severe in controls and mild to moderate in the yoga group. Anticipatory vomiting was very mild in both groups, and nausea was mild to moderate in controls and very mild in the yoga group as seen with any moderately emetogenic treatment. Both the groups received antiemetics for an average of 2.6 ± 0.5 days.

Independent samples *t*-tests on MANE scores showed that yoga intervention significantly reduced post-chemotherapy nausea frequency ($t = 2.587$, $P = 0.01$) and nausea severity ($t = -2.670$, $P = 0.01$), but not frequency of vomiting and severity, even though they tended to decrease more so in the yoga group as compared with controls (Table 3).

Pearson correlation analysis was performed to see the relationship between MANE scores, anxiety states, depression, symptom number, severity and distress, chemotherapy-related toxicity and global quality-of-life scores during the mid-cycle of chemotherapy. Post-chemotherapy-related nausea frequency, nausea severity, vomiting frequency and severity correlated significantly and positively with anxiety state, depression, chemotherapy-related toxicity and distressful symptoms, and inversely with quality of life. The correlation was not significant for chemotherapy regimen and number of chemotherapy cycles (Table 4).

Anticipatory nausea and vomiting (Tables 2,4,5)

Independent samples *t*-tests on anticipatory nausea and vomiting showed a significant reduction in anticipatory

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Table 2. Influence of age group (<50 years or >50 years), chemotherapy treatment regimen, class of antiemetic treatment regimen and days of oral antiemetic administration following chemotherapy on measures of Morrow Assessment of Nausea and Emesis (MANE)

MANE outcome measure	Nausea intensity	Nausea frequency	Vomiting frequency	Vomiting intensity	An Nau frequency	An Nau intensity	An Vom frequency	An Vom intensity
Age group								
<50 years ($n = 33$), mean ± SD	2.79 ± 1.2	4.45 ± 1.2	2.76 ± 1.4	1.94 ± 1.3	1.79 ± 1.2	1.13 ± 1.5	1.33 ± 0.96	0.63 ± 1.2
>50 years ($n = 29$), mean ± SD	2.97 ± 1.3	3.72 ± 1.4	2.45 ± 1.4	1.86 ± 1.3	1.45 ± 1.1	1.21 ± 1.3	0.97 ± 0.5	0.57 ± 0.9
t-value	–0.56	2.25	0.87	0.24	1.14	–0.24	1.86	0.22
d.f.	60	60	60	60	60	58	58	56
P-value	0.58	0.028	0.39	0.81	0.26	0.81	0.07	0.83
CT regimen								
FAC ($n = 35$), mean ± SD	2.94 ± 1.2	4.11 ± 1.3	2.56 ± 1.2	1.86 ± 1.13	1.58 ± 1	1.08 ± 1.3	1.06 ± 0.5	0.48 ± 0.83
CMF ($n = 21$), mean ± SD	2.7 ± 1.3	3.95 ± 1.5	2.55 ± 1.5	1.75 ± 1.3	1.80 ± 1.4	1.47 ± 1.5	1.4 ± 1.19	0.89 ± 1.5
t-value	0.70	0.42	0.02	0.33	–0.66	–0.97	–1.76	–1.28
d.f.	54	54	54	54	54	53	54	50
P-value	0.49	0.68	0.99	0.75	0.51	0.36	0.084	0.28
Class of antiemetic treatment								
$5HT_3$ receptor antagonists ($n = 33$), mean ± SD	2.94 ± 1.3	4.09 ± 1.3	2.52 ± 1.4	1.7 ± 1.9	1.55 ± 1	124 ± 1.4	1.03 ± 0.5	0.55 ± 0.89
Antidopaminergics ($n = 29$), mean ± SD	2.8 ± 1.2	4.14 ± 1.5	2.72 ± 1.4	2.14 ± 1.3	1.72 ± 1.4	1.07 ± 1.5	1.31 ± 1.0	0.67 ± 1.3
t-value	0.46	–0.14	–0.59	–1.39	–0.59	0.46	–1.39	–0.49
d.f.	60	60	60	60	60	60	60	56
P-value	0.64	0.89	0.56	0.17	0.56	0.65	0.17	0.68
No. of days of antiemetic administration								
2 days ($n = 25$), mean ± SD	2.64 ± 1.3	4.28 ± 1.3	2.6 ± 1.4	2 ± 1.4	1.76 ± 1.5	1.09 ± 1.6	1.28 ± 1.06	0.63 ± 1.4
3 days ($n = 37$), mean ± SD	3.03 ± 1.2	4.0 ± 1.33	2.62 ± 1.4	1.84 ± 1.1	1.54 ± 0.96	1.22 ± 1.3	1.08 ± 0.55	0.59 ± 0.89
t-value d.f	–1.21	0.82	–0.059	0.49	0.72	–0.34	0.97	0.13
	60	60	60	60	60	58	60	60
P-value	0.23	0.42	0.95	0.64	0.51	0.73	0.39	0.90

An Nau, anticipatory nausea; An Vom, anticipatory vomiting; CT, chemotherapy; RT, radiotherapy; SD, standard deviation.

