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Effects of yoga program on quality of life and affect in early breast cancer patients undergoing adjuvant radiotherapy: A randomized controlled trial[☆]

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KEYWORDS

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Summary

Objectives: This study compares the effects of an integrated yoga program with brief supportive therapy in breast cancer outpatients undergoing adjuvant radiotherapy at a cancer centre.

Methods: Eighty-eight stage II and III breast cancer outpatients were randomly assigned to receive yoga ($n = 44$) or brief supportive therapy ($n = 44$) prior to their radiotherapy treatment. Intervention consisted of yoga sessions lasting 60 min daily while the control group was imparted supportive therapy once in 10 days. Assessments included European Organization for Research in the Treatment of Cancer-Quality of Life (EORTCQoL C30) functional scales and Positive and Negative Affect Schedule (PANAS). Assessments were done at baseline and after 6 weeks of radiotherapy treatment.

Results: An intention to treat GLM repeated measures ANOVA showed significant difference across groups over time for positive affect, negative affect and emotional function and social function. There was significant improvement in positive affect ($ES = 0.59$, $p = 0.007$, 95%CI 1.25 to 7.8), emotional function ($ES = 0.71$, $p = 0.001$, 95%CI 6.45 to 25.33) and cognitive function ($ES = 0.48$, $p = 0.03$, 95%CI 1.2 to 18.5), and decrease in negative affect ($ES = 0.84$, $p < 0.001$, 95%CI -13.4 to -4.4) in the yoga group as compared to controls. There was a significant positive correlation between positive affect with role function, social function and global quality of life. There was a significant negative correlation between negative affect with physical function, role function, emotional function and social function.

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Conclusion: The results suggest a possible role for yoga to improve quality of life and affect in breast cancer outpatients.

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Introduction

Quality of life is an important concern and outcome of cancer treatment. Several studies have documented that both diagnosis and treatment of breast cancer have an impact on quality of life.^{1,2} Further, there is evidence to suggest that decrements in quality of life are related to treatment related distress and psychological well being.^{2,3} Various dimensions of quality of life such as physical, emotional, social, functional and spiritual well being are affected in both newly diagnosed and long-term survivors of breast cancer.^{2,4–6} However, growing evidence suggests that psychosocial and psycho-educational interventions are beneficial adjunctive treatments for cancer patients.^{7–11} Patients who have used active behavioral coping methods have reported positive affective states, decrease in anxiety and depression, higher levels of self-esteem and fewer physical symptoms while those with avoidance coping showed greater depression, anxiety and lower quality of life.¹² Similarly mind–body approaches such as prayer, meditation, affirmation, imagery and movement therapies have shown improvements in overall quality of life in cancer patients.^{13–15}

Yoga as a mind–body intervention is being practiced increasingly in both Indian and western populations. It is an ancient Indian science that has been used for therapeutic benefits in numerous health care concerns where stress is believed to play a role.¹⁶ Beneficial effects have been seen on a variety of outcomes, including sleep quality, mood, stress, cancer-related distress, cancer-related symptoms, and overall quality of life, as well as functional and physiological measures. These effects were similar across a number of different therapeutic approaches that employed postures, meditation breathing practices or a combination of all these.¹⁷ The results from these studies are bolstered by several randomized studies using yoga interventions in both healthy and chronically ill populations.^{18–20} Results from recent randomized controlled studies are mixed with one study showing improvement in various quality of life domains in breast cancer population at different stages of cancer treatment²¹ and the other showing no improvement in quality of life domains.²² In both these studies adherence to intervention and contact time for yoga intervention was low compared to our earlier study that has shown decrements in anxiety states²³; reduction in chemotherapy induced nausea and emesis²⁴ and improved immune outcomes.²⁵ In the former adherence seemed to be affected by radiotherapy treatment and distress and in the latter the intervention was based on a different form of yoga intervention known as Tibetan yoga.

