Treatment of Radiotherapy-Induced Fatigue Through a Nonpharmacological Approach

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Background: **Cancer-related fatigue (CRF) is a frequently occurring, burdensome side effect of radiation therapy that can result in detrimental effects to health-related quality of life (HRQL). The findings from a pilot study examining the efficacy of the complementary and alternative practice of Polarity Therapy (PT) in reducing CRF and improving HRQL are reported.** ***Methods:*** **Fifteen women undergoing radiation therapy for breast cancer and experiencing fatigue were randomized to receive 1, 2, or no PT treatments. Treatments were given 1 week apart to the patients receiving 2 treatments. Fatigue and HRQL were assessed at baseline prior to PT, 3 days following the first PT treatment (week 1), and 3 days following the second PT treatment (week 2).** ***Results:*** **There was a statistically significant improvement in both CRF and HRQL in the 10 patients who received a PT treatment compared to the 5 control patients at the week 1 assessment. In addition, there was a statistically significant difference among the 3 treatment groups in improvement in CRF at the week 2 assessment. This finding, coupled with a visual inspection of the means, supports the plausibility of a dose response concerning PT.** ***Conclusion:*** **Results from this pilot investigation suggest that PT may have a positive influence on CRF and HRQL in women undergoing radiation treatment for breast cancer. Randomized, controlled clinical trials with larger sample sizes are needed.**

Keywords: cancer-related fatigue; radiation; Polarity Therapy; complementary and alternative medicine

Cancer-related fatigue (CRF) may be defined as "a state characterized by overwhelming, sustained exhaustion, and a decreased capacity for physical and mental work that is not relieved by rest."[1] It is the most frequently reported side effect resulting from surgical, chemotherapeutic, and hormonal treatment for many cancers and is a common and burdensome side effect of radiation therapy.[2] Reports suggest that between 60% and 96% of all cancer patients experience CRF.[3,4] More specifically, radiotherapy-induced fatigue is reported by nearly 80% of patients who undergo treatment.

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CRF results in pervasive and detrimental effects on a patient's health-related quality of life (HRQL).[5-7] Patients with fatigue experience difficulties with treatment compliance, activities of daily living, muscle weakness, pain, sleep, and cognitive tasks.[3,7-9] As such, CRF can significantly interfere with the ability of an individual to sustain a "normal life" by negatively influencing relationships with loved ones,[10] occupational and social pursuits,[11,12] and participation in leisure activities.[13]

Although several explanatory theories have been proposed (eg, anemia, disruptions in adenosine triphosphate, vagal afferent activation, cytokine disruptions, and interactions among specific cytokines and serotonin),[1] the specific etiology of CRF is not well established.[7] Given the multifaceted nature of CRF, the National Comprehensive Cancer Network CRF Panel[14] has established a 2-phased methodology for the treatment of CRF: (1) alleviate any treatable factors contributing to CRF (eg, anemia, emotional distress, deconditioning, comorbidities) and (2) manage remaining CRF through additional nonpharmacological interventions, behavioral strategies, education, and pharmacological treatment. Unfortunately, CRF and the associated detrimental effects on HRQL are not alleviated by periods of rest, as is the case with fatigue induced by physical activity, and they often remain despite the amelioration of treatable factors, such as anemia.[10]

As a result of the persisting and, sometimes, debilitating nature of CRF, increasing numbers of cancer patients are turning to complementary medicine for nonpharmacological solutions to this problem. Some of these interventions (eg, Therapeutic Touch, Reiki, and Polarity Therapy) use gentle human touch that is purported to balance the energy fields of living organisms and restore a state of well-being. These "energy

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therapies" take advantage of the fact that human touch can affect physiological processes in different ways and employ long-standing beliefs about healing forces in the body, frequently referred to as a universal life force and known as prana or qi (chi).[15] Three assumptions form the foundation for these energy therapies: (1) illness is the result of an impeded energy flow (blockage), ultimately disrupting the natural homeostatic state of the human body; (2) the body has the power to heal itself; and (3) healing can be facilitated through gentle manipulation of the patient's immediate energy fields and internal energy flow, known as the "life force."[16,17] The energetic model has a lengthy history and is rooted in the ancient healing practices of Greece, Egypt, India, and China.[18]