Table 3. Independent samples *t*-test on measures of Morrow Assessment of Nausea and Emesis scores between yoga and control groups during CT

Groups	Yoga group ($n = 28$) Mean ± SD	Control group ($n = 34$) Mean ± SD	*t*-value (d.f.)	*P*-value
Post-CT nausea frequency	3.6 ± 1.6	4.5 ± 0.9	–2.67 (60)	0.01
Post-CT nausea intensity	2.3 ± 1.2	3.4 ± 1.1	–3.71 (57)	<0.001
Post-CT vomiting frequency	2.3 ± 1.4	2.9 ± 1.4	–1.9 (58)	0.06
Post-CT vomiting intensity	1.6 ± 1.0	2.2 ± 1.4	–1.99 (60)	0.05
Anticipatory nausea frequency	1.3 ± 0.98	1.9 ± 1.3	–1.9 (60)	0.06
Anticipatory nausea intensity	0.6 ± 1.03	1.7 ± 1.5	–3.17 (55)	0.003
Anticipatory vomiting frequency	1.1 ± 0.88	1.2 ± 0.73	–0.476 (53)	0.63
Anticipatory vomiting intensity	0.3 ± 0.67	0.87 ± 1.3	–2.05 (56)	0.04

CT, chemotherapy; SD, standard deviation.

Table 4. Pearson correlation between Morrow Assessment of Nausea and Emesis measures, mood states, quality of life and toxicity scores during chemotherapy

	Pearson correlation coefficient values, *r*							
All subjects ($n = 62$)	Nausea frequency	Nausea intensity	Vomiting frequency	Vomiting intensity	An Nau frequency	An Nau intensity	An Vom frequency	An Vom intensity
STAI score	0.29*	0.56**	0.42**	0.43**	0.50**	0.59**	0.27*	0.50*
BDI score	0.38**	0.53**	0.441**	0.41**	0.38**	0.39**	0.14	0.33*
Symptom distress score	0.50**	0.62**	0.44**	0.35**	0.37**	0.35**	0.28*	0.19
FLIC score	–0.46**	–0.59**	–0.50**	–0.37**	–0.47**	–0.43**	–0.32*	–0.34*
CT regimen	0.17	0.01	0.12	0.14	0.01	0.04	0.08	0.09
No. of CT cycles	0.08	–0.06	–0.12	0.03	–0.07	0.03	0.00	0.05
Mid CT toxicity score	0.37**	0.47**	0.36**	0.42**	0.30*	0.30*	0.23	0.27*

*$P < 0.05$, **$P < 0.01$.

An Nau, anticipatory nausea; An Vom, anticipatory vomiting; BDI, Beck's Depression Inventory; CT, chemotherapy; FLIC, Functional Living Index for Cancer; STAI, State Trait Anxiety Inventory.

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nausea frequency ($t = 1.979$, $P = 0.053$), nausea severity ($t = -3.08$, $P = 0.003$) and vomiting severity ($t = -2.056$, $P = 0.044$) in the yoga group as compared with controls (Table 3).

Anticipatory nausea frequency and severity correlated significantly and positively with anxiety state, depression, chemotherapy-related toxicity and distressful symptoms, and inversely with quality of life. Anticipatory vomiting frequency correlated significantly and positively with anxiety state and distressful symptoms, and inversely with quality of life. Severity of anticipatory vomiting correlated significantly and positively with anxiety state, depression and chemotherapy-related toxicity, and inversely with quality of life (Table 4).

Approximately 35% of the subjects in the study received anxiolytic administration in both the groups. Administration of anxiolytic tended to be beneficial in reducing the severity of post-chemotherapy vomiting overall in both the groups ($t = 4.04$, $P < 0.001$), and individually in the intervention ($t = 2.147$, $P = 0.04$) and control groups ($t = 3.39$, $P = 0.002$). Anxiolytics were also effective in reducing nausea severity ($t = 2.01$, $P = 0.05$) and anticipatory nausea frequency ($t = 2.56$, $P = 0.016$) in the control group alone (Table 5).