Overall effects following yoga or similar interventions have been attributed to an improvement in positive affect and decrease in negative affect.^{26–28} Patients on radiotherapy experience distressing side effects such as fatigue, skin

changes, pulmonary symptoms during radiotherapy and anxiety and depression before, during, and after radiotherapy.²⁹ Reducing treatment related distress and improving quality of life is known to improve adjustment later³⁰ and manage related morbidity that accumulates over time.³¹ Moreover earlier study has shown radiotherapy to predict poorer adherence to yoga intervention.²¹

We hypothesize that yoga intervention would help improve quality of life, improve positive affect and decrease negative affect in stage II and III breast cancer patients undergoing adjuvant radiotherapy.

In this study, we compared the effects of a 6-week ‘‘Integrated yoga program’’ with ‘‘Brief supportive therapy’’ as a control intervention in early operable breast cancer patients undergoing adjuvant radiotherapy.

Methods

Subjects

This randomized control trial recruited 85 recently diagnosed women with stage II and III breast cancer from two different urban cancer centres. All subjects had undergone primary treatment as surgery and were receiving adjuvant radiotherapy. Subjects in this study were recruited over a 2-year period from January 2004 to June 2006. Patients were eligible to participate in this study if they met the following selection criteria at the study start: (i) women with recently diagnosed operable breast cancer, (ii) age between 30 and 70 years, (iii) Zubrod's performance status 0–2 (ambulatory >50% of time), (iv) high school education and, (v) consenting to participate in the study. Subjects were excluded, (i) if they had any concurrent medical condition that was likely to interfere with the treatment, (ii) major psychiatric, neurological illness or autoimmune disorders, and, (iii) any known metastases. Each study participant was prescribed adjuvant radiotherapy with a cumulative dose of 50.4 Gy with fractionations spread over 6 weeks. The details of the study were explained to the participants and their informed consent was obtained in writing.

Randomization

Of the 103 eligible participants 88 (85.4%) consented to participate and were randomized to receive yoga ($n=44$) or supportive therapy ($n=44$) initially before intervention (prior to radiotherapy) using computer generated random numbers. Randomization was performed using opaque envelopes with group assignments. Personnel who had no part in the trial performed randomization. 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 radiation therapy 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.

Sample size

Earlier study with Mindfulness Based Stress Reduction Program (MBSR) had shown a modest effect size ($ES = 0.38$) on EORTC QLC30 global quality of life measure.³² We used G power to calculate the sample size with $\alpha = 0.05$ and $\beta = 0.2$ and above effect size of 0.38 for repeated measures ANOVA between factor effects. The sample size thus required was $n = 44$ in each group.

Among the 88 participants 75 (yoga $n = 42$; control $n = 33$) completed their prescribed radiation therapy of 6 weeks and follow-up assessment. There were 13 dropouts in the study (see trial profile, Fig. 1). The reasons for dropouts were migration to other hospitals ($n = 4$), use of other complementary therapies (e.g. homeopathy or ayurveda) ($n = 2$), refusal to continue the study ($n = 2$), time constraints ($n = 4$) and other concurrent illnesses such as infections delaying radiotherapy and intervention ($n = 1$).

Measures

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

Positive and Negative Affect Schedule (PANAS)

Positive affect and negative affect was assessed using the PANAS scale.³³ PANAS contains two subscales, each consisting of 10 items: positive affect (PA) and negative affect (NA). PA reflects the extent to which a person feels enthusiastic, active, and alert. A high PA score reflects a state of high energy, full concentration, and pleasurable engagement. In contrast, NA is a general dimension of subjective distress with a variety of aversive mood states, and a high NA score indicates more distress. Patients were instructed to indicate how they had been feeling during the last 2 weeks. The reliability of this descriptive scale has been reported to range from 0.86 to 0.90 for PA and from 0.84 to 0.87 for NA.³³

European Organization for Research and Treatment of Cancer-Quality of life C30

Health related quality of life was assessed using the European Organization for the Research and Treatment of Cancer-Quality of Life (EORTCQoL C30 questionnaire version 1).³⁴ This 30-item questionnaire provides a measure on the dimensions of global health status, physical, role, emotional, cognitive and social functioning (with high scores representing good quality of life) and cancer-related symptomatology. The reliability of this descriptive scale during the study has been reported to range from 0.52 to 0.89 for functional and global quality of life scales. Assessments were carried out before and after radiotherapy treatment. However, we report results for only functional quality of life subscales in this study.

