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Does Yoga aid in the Reduction of Short-Term Anxiety in Adult Female Breast Cancer Patients?

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A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

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ABSTRACT

OBJECTIVE: The objective of this selective EBM review is to determine whether or not yoga aids in the reduction of short-term anxiety in adult female breast cancer patients.

STUDY DESIGN: Review of three English language primary studies, published between 2007 and 2010.

DATA SOURCES: Two randomized controlled trials (RCTs) and one before and after comparison study were found using PubMed, Medline, and OVID. These studies analyzed yoga intervention in adult female breast cancer patients suffering from anxiolytic effects.

OUTCOMES MEASURED: The main outcomes measured were anxiety state level and symptom severity and distress experienced by patients through use of the State Trait Anxiety Inventory (STAI) and subjective symptom checklist. The tools used to assess significance of outcomes measured were p-values, change in mean from baseline, ANOVA F-score, and t-values.

RESULTS: All three trials showed a significant decrease in anxiety levels after yoga-based intervention. When yoga intervention was employed in the Raghavendra et al study, a significant decrease in anxiety levels were found (t-value = -5.18, $p < 0.001$). In the Rao et al study, GLM-repeated measures ANOVA showed an overall decrease in self-reported state anxiety levels (f-score = 10,8, $p < 0.001$) and a positive correlation between anxiety states with symptom severity and distress during conventional treatment intervals. In the Ulger et al study, there was a statistically significant decrease in the patients' stress levels ($p < 0.05$).

CONCLUSIONS: The results of the RCTs and before and after comparison study, demonstrate the yoga practice to be an effective treatment for reducing anxiety in adult female breast cancer patients. The implementation of yoga intervention into the lives of cancer patients results in a reduction of stress and chemotherapy-related symptoms, further reducing anxiety levels. Further research is needed to determine length, intensity, and specific yoga asanas that may yield maximum results and relief from anxiety.

KEY WORDS: Anxiolytic, yoga, breast cancer

INTRODUCTION

Anxiety, worry, and fear are a few of the many emotions provoked after being diagnosed with a life-threatening illness such as cancer. These emotions may be associated with the diagnosis of cancer itself, or with treatment-related concerns, including surgical complications, unpleasant adverse reactions to chemotherapy, or long-term side effects of radiation.

Anxiety is characterized by worrying, nervousness, and tension¹. Over the course of one's lifetime, approximately 5% of individuals, particularly females, will be diagnosed with generalized anxiety disorder (GAD)¹.

While health care costs and visits vary depending on diagnosis and treatment, the demand for mental health care in the U.S. has dramatically increased, being one of the most expensive health care conditions with a yearly spending of over 72.1 billion dollars in the U.S.²

Though thought to be under diagnosed, anxiety is one of the most common psychiatric problems encountered in cancer patients, with a prevalence of nearly 64% in those undergoing treatment³. Cancer patients who may be more likely to develop anxiety are those with a history of anxiety disorders, those who are in severe pain, are disabled, or lack a support system⁴. With a high prevalence for developing anxiety in cancer patients, psychological distress, side effects, and poorer patient outcomes may be heightened, ultimately decreasing one's quality of life and survival time³. Therefore, increasing one's quality of life is equally as important as survival.

Signs and symptoms of anxiety can include those that are emotional or behavioral, such as difficulty concentrating, irritability, avoiding certain situations, or the inability to relax or enjoy time with others. Anxiety may also produce physical symptoms such as muscle tightness, body aches, insomnia, restlessness, nausea, vomiting, diarrhea, heart palpitations, chest pain, and

shortness of breath¹. These distressing symptoms caused by anxiety 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.

Cognitive behavioral therapy (CBT) has been used as one of the most common and effective treatment methods for anxiety with or without the administration of anti-anxiety and/or anti-depressant medications⁴. Group therapy, hypnosis, herbal remedies, massage, aromatherapy, acupuncture, and daily exercise have also been used to help eliminate anxiety⁴.