When intervention effects were compared in the sample who did not use anxiolytics, the interventions were found to reduce significantly post-treatment related nausea frequency ($t = 2.03$, $P = 0.05$) and severity ($t = 3.42$, $P = 0.002$), and vomiting frequency ($t = 2.16$, $P = 0.039$) and severity ($t = 2.29$, $P = 0.03$). Yoga intervention was also effective in significantly reducing anticipatory nausea severity ($t = 2.49$, $P = 0.02$) and anticipatory vomiting severity ($t = 2.77$, $P = 0.01$) (Table 6).

Table 5. Effects of anxiolytic administration on measures of Morrow Assessment of Nausea and Emesis in each group and in the overall study sample.

	Nausea intensity	Nausea frequency	Vomiting frequency	Vomiting intensity	An Nau frequency	An Nau intensity	An Vom frequency	An Vom intensity
Administration of anxiolytics								
Yoga group								
Yes ($n = 10$), mean ± SD	2.22 ± 1.2	3.3 ± 1.6	2.06 ± 1.4	1.28 ± 0.89	1.22 ± 1	0.61 ± 1.0	1.1 ± 1.08	0.22 ± 0.55
No ($n = 18$), mean ± SD	2.4 ± 1.1	4.2 ± 1.5	2.6 ± 1.2	2.1 ± 1.1*	1.5 ± 0.97	0.6 ± 1.1	1.1 ± 0.32	0.44 ± 0.88
Control group								
Yes ($n = 14$), mean ± SD	3.05 ± 1.1	4.35 ± 0.93	2.55 ± 1.32	1.60 ± 0.88	1.45 ± 1.1	1.28 ± 1.13	1.15 ± 0.59	0.56 ± 0.78
No ($n = 20$), mean ± SD	3.79 ± 1.1*	4.71 ± 0.8	3.43 ± 1.34	3.0 ± 1.52**	2.5 ± 1.3*	2.14 ± 1.83	1.29 ± 0.91	1.31 ± 0.75
Overall								
Yes ($n = 24$), mean ± SD	2.7 ± 1.9	3.87 ± 1.4	2.32 ± 1.3	1.45 ± 0.89	1.3 ± 1.0	0.94 ± 1.1	1.13 ± 0.84	0.39 ± 0.69
No ($n = 38$), mean ± SD	3.21 ± 1.3	4.50 ± 1.1	3.1 ± 1.3	2.63 ± 1.4	2.08 ± 1.3	1.5 ± 1.7	1.21 ± 0.72	0.95 ± 1.5
t-value	1.74	1.87	2.17	4.04	2.52	1.51	0.36	1.96
d.f.	60	60	60	60	60	58	60	56
P-value	0.087	0.067	0.034	<0.001	0.014	0.134	0.714	0.055

An Nau, anticipatory nausea; An Vom, anticipatory vomiting.
*p < 0.05.
**p < 0.01.

Secondary outcome measures (Table 7)

There was a significant decrease in reactive anxiety states, depression, number of treatment-related distressful symptoms, severity of symptoms and distress experienced, and improvement in quality of life during chemotherapy in the yoga group as compared with controls.

Common toxicity criteria (Table 3)

Common toxicity criteria guidelines were used to evaluate the chemotherapy-induced systemic and organ toxicity. Both systemic and organ toxicity were graded from 0 to 4 (no toxicity to very severe toxicity) using clinical notes and laboratory data , and the total score was extrapolated. Independent samples *t*-test showed the yoga group with significantly reduced toxicity scores as compared with controls ($t = -4.1$, $P < 0.001$).

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Table 6. Effects of intervention on measures of Morrow Assessment of Nausea and Emesis in subjects not on anxiolytic medication during chemotherapy

	Nausea intensity	Nausea frequency	Vomiting frequency	Vomiting intensity	An Nau frequency	An Nau intensity	An Vom frequency	An Vom intensity
Yoga group ($n = 15$), mean ± SD	2.07 ± 1.0	3.4 ± 1.6	2.07 ± 1.4	1.13 ± 0.8	1.27 ± 1	0.53 ± 0.92	1.13 ± 1.1	0.13 ± 0.35
Control group ($n = 17$), mean ± SD	3.41 ± 1.2	4.35 ± 0.9	3.12 ± 1.3	1.88 ± 0.9	2.5 ± 1.3	2.14 ± 1.83	1.29 ± 0.91	1.31 ± 1.75
t-value	1.74	1.87	2.17	4.04	2.52	1.51	0.36	1.96
d.f.	60	60	60	60	60	58	60	56
P-value	0.087	0.067	0.034	<0.001	0.014	0.134	0.714	0.055

An Nau, anticipatory nausea; An Vom, anticipatory vomiting.