Interventions

The intervention group received integrated yoga program and the control group received brief supportive therapy both imparted individually. This integrated yoga program has a combination of a set of *asanas* (postures done with awareness) breathing exercises, *pranayama* (voluntarily regulated nostril breathing), meditation and yogic relaxation that are based on principles of stimulation and relaxation taken from ancient Indian texts called Upanishads. Contrary to the west where yoga is considered to be a form of exercise and various components such as asanas, meditation and breathing exercises are being used separately, in the east these practices are interspersed with a view to developing greater relaxation and internal awareness.³⁵ Subjects develop insight in recognizing inherent tensions and stress responses and learn ways to relax them. This would be particularly useful in cancer patients who perceive cancer as a threat. These practices were based on principles of attention diversion, mindful awareness and relaxation to cope with day-to-day stressful experiences. Participants were asked to attend a minimum of at least three in-person sessions/week for 6 weeks during their adjuvant radiotherapy treatment in the hospital with self-practice as homework on the remaining days. Each of these sessions lasted 1 h and was administered by a trained yoga therapist either before or after radiotherapy. These sessions started with a few easy yoga postures, breathing exercises and *pranayama* (voluntarily regulated nostril breathing), and yogic relaxation. After this prepara-

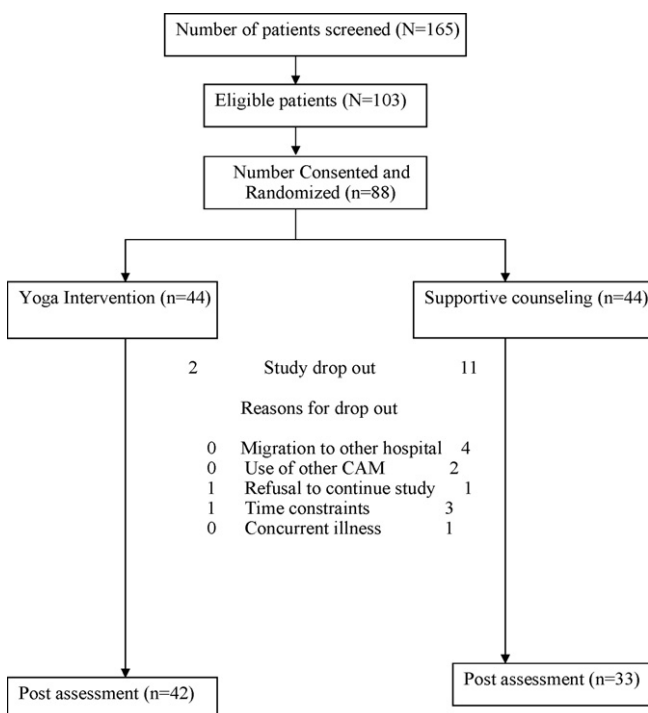


Figure 1 Trial profile.

tory 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,³⁶ or breath awareness and impulses of touch emanating from palms and fingers while practicing yogic mudras, or a dynamic form of meditation that involved practicing with eyes closed of four yoga postures interspersed with relaxation while supine, thus achieving a combination of both 'stimulating' and 'calming' practice.³⁷ The instructions were recorded on an audio tape so that the patients could practice the same at home. The control intervention consisted of brief supportive therapy with education as a component that is routinely offered to patients as a part of their care in this centre. We chose to have this as a control intervention mainly to control for the non-specific effects of the yoga program that may be associated with factors such as attention, support and a sense of control as described in our earlier study.²³ Subjects and their caretakers underwent counseling by a trained social worker (once in 10 days, 15 min sessions) during their hospital visits for adjuvant radiotherapy. The control group received 3–4 such counseling sessions during a 6-week period, where as the intervention group received anywhere between 18

and 24 yoga sessions. Supportive counseling was a part of routine care offered in hospitals. While the goals of yoga intervention were stress reduction and appraisal changes, the goals of supportive therapy were education, reinforcing social support and coping preparation.

