Effectiveness of pranayama on cancer-related fatigue in breast cancer patients undergoing radiation therapy: A randomized controlled trial

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ABSTRACT

Context: Incidence of breast cancer is very high among women around the world. Breast cancer patients experience cancerrelated fatigue at some points during the treatment for breast cancer. Since cancer-related fatigue is of multifactorial origin, there are no evidence-based treatment strategies for fatigue. This study tested the effectiveness of certain pranayama techniques in reducing cancer-related fatigue among breast cancer patients undergoing radiation therapy.

Aims: The objective of this study was to determine the effectiveness of pranayama on cancer-related fatigue among breast cancer patients undergoing radiation therapy as measured by cancer fatigue scale.

Settings and Design: Shirdi Sai Baba Cancer Hospital and Research Center, Kasturba Hospital Manipal.

Materials and Methods: Study was a randomized controlled trial done among breast cancer patients receiving radiation therapy.

Statistical Analysis Used: Demographic characteristics of the participants are presented as frequency and percentage. Comparison of means of cancer-related fatigue between the two groups is done by Mann–Whitney U-test and comparison of pre- and post-test means of cancer-related fatigue among the experimental group is done by Wilcoxon sign rank test.

Results: There was a significant difference between the two groups with regard to the scores of cancer-related fatigue. The experimental group of patients who performed pranayama along with radiation therapy experienced less fatigue.

Conclusions: Pranayama can be used as a supportive therapy for breast cancer patients undergoing radiation therapy.

Key words: Breast cancer; cancer-related fatigue; pranayama; radiation therapy.

INTRODUCTION

Breast cancer is the most frequent cancer diagnosed in women world over.^[1] Asian countries also show the trend of increasing number of breast cancer among women.^[2] The incidence of breast cancer has been increasing in India as well in the past few years.^[3] Based on 2004-2005 data from population-based cancer registries (PBCRs),

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it was observed that breast cancer has been ranked as a leading site of cancer among women in most of the cities of India with Chennai reporting the highest age adjusted rates (AAR) as 29.3 followed by Delhi (29.2).^[4] First report of 20 PBCRs in India for 2006-2008 show that Bangalore has the highest AAR for breast cancer (36.06).^[5]

Breast cancer is conventionally treated with surgery, chemotherapy, and radiation therapy. Adjuvant radiation is used among breast cancer patients to prevent loco-regional recurrence of the tumor.^[6]

Almost all breast cancer patients experience fatigue during the course of treatment and the intensity of fatigue increases during the course of chemotherapy and radiotherapy. National Comprehensive Cancer Network has defined cancer-related fatigue as a "distressing persistent, subjective sense of physical, emotional and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with usual functioning."^[7]

Curt *et al.* in 2000 reported cancer-related fatigue as very common in advanced cancers and its prevalence reported to be as high as 95% among patients with advanced cancer receiving adjuvant therapies. They identified that cancer-related fatigue is a problem before, during and after therapy, and it can continue to be a problem in cancer survivors as well. The authors also stated that fatigue can affect the activities of daily living of the people affected.^[8]

Assessment of fatigue and health status in Greek patients with breast cancer undergoing adjuvant radiotherapy has shown that approximately 13% of the women in the study experienced moderate to high levels of fatigue and fatigue increased during radiotherapy.^[9]

Cancer-related fatigue has a very strong negative effect on quality-of-life (QOL) as many patients find it difficult to carry out their activities of daily living. Thus, cancer-related fatigue a problem often less understood and underdiagnosed, should be considered as an important issue to challenge during cancer and its treatment.^[8]

Yoga and pranayama have been tried for managing cancer-related fatigue by few researchers. A pilot study done by Carson *et al.* observed that gentle yoga postures, and breathing exercises were effective in lowering fatigue in women with metastatic breast cancer.^[10] Bower *et al.* have observed that 'Iyengar yoga' classes resulted in statistically significant improvements in fatigue severity and vigor in breast cancer survivors.^[11]

Researchers observed that a good number of breast cancer patients admitted for radiation therapy in the setting complains of fatigue. Cancer-related fatigue is considered as an expected problem among these patients and is currently not actively diagnosed and treated. Since yoga and pranayama can be easily adopted as supportive therapies and encouraged by the results of the abovementioned studies, this study tested the effectiveness of pranayama on cancer-related fatigue among breast cancer patients undergoing radiation therapy in Shirdi Sai Baba Cancer Hospital and Research Center, Manipal.