Table 7. Comparison of scores of STAI, BDI, symptom number, severity, distress and FLIC during chemotherapy in yoga and control groups

Secondary outcome measure	Yoga ($n = 28$) Mean ± SD	Control ($n = 34$) Mean ± SD	*t*-value	d.f	*P*-value
STAI – anxiety state score	29.2 ± 3.8	37.5 ± 7.6	–5.18	59	<0.001
Beck's depression score	6.6 ± 4.6	14.2 ± 6.6	–5.50	57	
Number of distressful symptoms	11.4 ± 4.5	14.7 ± 3.6	–3.34	53	0.002
Severity of symptoms	17.6 ± 9.3	27.3 ± 9.2	–3.89	58	<0.001
Symptom distress	16.6 ± 10.1	29.9 ± 11.2	–4.70	59	<0.001
FLIC – overall quality of life	142.1 ± 10.2	111.7 ± 25.5	6.48	59	<0.001
Total toxicity score	7.3 ± 2.7	11.1 ± 4.3	–4.1	56	<0.001

BDI, Beck's Depression Inventory; FLIC, Functional Living Index for Cancer; STAI, State Trait Anxiety Inventory.

DISCUSSION

The results of the study suggest that yoga intervention helped reduce post-chemotherapy-related nausea and anticipatory nausea and vomiting compared with supportive therapy and coping preparation in stage II and III breast cancer subjects receiving adjuvant chemotherapy. There was a trend towards reduction in post-chemotherapy-related vomiting in the yoga group.

Yoga intervention helped significantly to reduce the frequency and intensity of post-chemotherapy nausea by 18% as compared with the supportive therapy group. Our intervention was also helpful in significantly reducing the frequency and intensity of anticipatory nausea by 12% and 18%, and vomiting intensity by 9% as compared with controls. Even though yoga intervention helped reduce the frequency and intensity of post-chemotherapy vomiting by 13% and 10% and anticipatory vomiting frequency by 2% compared with controls, the effects were not significant. However, when the effects of intervention were compared in the yoga and control groups, which did not receive anxiolytic medications, yoga intervention decreased nausea intensity by 39%, nausea frequency by 21.8%, vomiting frequency by 33.65%, vomiting intensity by 39.9%, anticipatory nausea intensity by 63.2%, and anticipatory vomiting intensity by 83%. These results indicate that addition of anxiolytics may have created a floor effect (Razavi *et al*. 1993), masking the actual effects of yoga intervention. Furthermore, these results also indicate that yoga may have had a significant anxiolytic effect in subjects who were not on any anxiolytic medication.

Another reason why the intervention was not effective in reducing post-treatment vomiting could be that administration of 5-HT_3 receptor antagonist class of antiemetics may have significantly decreased the episodes of vomiting but increased the frequency and duration of nausea (Roscoe *et al*. 2000). Our results are similar to the studies reviewed by Burish and Tope (1992), in which supportive therapy and coping preparation interventions have been beneficial in reducing the conditioned side effects of chemotherapy.

Our results are similar to other studies using behavioural interventions that have shown reductions in anticipatory and post-chemotherapy-related nausea and emesis, anxiety and levels of distress associated with chemotherapy (Redd *et al*. 2001; Mundy *et al*. 2003). Our results are also in congruence with other studies using relaxation that have shown decreases in the frequency and duration of chemotherapy-related nausea and emesis (Burish & Tope 1992; Arakawa 1997; Molassiotis *et al*. 2002). However, the effect sizes seen with our intervention on nausea and vomiting variables was larger compared to above studies using relaxation. We could attribute these effects to two reasons. First, unlike earlier studies using relaxation intervention, where subjects were followed up over a single chemotherapy cycle, interventions in our study were given over the complete course of chemother-

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apy. Second, subjects in both the groups were given the intervention much before the commencement of chemotherapy, during their surgery and radiotherapy. This long-term intervention may have contributed to increasing benefits resulting from our intervention against the earlier studies using relaxation.