Data analysis

Data were analyzed using Statistical Package for Social Sciences version 10.0. Descriptive statistics were used to summarize the data. A GLM repeated measures ANOVA was done with the within-subjects factor being time/assessments at two levels and between-subjects factor being groups at two levels (yoga vs. supportive therapy). Both group by time interaction effects, between-subjects and within-subjects effect were assessed. Post hoc tests were done using Holms–Bonferroni correction for changes at different time points between groups. Intention to treat analysis was also done on the initially randomized sample ($n = 88$) with baseline measure (T1) and post-measure (post-RT, T2) for all participants. Missing value analysis was done using SPSS 16 by regression using the corresponding baseline

Table 1 Demographic and medical characteristics of the initially randomized sample.

	All subjects		Yoga group		Control group	
	$n = 88$	%	$n = 44$	%	$n = 44$	%
Religion						
Hindu	73	83	36	81.8	37	84.1
Muslim	9	10.2	6	13.7	3	6.9
Christian	6	6.8	2	4.5	4	9
Stage of breast cancer						
I	5	5.7	2	4.5	3	6.8
II	18	20.4	11	25.0	7	15.9
III	65	73.9	31	70.5	34	77.3
Grade of breast cancer						
I	1	1.1	1	2.3	0	0
II	33	37.5	21	47.7	10	22.7
III	54	61.4	22	50	34	77.3
Menopausal status						
Pre	48	54.5	26	59.1	23	52.3
Post	40	45.5	18	40.9	21	47.7
Histopathology type						
IDC	72	81.8	37	84.1	35	39.7
ILC	7	7.9	2	4.5	5	11.4
IPC	3	3.4	2	4.5	1	2.2
DCI	2	2.2	2	4.5	0	0
CC	2	2.2	1	2.3	1	2.2
PC	2	2.2	0	0	2	4.5
Regimen						
After ChemoTherapy	68	77.3	32	72.7	37	84
After surgery	20	22.7	12	27.3	7	15.9
Marital status						
Single	2	2.2	1	2.3	1	2.2
Married	86	97.8	43	97.7	43	97.8

IDC- Infiltrating Ductal Carcinoma, IPC- Infiltrating Papillary Carcinoma, ILC- Infiltrating Lobular Carcinoma, CC- Comedo Carcinoma, PC- Papillary Carcinoma.

Table 2 Comparison of scores for affect and functional scales of EORTCQoL C30 scores using GLM repeated measures ANOVA between yoga and control groups.

Outcome variables	Yoga (<i>n</i> = 47)		Control (<i>n</i> = 44)		Effect size, Cohen's <i>f</i>
	Pre-mean (SD)	Post-mean (SD)	Pre-mean (SD)	Post-mean (SD)	
PANAS-positive	24.05 (7.28)	27.85(7.11)**	21.81 (7.37)	23.33(8.3)	0.59
PANAS-negative	22.15 (10.6)	12.91 (10.39)**	25.22 (8.82)	21.85 (10.86)	0.84
Physical function	73.2 (23.2)	73.26 (25.33)	62.72 (30.98)	68.96 (30.12)	0.16
Role function	72.72 (34.86)	79.88 (34.41)	71.59 (36.40)	72.85 (39.94)	0.19
Emotional function	56.45 (19.77)	75.12 (21.16)**	51.58 (17.44)	59.23 (23.32)	0.71
Cognitive function	85.29 (18.0)	90.57 (15.88)*	82.67 (21.12)	80.77 (24.10)	0.48
Social function	52.82 (26.55)	54.96 (23.98)	52.41 (24.43)	49.93 (24.23)	0.21

* *p*-Values < 0.05, for post hoc tests comparing groups at pre and post-radiotherapy using Holms–Bonferroni correction.