The energy therapy intervention used in the present study was Polarity Therapy (PT). It was developed in 1947 by Dr Randolph Stone[19] and derives its current form and much of its substance from integrating these ancient multicultural healing practices with chiropractic and osteopathic medicine. Polarity practitioners believe that their therapy promotes healing, relaxation, and well-being by unblocking and balancing energy flow and reestablishing homeostasis within the human energy field.[20] PT has established programs of training, specialized training centers, a certification process for new practitioners, and a national governing body (American Polarity Therapy Association [APTA]) to oversee and regulate the discipline. Practitioners must receive 155 hours of training to receive their initial certification and more than 600 hours of training to become registered providers. By 2000, approximately 1200 practitioners were members of the APTA in the United States, Canada, Mexico, and Europe.[21] There have been no malpractice claims against practitioners, and it is considered to be a safe technique that is increasingly used in integrative medical practices.[21]

Although there are no published studies evaluating the safety or efficacy of PT, it is reported, anecdotally, to be useful in treating chronic fatigue, fibromyalgia, anxiety, and malaise.[21] It is interesting that during verum PT sessions, one research team observed a statistically significant decrease compared to sham sessions in the high-frequency electromagnetic fields that normally emanate from people.[22] The actual medical benefit of this, if any, is not clear. The rigorous training requirements and regulations, the foundations on which polarity was developed, and the gentle noninvasive nature of the therapy are why PT was chosen from among the various extant energy therapies for this initial pilot study, which examined the efficacy of PT for reducing CRF and improving HRQL in women receiving radiation treatments for breast cancer.

Methods

Patients

Women, 18 years of age or older, who were in their third week of radiation therapy for breast cancer and reported a level of fatigue ≥2 on an 11-point scale anchored by 0 = *not present* and 10 = *as bad as you can imagine* were eligible to participate in the study. Additional eligibility criteria included (1) the previous completion of at least 10 radiation treatments, (2) scheduled radiation therapy for at least 14 additional treatments, and (3) the ability to read English (since all study materials are printed and validated in English). Approval by the University of Rochester Human Subjects Review Board and written informed consent from the patients were obtained prior to the collection of any data for this study.

Procedures

Study personnel met with potentially eligible patients on the first Tuesday after their 10th radiation treatment (third treatment week) to describe the proposed study. Interested patients then signed the written consent form, and an on-study form was completed using a brief interview format to obtain demographic information. Participants were immediately randomized to 1 of the 3 study arms. Arm 1 patients continued with standard care and did not receive any polarity treatments. Patients assigned to arm 2 received a polarity treatment on the following Tuesday, that is, week 1 of the study. Patients assigned to arm 3 received polarity treatments on Tuesdays during both week 1 and week 2 of the study. Following the informed consent procedure, all study participants were given a set of questionnaires to take home and complete on the upcoming Friday evening to provide baseline data. The questionnaire packets were retrieved by study personnel the following Monday when participants came into the Radiation Oncology Clinic for treatment, and a new set of forms was provided to the patients for completion again on the upcoming Friday evening, that is, week 1. This exchange of forms took place the following week as well (ie, week 2). Reminder phone calls were made each Friday to assist the participants in remembering to complete the study packet.

PT

A single registered polarity practitioner in a designated PT treatment room administered all PT. Study

participants removed their shoes but otherwise remained fully clothed prior to positioning themselves supine on the treatment table. A blanket and pillow were provided. The therapist sequentially began at the head, worked down the right side, and up the left side of the body. The patient was then moved to a prone position on the treatment table, and the therapist repeated the treatment sequence as necessary. The therapist used anatomical hand positions, known as connectors, to examine energy flow, discover trigger points (energy impediments), and restore homeostatic energy flow. Trigger points manifest as tenderness, tightness, warmth, coolness, heaviness, density, or any sense of discomfort. These trigger points were felt by the therapist, communicated by the patient, and collectively confirmed. The hand positions involved gentle contact, not manipulative, forceful, or mechanical touch/bodily movement and were maintained for a sufficient duration to relieve the trigger point discomfort as discerned by the polarity therapist. The treatments lasted between 60 and 75 minutes. While conversation between the polarity therapist and the patient was not prohibited, the therapist was instructed to keep it to the minimum necessary to effectively provide the treatment.