This long-term intervention may have also helped in improving quality of life and reducing anxiety, depression, distressful symptoms and treatment-related toxicity. Thus, maintenance of such interventions over a longer period could enhance the care provided to cancer patients and help them control the undesirable effects of chemotherapy.

One of the major limitations of this study was that management of delayed emesis was not according to current guidelines and consensus statements, as this study was carried out much before the publication of these guidelines (Gralla *et al*. 1999). Thus, the results of this study may be applicable only to chemotherapy patients with a poor control of delayed nausea and emesis. Second, subjects in the control group were offered supportive counselling and coping preparation less frequently than their counterparts who received yoga intervention, and this discrepancy in the duration of interventions could account for the significant differences seen between the groups. However, it should be noted that most of these CAM interventions are time-intensive and involve more contact hours than these standard supportive therapy sessions. For practical purposes, this difference was acceptable, as we are using supportive therapy interventions only with an intention of negating the confounding variables, such as social support, attention, education and self-control, which are known to improve the psychological and social functioning of cancer patients (Roscoe *et al*. 2000). Since both the groups received the same supportive therapy and coping preparation programme, in addition to yoga intervention in the yoga group, it is possible to attribute the effects of the yoga programme to stress reduction rather than supportive care. However, because of the desire to incorporate support and education in the yoga programme, it is not clear whether a yoga programme without support and education would have resulted in the same benefits. Third, subjects were given yoga intervention much before the start of chemotherapy during surgery and radiotherapy, and pre-exposure to interventions before chemotherapy may have reduced the responses of patients to conditioning stimuli during chemotherapy. This may also be the reason why our intervention was better than coping preparation and counselling which had the same beneficial effects as progressive muscle relaxation training in earlier studies (Burish *et al*. 1991). Finally, because of the overlap with physical symptoms of cancer, the use of BDI and STAI in cancer populations has its limitations and results should be interpreted with caution.

Overall, the beneficial effects observed in this study can be attributed to yoga practices that helped in stress reduction, rather than to mere social support and education. This is consistent with other behaviourally orientated programmes, which have shown better results with stress reduction than with purely supportive interventions (Telch & Telch 1986; Vasterling *et al*. 1993). It is in this context that our study has been able to elucidate the effects of a yoga-based stress reduction programme.

Several studies mentioned above have demonstrated the effectiveness of attention-diversion strategies for the reduction of stress and pain. It is likely that relaxation and deep somatic restfulness induced by yoga practices may reduce anxiety, physiological arousal and stress associated with chemotherapy and prevent the exacerbation of responses induced by post-chemotherapy nausea and vomiting, thereby reducing the general feelings of distress. The yoga postures may have also helped reduce muscular contractions in the gastrointestinal tract (Taneja *et al*. 2004) that accompany post-chemotherapy nausea and vomiting, or may have decreased the sensitivity of chemoreceptor trigger zone to vomiting response (stimuli) (Borison & McCarthy 1983).

This indicates that yoga probably shares some common techniques with other behavioural interventions that influence pathways from stress to somatic symptoms. Yoga is one such intervention, which is gaining popularity among the Indian masses, and oncology clinics could adopt these interventions by training nurses involved in cancer care. Approximately 56% of the cancer patients in a developing country like India take recourse to complementary and alternative therapies with an intention to gain benefit and not because of dissatisfaction with conventional treatment (Gupta *et al*. 2002). The popular beliefs associated with these treatments have helped cancer patients to adopt healthy self-care behaviours. Use of these interventions in a hospital setting could help complement the effects of conventional antiemetic treatments in managing chemotherapy-related nausea and emesis. These interventions can be particularly useful in the Indian context and in developing countries where subjective concerns regarding treatment-related side effects are not given due their concern. Moreover, infrastructure for offering supportive care and cancer support groups rarely exists, and access to care is not affordable for the majority of the cancer population.

In summary, our yoga-based intervention was more effective in reducing post-chemotherapy and anticipatory

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nausea compared with supportive therapy and coping preparation. Yoga intervention served as a useful additive to antiemetic treatment in reducing post-chemotherapy and anticipatory vomiting. However, larger experimental studies under controlled conditions are required to validate our findings.

ACKNOWLEDGEMENTS

This research was supported by a grant from the Central Council for Research in Yoga and Naturopathy, Ministry of Health and Family Welfare, Government of India. We are thankful to Dr Jayashree and Mrs Anupama for imparting the yoga intervention.

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