** *p*-Values < 0.01, for post hoc tests comparing groups at pre and post-radiotherapy using Holms–Bonferroni correction.

value as predictors. Pearson correlation analyses were used to study the bivariate relationships between quality of life domains and affect.

Results

75 Participants (yoga *n* = 42; control *n* = 33) completed the prescribed radiotherapy regimen. All participants were ambulatory and had a Zubrod's performance status score of 0–2. All patients had mastectomy as primary treatment, 16 subjects received radiotherapy following mastectomy and 59 subjects received radiotherapy following mastectomy and three cycles of chemotherapy. The mean age of the study population in yoga group was (46.7 ± 9.3 years) and control group was (48.5 ± 10.2 years). Majority of subjects belonged to middle class (94.2%) and remaining 5.8% belonged to upper middle class. 9% of the population had some previous exposure to yoga practices though none of them seemed to practice it in the last few years. Participants in both groups were comparable with respect to socio-demographic and medical characteristics (Table 1). All subjects in the intervention group tolerated the intervention with out any adverse events.

Outcome measures

A repeated measures analysis of variance was done using post hoc Holms–Bonferroni correction on positive affect scores. Intention to treat analysis on the initially randomized sample showed significant improvement in PA (Mean difference ± SE, *p*-value, 95%CI) (4.52 ± 1.7, *p* = 0.007, 1.25 to 7.8), decrease in NA (−8.95 ± 2.3, *p* < 0.001, −13.4 to −4.4), improvement in emotional function (15.88 ± 4.75, *p* = 0.001, 6.45 to 25.33) and cognitive function (9.8 ± 4.35, *p* = 0.03, 1.2 to 18.5) in yoga group as compared to controls following intervention. There was a significant improvement in positive affect (−3.81 ± 1.1, *p* < 0.001, 1.75 to 5.89), decrease in negative affect (9.25 ± 1.45, *p* < 0.001, 6.4 to 12.1), improvement in emotional (−18.63 ± 2.8, *p* < 0.001, −24.3 to −12.9) and cognitive function (5.27 ± 2.69, *p* = 0.05, −10.63 to −0.007) in yoga group following intervention (T1–T2). There was also a significant decrease in negative affect (3.37 ± 1.5, *p* = 0.02, 0.49 to 6.24), improvement in

physical function (−6.23 ± 2.9, *p* = 0.03, −11.9 to −0.49) and emotional function (−7.66 ± 2.88, *p* = 0.009, −13.4 to −1.9), in control group following intervention.

There was no significant change in social function and role function following intervention in both the groups (Table 2).

Bivariate relationships

Bivariate relationships were determined between the outcome measures. There was a significant positive correlation between PA with physical function (*p* = 0.002), emotional function (*p* < 0.001), cognitive function (*p* = 0.01), social function (*p* = 0.007) and global quality of life (*p* < 0.001). There was a significant negative correlation between NA with emotional function (*p* < 0.01), physical function (*p* = 0.004), cognitive function (*p* = 0.001), global quality of life (*p* = 0.001) and social function (*p* = 0.008) (Table 3).

Adherence to intervention

Adherence to intervention was good with 29.7% attending 10–20 supervised sessions, 56.7% attending 20–25 supervised sessions and 13.7% attending >25 supervised sessions over a 6-week period. Level of adherence did not seem to affect quality of life or affect scores (results not shown).

Table 3 Pearson correlation (*r*-values) between affect (PANAS) and functional subscales on EORTCQoL C30.