The objective of this study was to determine the effectiveness of pranayama on cancer-related fatigue among breast cancer patients undergoing radiation therapy as measured by cancer fatigue scale.

MATERIALS AND METHODS

Participants

Breast cancer patients undergoing daily adjuvant radiation therapy for 6 weeks. Patients were of age 18 years or older and have undergone surgical treatment and chemotherapy for their breast cancer. Patients with any diagnosed psychiatric disorder, those who have practiced yoga or taken yoga classes prior to diagnosis, those who are diagnosed with lymphedema at baseline, extreme mobility issues, and recurrent breast cancer were excluded.

Research design

This study was randomized controlled trial.

As shown in Figure 1, a total of 331 breast cancer patients were assessed for eligibility. Out of these, 171 patients were excluded based on the exclusion criteria. The remaining 160 were allocated to experimental group and control group using block randomization.

Randomization

This study was conducted after obtaining Institutional Ethical Committee Clearance. Of the 170 eligible participants, 160 (94.11%) consented to participate and were randomized to perform pranayama along with radiation therapy (n = 80) or only radiation therapy with routine care (n = 80) at the beginning of radiotherapy. The patients were allocated into experimental group and control group using block randomization procedure (16 blocks of 10 patients) after getting informed consent. Random sequence generation and concealed allocation were achieved by using concealed and numbered envelopes.

The study was conducted at Shirdi Sai Baba Cancer Hospital and Research Center, Manipal.

Assessments

Assessment of fatigue was done using the cancer fatigue scale, which measured fatigue in physical and functional aspects, affective, and cognitive areas. The cancer fatigue scale was prepared by the researchers. It had 18, 11 point scales to measure fatigue in physical and functional aspects, affective and cognitive areas. Content validity of the tool was done by giving it to three experts in the field of radiation oncology, one expert in the field of psychiatry and one expert in the field of clinical psychology and two experts in the field of nursing. Reliability of the scale was done on 20 breast cancer patients each undergoing radiation therapy in Shirdi Sai Baba Cancer Hospital and Research Center, Kasturba Hospital, Manipal, and it was found to be 0.82. Reliability was calculated using Cronbach's alpha.



Figure 1: Consort flow chart of randomized controlled trial

Interventions

Pranayama

Experimental group of patients performed pranayama, morning and evening for 5 days a week for 6 weeks (from the day of starting radiotherapy until the last day of radiotherapy). Patients performed Nadi Sodhana for approximately 5 min (21-25 cycles), Sheethali for approximately 5 min (50-60 cycles) and Brahmari for approximately 8 min (10 cycles). The initial sessions on pranayama were given in the Yoga Department for 1 week. The patients performed pranayama morning and evening for the next 5 weeks in a separate room in the hospital under supervision.

In Brahmari pranayama, patients were taught to take deep inhalations and deep exhalations with a humming sound.^[12]

In Sheethali pranayama, patients were taught to draw in air slowly and deeply through a curled tongue, which is stretched out of the mouth. After the inspiration, the tongue is withdrawn and the mouth is closed, and they were asked to exhale passively through the nose. Those who had difficulty in making a curled tongue were taught to draw in air slowly and deeply through clenched teeth and exhale passively through the nose.^[12]

In Nadi Shodhana pranayama, the patients were taught the following procedure. "The right hand was brought to the nostrils. Left nostril was blocked completely with the ring finger and small finger of the right hand without disturbing the septum." Patients were instructed to exhale through the right nostril slowly, steadily and deeply and inhale though the same side in the same way. When the inspiration was completed, the right nostril was blocked with the thumb of the right hand, and they were asked to exhale slowly and steadily through the left nostril. Once the exhalation is completed through the left nostril, patients were instructed to inhale slowly and steadily through the same nostril. Again, they were asked to slowly and steadily exhale through the right nostril. This completed one cycle of Nadi Shodhana pranayama.^[12]

While doing pranayama, the patients were taught to sit on the floor in padamasana. Those who had difficulty sitting in padmasana were sitting in "ardha padmasana or sitting on a chair with the spine straight."