Although patients will often gain relief from anxiety with medications and the treatment options mentioned above, many individuals may not want to take medications for their own personal reasons. Even more so, medicine does not address the provoking agent or initial cause to their anxiety (i.e. the cancer patient who becomes anxious when thinking about chemotherapy due to the association of chemotherapy-related side effects such as nausea, vomiting, and fatigue). Treatment-related distress experienced by many cancer patients is predictive of poorer treatment outcomes and compliance, greater pain, longer hospital stays, more post-operative complications, and immune suppression³. If yoga programs can reduce chemotherapy-related symptoms, patients may ultimately have a reduction in anxiety knowing that they may never experience these unpleasant side effects.

Recent studies have emphasized a close association between physical activity and the quality of life⁵. Yoga specifically, has gained popularity within recent years as a form of exercise that is thought to build inner awareness and alter the perceptions and mental responses to both external and internal stimuli. In addition, it has been thought to instill a greater control

over stressful situations, all of which could be particularly useful in cancer patients who perceive their illness as a threat⁶.

OBJECTIVE

The objective of this selective EBM review is to determine whether or not yoga aids in the reduction of short-term anxiety in adult female breast cancer patients.

METHODS

The three studies analyzed in this review all met the following criteria. The population included female breast cancer patients ranging from 30 to 70 years old whom received chemotherapy. Articles that compared yoga as an intervention for reducing anxiolytic effects of chemotherapy to a control group were considered. Comparison groups in the two RCTs included similar participants in which received supportive therapy. The third study which was a before and after comparison study did not have a comparison group. The outcomes measured were anxiety level and total number of symptoms experienced by each patient.

A detailed search using PubMed, Medline, and OVID databases were completed by the author using the key words “anxiolytic,” “yoga,” and “breast cancer.” Articles were selected based on their relevance to practice and importance to patient-oriented outcomes (POEMs – Patient Oriented Evidence that Matters). All articles were published in peer-reviewed journals in the English language. Inclusion criteria for article selection were as follows. All articles were published during or after 1996 with POEMs. Review articles, meta-analyses and systemic reviews posted on the COCHRANE database that answered the same question were excluded. Two RCTs and one before and after comparison study were selected and included in this review based on these criteria. Those excluded were studies with cancer patients that had a reduction in

anxiety not related to yoga intervention. A summary of statistics reported or used include p-values, change in mean from baseline, ANOVA F score, and t-values. Table 1 displays the demographics and characteristics of these articles.

Table 1 – Demographics and Characteristics of Included Studies

Study	Type	# Pts	Age (yrs)	Inclusion Criteria	Exclusion Criteria	W/D	Interventions
Raghavendra ⁵ 2007	RCT	98	30-70	Recently dx'd operable breast cancer; 30-70 y/o; Zubrod's performance status 0-2; high school edu.; willingness to participate; tx plan including surgery followed by adj. radiotherapy and chemo	Concurrent medical condition likely to interfere w/ tx; any major psychiatric, neurological illness or autoimmune d/o; secondary malignancy; hx of intestinal obstruction; any known sensitivity to any class of antiemetics and/or corticosteroids	36	60 min of supervised, daily yoga sessions either at home (provided w/ audio and video cassettes of yoga modules) or taught by a certified yoga instructor while at the hospital. Bedside yoga relaxation taught 30 min after the admin. Of every chemo cycle.
Rao ¹ 2009	RCT	38	30-70	Recently dx'd operable breast cancer; 30-70 y/o; Zubrod's performance status 0-2; high school edu.; willingness to participate; tx plan including surgery followed by adj. radiotherapy and chemo	Concurrent medical condition likely to interfere w/ tx; any major psychiatric, neurological illness or autoimmune disorders; secondary malignancy	0	Yoga for 60 min daily; 4 in-person sessions during pre and post op period; 3 in-person sessions per wk x 6 wks during adj. radiotherapy in the hospital w/ self-practice on the remaining days
Ulger ⁶ 2009	Before and after comparison study	20	30-50	Received phase I/II chemo; ≥6 mos have passed since chemo; 30-50 y/o; medically supervised	Not under physicians control; risk of infection; actively receiving chemo or radiation	0	Two 1 hour yoga sessions per wk x 4 wks