Functional subscales on EORTCQoL C30	PANAS-P, <i>r</i>	PANAS-N, <i>r</i>
Physical function	0.32**	−0.31**
Role function	0.26*	−0.16
Cognitive function	0.27***	−0.35**
Emotional function	0.4***	−0.64***
Social function	0.29**	−0.28**
GQOL	0.50***	−0.36**

p-Values for Pearson correlation coefficients.

* *p* < 0.05.

** *p* < 0.01.

*** *p* < 0.001.

Discussion

We compared the effects of a 6-week integrated yoga program with supportive therapy in stage II and III breast cancer patients undergoing adjuvant radiotherapy. There was a significant difference across groups over time for positive affect, negative affect, and emotional function. There was significant improvement in positive affect, emotional function and cognitive function, and decrease in negative affect in the yoga group as compared to controls.

Though intervention showed small to large effect size for these outcome measures, the effect size was highest for decrease in negative affect and lowest for physical function scores on quality of life subscale. This is in contrast to earlier study (Moadel et al.) that has shown improvements in quality of life, emotional, social and spiritual well being even with poor adherence to yoga intervention. This could be due to the fact that their study²¹ lacked a control intervention and differed from ours with respect to scales used for measuring QoL (Functional Assessment of Cancer Treatment-Breast), ethnicity of study population and heterogeneity in conventional cancer treatments. In their study radiotherapy predicted poor adherence to treatment and outcome measures. However, adherence to intervention was better in our study with 56.7% attending 20–25 supervised yoga sessions and 13.7% attending >25 supervised yoga sessions over a 6-week period. This was primarily due to the fact that all patients were undergoing adjuvant radiotherapy and were visiting the hospital 5 days a week for six consecutive weeks and this could have contributed to improved adherence. Our results are also in contrast to earlier study using MBSR intervention that has shown some improvement in functional scales that were not significant following intervention. In this study too adherence to intervention, duration and heterogeneity in cancer population could have confounded the actual effects of intervention.³² However, adherence did not seem to influence the outcome measures possibly due to the fact that an improved adherence created an “overall floor effect” thereby not influencing the outcome measures.

Several studies have shown that both psychological and treatment related distress affect quality of life concerns in cancer patients.^{38–41} Cancer patients have to constantly make lifestyle changes to adjust and cope with these treatment related distress and seek supportive care.⁴² Yoga and exercise as a lifestyle and stress reduction intervention has shown to decrease negative affect and improve positive affect.^{26–28} This change in affect could have contributed to improvement in quality of life concerns in these patients. This is further corroborated by our results with decrease in negative affect being related to improvement in physical function, emotional function and social function and improvement in positive affect being related to improvement in role function. Possible threat perceptions and intrusive thoughts could motivate cancer patients to pursue health care behaviors that offer spiritual solace.⁴³ It is here that yoga as a psycho-spiritual intervention could offer much needed support. However, in our study we were not able to assess this spiritual component in quality of life, nevertheless it could be one of the possible mechanisms by which yoga could have influenced other quality of life domains.

Using patients with high school education could have affected the generalizability of the study findings. Though the intervention was imparted as individual sessions, group sessions could have been more feasible and far more accessible. Sessions in a group setting could have instilled a sense of community where patients could model successful coping and gain self-esteem and motivation in their ability to help others in a group contributing to improvement in outcome measures.^{44,7} This could have confounded the effects of our intervention and hence we chose to have individual sessions in this study. However, considering the adherence neither access nor feasibility was a problem. None of the subjects who underwent intervention had any adverse effects of intervention suggesting that these interventions were safe and feasible.

The contrast in results from earlier studies could be due to lack of concordance between EORTCQoL C30 and FACT scales on several domains of quality of life.⁴⁵ Though this could be a limitation, our results still offer support for improving quality of life concerns in a homogenous group of breast cancer patients similar to our earlier observations on reductions in anxiety²³ and distressful symptoms.²⁴ However, larger randomized controlled studies using more structured behavioral approaches and multiple assessment tools are needed to further validate our findings.

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