Treatment received by breast cancer patients

Patients who were having locally advanced breast cancer and who underwent modified radical mastectomy or breast conserving surgery, followed by eight cycles of chemotherapy (doxorubicin 60 mg/m² IV d1 [cyclophosphamide 600 mg/m² d1] 3 weekly \times 4 cycles followed by paclitaxel 175 mg/m² IV 3 weekly \times 4 cycles) were enrolled in this study. After chemotherapy, patients were given external-beam radiation of 50 Gy in divided doses. Patients performed pranayama on same days when they came for radiation therapy. Cancer-related fatigue was assessed at the beginning of radiation therapy and at the completion of radiation therapy from both groups using cancer fatigue scale.

Data extraction

Data were collected on cancer-related fatigue using cancer fatigue scale at the beginning of radiation therapy and at the completion of radiation therapy. The cancer fatigue scale was administered by the researchers in the radiation oncology wards or in the linear accelerator room when the patients came for radiation therapy. The time taken by the patients to complete the self-report questionnaire was approximately 10-15 min.

Data analysis

The *SPSS* (16.0 version) was used for the analysis of the data. Demographic characteristics of both groups of breast cancer patients are given as frequency and percentage. Comparison of demographic characteristics was done to check whether the groups differed significantly at baseline. Tests like Chi-square and independent *t*-test were used to compare the baseline characteristics.

RESULTS

Sample characteristics

Breast cancer patients (160) who came for radiation therapy were randomized into the experimental and control group. Distribution of breast cancer patients according to age, stages of breast cancer, hemoglobin levels, and surgery is given in table below as frequency and percentage.

The data presented in Table 1 show that majority of the breast cancer patients 140 (87.5%) out of 160 were in the stages of Stages 2 and 3. Most of the patients 123 (76.87%) have undergone modified radical mastectomy as the surgical treatment and majority 118 (73.75%) had hemoglobin levels below 12 g/dL.

Comparison of pretest values between the experimental and control group at the beginning of radiation therapy

The pretest values for all the variables were statistically tested (using Chi-square test and independent t-test) between the experimental group and control group at the beginning of radiation therapy to know whether the group differed significantly in their characteristics.

To determine whether the group differed significantly in their demographic characteristics, Chi-square test and *t*-test was done, and *P* value was computed at 0.05 level of significance data in Table 2 indicate that all variables were similar in baseline characteristics.

Comparison of pretest scores of cancer-related fatigue

Pretest scores of cancer-related fatigue were compared to check whether the group differed in this at baseline. Mann–Whitney U-test was used to compare the two groups since the data were not following normality. Data presented in Table 3 show that there was no significant difference in the scores of cancer-related fatigue between the control group and the experimental group at the beginning of radiation therapy (p - 0.635).

Table 1: Demographic characteristics of breast cancer patients in experimental and control group

Characteristics	Experim	ental (80)	Control (80)	
	F	%	f	%
Age in years				
≤45	46	57.5	35	43.75
>45	34	42.5	45	56.25
Stages of breast cancer				
Stage 1	12	15	8	10
Stage 2	38	47.5	40	50
Stage 3	30	37.5	32	40
Hemoglobin levels				
<12	50	62.5	58	72.5
>12	30	37.5	22	27.5
Surgery				
Modified radical mastectomy	63	78.75	60	75
Breast conservation	17	21.25	20	25

Characteristics	Experimental (n=80)	Control (n=80)	P value significance	Confidence interval	Pearson Chi-square
Age in years	Mean±	SD			
	43.57±8.5	43.57±8.5	0.632*	-7.379-1.944	†
Age in years	Frequer	су			
<45	46	35	0.112 [‡]	-1.55-18.13	-2.51
>45	34	45			
Stages of breast cancer	Frequer	су			
Stages 1 and 2	50	48	0.312 [‡]	-4.4-5.6	4.31
Stage 3	30	32			
Hemoglobin levels	Mean±	SD			
	11.5±0.9	11.5±1.2	0.42*	-3.78-3.6	t
Hemoglobin levels	Frequer	су			
<12	50	58	0.540‡	-8.98-4.18	3.86
>12	30	22			
Surgery	Frequer	су			
Modified radical mastectomy	63	60	0.722 [‡]	-3.4-7.8	0.316
Breast conservation	17	20			