OUTCOMES MEASURED

The outcomes measured were POEMs. To help measure the outcomes of each study, several subjective tools were used by the participants. Raghavendra et al and Rao et al both used the State-Trait Anxiety Inventory (STAI) and subjective symptom checklist, while Ulger et al used only the STAI. The STAI measured and assessed each patient's stress, anxiety, and emotion levels. The STAI consisted of two types of statements: direct statements expressing negative feelings and reversed statements expressing positive feelings, with four options ranging from "never" to "completely". Answers for direct and reversed statements were tallied individually. The total of the answers for the reversed statements were then deducted from the total of the answers for the direct statements. A predetermined constant (ie. 50) was then added to this number for a final value in which indicated the individuals anxiety score. The subjective symptom checklist was developed to measure the severity and distress of thirty-one (31) symptoms, including treatment-related side effects, problems with sexuality and image, and relevant psychological and somatic symptoms. The symptom checklist calculated the total and mean of the severity and distress of symptoms experienced by each patient based on a scale from 0 to 4 (0 = not severe, not at all distressful; 4 = severe, very much distressful).

RESULTS

The two RCTs evaluated the significance of using yoga in comparison with standard supportive care. A before and after comparison study assessed the patient's stress and anxiety levels before, and after yoga intervention. All of the studies used the yoga intervention for treatment, but the interventions varied slightly with each study. Individual yoga therapy (versus group therapy) and supportive counseling sessions were executed to help understand the specific needs and concerns of participants and monitor individual progress in practice. Each study had similar inclusion and exclusion criteria (see Table 1). All of the studies maintained a level of

safety by providing certified yoga instructors to properly teach and monitor patients while practicing yoga. None of the patients in the studies reported any musculoskeletal complaints, distressful symptoms, or other adverse events that may be related to the yoga practice, indicating the yoga module developed for cancer patients was safe.

Note the data from all three studies included in this review contained continuous data that could not be converted to dichotomous data. Therefore, the analysis of risk reduction (RRR), absolute risk reduction (ARR), and numbers needed to treat (NNT) could not be calculated.

The study conducted by Raghavendra et al consisted of 62, randomly assigned participants to either a yoga group (n = 28) or a control group (n = 34). During the chemotherapy protocol, subjects in both groups were given 60 minutes of intervention before starting their first adjuvant chemotherapy cycle. Intervention consisted of 60 minutes of supervised, daily yoga sessions practiced either at home or taught by a certified yoga instructor while at the hospital. The subjects in the yoga group were provided with audio and video cassettes of the yoga modules for one hour of daily home practice. These home practices were supervised every 10 days by their yoga instructor through house visits. Bedside yoga relaxation was taught for thirty minutes after the administration of every chemotherapy cycle. The subjects who were assigned to the control group received 30 minutes of supportive care and education during their hospital visits over the complete course of chemotherapy by the same yoga instructors who were also trained in counseling cancer patients. Topics covered were chemotherapy-related nausea and vomiting, aversions, and nutrition.

Multiple outcomes were described in this study, but for the purpose of this review the outcomes measured were limited to anxiety state and symptoms experienced before and during

the course of chemotherapy through the STAI-I and subjective symptom checklist. According to the STAI-I and subjective symptom checklist, the yoga group showed a significant decrease in reactive anxiety states and severity and distress of symptoms experienced ($p < 0.001$) when compared to the control group. Table 2 summarizes the results of the study by Raghavendra et al.