Table	2:	Comparison	of	demographic	characteristics
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*Independent *t*-test, [†]Not applicable, [‡]Chi-square test. SD = Standard deviation

Table 3: Difference between the pretest scores of cancer-related fatigue among the experimental group and control group using Mann-Whitney U-test (n=80+80)

Variable	Group	Median	IOR	7 value	P value
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Cancer-related	Experimental	29	22-42	-0.475	0.635
fatigue	Control	32	21-43		
	1				

IQR = Interquartile range

Description of scores of cancer-related fatigue

Assessment of cancer-related fatigue was done using the cancer fatigue scale. The cancer fatigue scale had 18, 11 point scales to measure fatigue in physical and functional aspects, affective and cognitive areas. Scores of cancer fatigue scale were classified as no fatigue (0), mild (1-54), moderate (55-108), and severe (100-180).

As shown in Figure 2, majority of breast cancer patients in the experimental group 61 (76.25%) and control group 70 (87.5%) had only mild fatigue at the beginning of radiation therapy. Very few patients in the experimental group 9 (11.25) and control group 7 (8.75) had severe fatigue at the beginning of radiation therapy.

Effectiveness of pranayama on cancer-related fatigue

The data presented in Table 4 show that there was a significant difference in the pre- and post-test scores of cancer-related fatigue among the experimental group. The experimental group of patients experienced less amount of fatigue at the completion of radiation therapy.

Comparison of posttest scores of cancer-related fatigue between the experimental and control group at the completion of radiation therapy

For comparison of posttest fatigue scores between the two groups, normality was checked using Kolmogorov–Smirnov



Figure 2: Number of breast cancer patients (y-axis) based on the classification of scores of cancer-related fatigue (x-axis) at the beginning of radiation therapy

test. Since the data were not following normality, a Mann-Whitney U-test was done to compare the differences in scores of cancer-related fatigue at the completion of radiation therapy. Data presented in Table 5 show that there was a significant difference in the cancer-related fatigue experienced by the patients between the experimental group and control group at the completion of radiation therapy. The scores of the cancer-related fatigue show that the symptom experienced by the breast cancer patients who received only radiation therapy was more severe compared to the patients who performed pranayama while receiving radiation therapy.

DISCUSSION

The breast cancer patients who were randomized for this study were selected after completion of surgical treatment and chemotherapy for breast cancer. The patients have completed several cycles of chemotherapy before starting radiation therapy. Surgical and chemotherapeutic treatments for breast cancer cause some amount of fatigue in patients.

Table 4: Difference between the pre- and post-testscores of cancer-related fatigue among the experimentalgroup using Wilcoxon sign rank test (n=80+80)

Group	Variable	Median	IQR	Z value	P value
Experimental	Pretest score	29	22-42	-6.338	< 0.001
	Posttest score	19	8-30.5		

IQR = Interquartile range

Table 5: Difference between the posttest scores of cancer-related fatigue among the experimental and control group using Mann-Whitney U-test (n=80+80)

			/		/
Variable	Group	Median	IQR	Z value	P value
Cancer-related	Experimental	19	8-30	-3.414	0.001
fatigue	Control	31	17-45		

IQR = Interquartile range

Williams and Schreier^[13] have reported that all the women experienced some degree of fatigue and fatigue increased in severity during the course of chemotherapy. de Jong *et al.*^[14] have reported that that fatigue after completion of chemotherapy did not significantly differ from fatigue at baseline.

In Poirier's^[15] study, there were 40 (52%) with no fatigue, 36 (47%) with mild fatigue and one participant with moderate fatigue at baseline before starting radiation therapy.

In Lavdaniti *et al.* $study^{[9]}$ among breast cancer patients before radiation therapy, approximately 13% of women experienced moderate to higher levels of fatigue at baseline.