Table 2 - Comparison of scores of STAI, symptom severity, and symptom distress

	Yoga (n=28) Mean \pm SD	Control (n=34) Mean \pm SD	t-value	d.f	P-value
STAI anxiety state score	29.2 \pm 3.8	37.5 \pm 7.6	-5.18	59	<0.001
Severity of symptoms	17.6 \pm 9.3	27.3 \pm 9.2	-3.89	58	<0.001
Symptom distress	16.6 \pm 10.1	29.9 \pm 11.2	-4.70	59	<0.001

In the second study conducted, Rao et al compared the anxiolytic effects of 38, randomly assigned breast cancer patients who specifically received surgery followed by adjuvant radiotherapy and 6 cycles of chemotherapy. This study compared yoga intervention (n = 18) to supportive therapy (n = 20) for 24 weeks. Intervention consisted of 60 minutes of daily yoga including asanas, breathing exercises, pranayama, meditation, and yogic relaxation techniques with imagery. The subjects were given booklets and audiotapes with instructions for home practice use to better cope with stressful experiences, attention diversion, awareness, and relaxation. Subjects were encouraged to maintain a daily log listing the yoga practices performed, use of audiovisual aids, duration of practice, experience of distressful symptoms, intake of medication(s), and diet history. The instructor monitored the subjects on a day-to-day basis through telephone calls and house visits. Subjects were asked to attend 4 in-person sessions during their pre and post-operative period and 3 in-person sessions per week for 6 weeks during their adjuvant radiotherapy treatment in the hospital. In addition, subjects

underwent in-person sessions during their hospital visits for chemotherapy administration (once in 21 days) and were visited in-person at their home by their trainer once in 10 days. The control group received supportive therapy with education during their hospital visits as a part of routine care. Subjects who were part of the control group also completed daily logs on treatment-related symptoms, medication(s), and diet during their chemotherapy cycles. In addition, they were given homework based on the education component and were monitored through telephone calls and house visits.

The outcomes assessed in this study were anxiety state level and symptom severity and distress through use of the STAI-I and subjective symptom checklist. These outcomes were assessed at baseline, after surgery, before, during, and after radiotherapy and chemotherapy using FLM-repeated measures ANOVA (F-score = 10.8, $p < 0.002$) as described in Table 3. The results suggest yoga intervention reduced anxiety state scores by 0.5% following surgery, 4.9% and 6% during and following radiotherapy and 8.5% and 11.6% during and following chemotherapy from their respective baseline means than the control group.

Table 3 - Comparison of scores for anxiety state and symptom distress at various stages of conventional treatment using GLM-repeated measures ANOVA

Outcomes Measured	Pre-surgery	Post-surgery	During Radiotherapy		Post- RT	During Chemotherapy		Post- CT
			Pre-RT	Mid-RT		Pre-CT	Mid-CT	
STAI Anxiety State, mean (S.D.)								
Yoga	43.9±11	34±3.2*	34±3.2	29.3±3.6*	29.1±3.6*	29.1±3.6	29.3±3.3***	24.1±3.1**
Control	48.7±11.6	38.3±7.4	38.3±7.4	35.5±8.2	34.3±8.2	34.3±7.8	38.2±8.5	33.1±10.5
Symptom Distress, mean (S.D.)								
Yoga	13.9±9.5	9.2±8.3**	9.2±8.3	10.1±6.5***	5.4±5.6***	31.8±4.7	15.3±9.7***	5.1±6.5*
Control	15.8±8.5	15.3±5.7	34.4±8.7	19.8±10.1	10.1±4.7	37.6±7.8	31.6±11.1	12.8±10.7

*p values <0.05, **p values <0.01, ***p values <0.001, for post hoc tests comparing groups at different time points using Bonferroni correction.

The study conducted by Ulger et al analyzed 20 breast cancer patients before and after receiving 60 minute yoga sessions twice a week, for a total of 4 weeks. This yoga program included warming and breathing exercises (15 minutes in duration), asanas (15 minutes in duration), and relaxation and meditation in supine position (30 minutes in duration). Asanas were selected based on the patients' needs and ability in relation to their muscular strength and articular limitations.

The outcomes measured were anxiety levels before and after yoga intervention using the STAI-II. As seen in Table 4, this study found a statistically significant decrease in STAI-II scores after each yoga session compared to the score measured before the exercises ($p < 0.05$).

Table 4: Before- and after- sessions stress levels with respect to their STAI-II scores

Stress Levels	<u>Before Sessions $n = 20$</u> X \pm SD	<u>After Sessions $n = 20$</u> X \pm SD	<i>P value</i>
STAI-II (state anxiety)	54.95 \pm 11.01	41.20 \pm 11.18	0.001

DISCUSSION

Due to significant results from these studies, the yoga-based method of intervention has been recognized as a successful treatment for aiding in the reduction of short-term anxiety in adult female breast cancer patients. Although scientific evidence does not support yoga as an effective *treatment* for cancer, several cancer treatment centers offer yoga in addition to standard medical treatment. However, many healthcare providers and insurance companies do not view this form of therapy as necessary and therefore do not cover the costs. Aside, yoga is a feasible and cost effective complementary modality to conventional medicine, especially in developing

countries where supportive services for cancer patients are rarely available and access to care is not affordable.

Throughout the studies, there were various factors that may have affected the results in each study. In Raghavendra et al, a significant number of participants (30%) were lost to follow-up which could have very well affected the outcome and significance of findings. In addition, subjects in the control group of this study were offered supportive therapy and coping preparation less frequently than their counterparts, which could have potentially accounted for the significant differences between the groups. Subjects in the intervention group were also given yoga intervention much before the start of chemotherapy, during surgery, and radiotherapy. This pre-exposure to the intervention before chemotherapy may have reduced the responses of patients to conditioning stimuli during chemotherapy. One of the major limitations in Rao et al was the inequality in contact duration of interventions. This inequality may have affected the study's effectiveness as successes of such interventions depend mainly on contact duration and content. The effect size (Cohen's f) for anxiety state was 0.33 which appeared to be a modest effect size (modest effect size <0.5 ; large effect size <0.8). Factors which may have reduced the effects of the intervention and contributed to this decrease in effect size include, the study and subjects being controlled for education, support and attention, as well as having been followed over a long period of time with repeated measurements. Raghavendra et al and Rao et al both encouraged participants to perform at-home exercises throughout the duration of the study. However, it is nearly impossible to determine whether or not subjects were truthfully performing and logging their at home exercises, therefore maximum benefits that could have been achieved with daily yoga sessions may not have been. Another limitation in all of the studies was the inability to blind the yoga interventions from the study participants due to the

nature of the therapy itself, which involves asking the patients to perform asanas as well as a spiritual component that includes the knowledge they are performing yoga. Lastly, because of the overlap with physical symptoms of cancer, the use of the STAI in all three studies has its limitations and should be interpreted with caution.

CONCLUSION

Yoga intervention is an effective treatment for improving anxiolytic effects in adult female breast cancer patients. All three studies in this review provide evidence supporting that yoga significantly reduced anxiety in cancer patients. Rather than using a temporary method for anxiety relief, such as anti-anxiety medications, yoga may be used as a complementary modality to conventional medicine in which focuses on cultivating an inner place of stillness, emotional peace and connection to the mind, body, and spirit.

Due to the lack of studies investigating the effectiveness and use of yoga programs as part of cancer management, future studies need to be done focusing on yoga programs effectiveness on the course of disease and the patient's way of dealing with their chronic illness. Since improvement in anxiety and cancer-related symptoms are subjective outcomes, future studies must have tighter controls in order for results to be accurate, as well as determining the length, intensity, and specific yoga asanas that may yield maximum results and relief from anxiety.

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