Donovan *et al.*^[16] assessed fatigue in 134 women receiving chemotherapy and radiotherapy or radiotherapy only for early stage breast cancer. Fatigue severity at the start of radiotherapy among these women was statistically equivalent to their fatigue severity at the start of chemotherapy.

In this study, fatigue during the postoperative period and during and after chemotherapy was not assessed. However, the patients selected for this study have undergone surgical treatment and chemotherapy before starting with radiation therapy. The present study findings supports the findings of all the above-mentioned studies in that all the patients experienced some amount of fatigue when they came for radiation therapy. Although the breast cancer patients underwent surgery and chemotherapy before starting radiation therapy, majority of the patients had only mild fatigue at baseline before starting radiation therapy.

Goldstein *et al.*^[17] have reported that among breast cancer patients, case rate for cancer-related fatigue was 24% (n = 51) postsurgery and 31% (n = 69) at end of treatment; it became persistent in 11% (n = 24) at 6 months and 6% (n = 12) at 12 months. Manir *et al.*^[18] assessed the prevalence, course and degree of fatigue in breast cancer

patients on adjuvant treatments. Fifty-two patients (77%) had fatigue during radiotherapy. Prevalence increased in the 3^{rd} week of radiotherapy and decreased subsequently.

Whelan *et al.*^[19] have reported that the patients assigned to radiation therapy experienced more fatigue than the control group.

The above-mentioned studies have shown that breast cancer patients experienced fatigue during treatment for cancer. Patients receiving radiation therapy mostly experienced increasing levels of fatigue during the course of treatment. The present study findings also show that breast cancer patients experienced fatigue during the course of radiation therapy with the exception that breast cancer patients who performed pranayama along with radiation therapy experienced less amount of fatigue.

Many studies have attempted various nonpharmcological approaches for treating cancer-related fatigue.

Danhauer *et al.*^[20] have reported that fatigue and QOL improved with restorative yoga intervention. The restorative yoga intervention included combined physical postures, breathing, and deep relaxation given for 75 min for a period of 10 weeks. Fatigue was assessed at baseline, immediately postintervention, and 2 months postintervention. Fatigue improved significantly between pre- and post-intervention. Women with breast cancer reported a higher QOL after the intervention. Although the restorative yoga intervention was not designed to provide group support, many of the participants noted the value of the social aspects of the yoga classes.

This study also found that there was a reduction in the level of fatigue experienced by the women who practiced pranayama than the women who had undergone radiation therapy only. The researchers have also noted group cohesion between the study participants and the easiness with which the participants shared and discussed their problems with each other.

Bower *et al.*^[11] assessed fatigue severity and vigor among breast cancer survivors with persistent posttreatment fatigue. The experimental group performed Iyengar yoga for 90 min twice a week for 12 weeks and the control group received health education for 120 min once in a week for 12 weeks. It was found that yoga resulted in statistically significant improvements in fatigue severity and vigor. These findings are consistent with the present study findings in that the group who performed yoga reported less amount of fatigue compared to the control group.

This study does not support the findings by Moadel *et al*. Moadel *et al*.^[21] showed no significant difference in the levels of fatigue among breast cancer patients between the group who performed yoga (34.37 ± 11.26) and the waitlist control group (33.82 ± 12.97) at 3 months follow-up.

Findings, contradictory to the present study findings were observed also by Chandwani *et al.*^[22] They assessed the effects of yoga on QOL and psychosocial outcomes in 61 women with breast cancer undergoing radiotherapy. Experimental group received yoga classes biweekly during the 6 weeks of radiotherapy. Assessment of QOL and fatigue was done before radiotherapy and then again 1 week, 1 month, and 3 months after the end of radiotherapy. There was no significant difference between the groups with regard to fatigue, depression or sleep scores at any observation point. Whereas in this study even though sleep improvement was not the primary outcome, majority of patients who performed yoga reported an improvement in sleep along with reduction in fatigue.

CONCLUSION

Although there are studies with contradicting results the authors conclude that pranayama may be utilized as an adjunct in the management of breast cancer patients.

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