Measures

Brief Fatigue Inventory (BFI). Fatigue was assessed with the revised BFI, a 9-item, patient-report instrument with well-established reliability and validity.[23] It allows for the rapid assessment of fatigue level in cancer patients and identifies those patients with severe fatigue. Three items ask patients to rate their fatigue "now," fatigue at its "worst," and "usual" fatigue for the past 24 hours. The 11-point scales are bounded by 0 = *no fatigue* and 10 = *fatigue as bad as you can imagine.* Using the same type of scales, the remaining questions ask patients to rate how their fatigue interferes with several HRQL domains, including general activity, walking, mood, work, and relations with others. These scales are bounded by 0 = *does not interfere* and 10 = *interferes completely.*

Functional Assessment of Chronic Illness Therapy–Fatigue (FACIT-F). HRQL was assessed using the FACIT-F. The FACIT is a 28-item scale developed specifically for use in cancer clinical trials, and the FACIT-F includes 13 additional questions directly related to the impact of fatigue on daily activities.[24] The basic measure has shown very good test/retest reliability, as well as validity.[25,26]

Polarity Feedback Survey. Following the final assessment, patients assigned to arms 2 and 3 were also given feedback questionnaires to complete concerning their experience with the polarity treatment(s).

Statistical Methods

Data analyses were conducted using SPSS version 12.0 software. Since this was a pilot study with a small sample size, the general analytic plan included calculating raw change scores to be used for analyzing between-group differences on CRF and HRQL employing the nonparametric Kruskal-Wallis H Exact Test.

Results

Patient Sample

Twenty-two women diagnosed with breast cancer were initially approached to participate in the study; 16 (72%) agreed to participate, and 15 (94%) of the enrolled participants provided usable data. The patients were randomly assigned to 1 of the 3 trial arms. The mean age of the women participating in the study was 52.5 years (range, 35-72). The majority of participants (n = 14) were Caucasian.

Treatment Effects

CRF. The primary CRF outcome measure was the total fatigue score of the BFI. Simple change scores were calculated from baseline to week 1 and baseline to week 2 (see Figure 1). At week 1, analyses revealed a statistically significant difference on "improvement in CRF" between the 10 patients who had a polarity treatment and the 5 patients who did not (mean change score: 1 polarity treatment = 1.0, SD = 1.46; no polarity treatment = –0.6, SD = 0.93; $P = .04$). Eight of the 10 patients receiving PT reported an improvement in CRF following their first polarity treatment. Only 1 of the 5 patients in the control group had an improvement in CRF during the same time frame. At week 2, a statistically significant overall difference on "improvement in CRF" among the 3 treatment groups was observed (mean change score: 2 polarity treatments = 2.2, SD = 1.03; 1 polarity treatment = 1.6, SD = 1.10; no polarity treatment = 0.6, SD = 0.88; $P = .05$). While patients who received 2 polarity treatments did not have a statistically significant improvement in fatigue vis-à-vis patients who received only a single treatment, visual inspection of the means suggests a possible dose response regarding the number of polarity treatments and the amount of improvement in CRF reported by women in the study.

HRQL. The analyses examining HRQL used the total score from the FACIT-F as the outcome measure. Simple change scores were calculated from baseline to

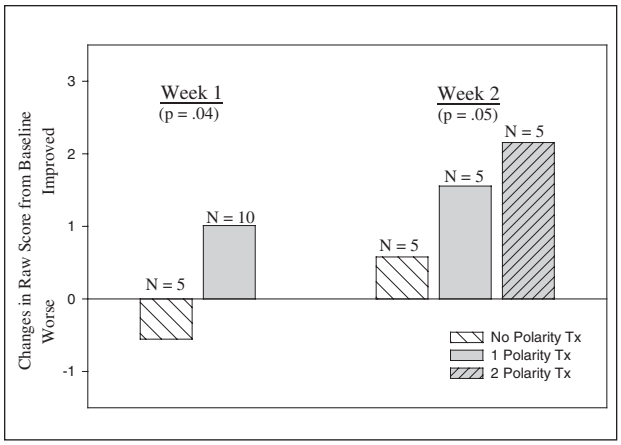

Figure 1 *Raw change in fatigue (Brief Fatigue Inventory) at 1 and 2 weeks following baseline by polarity treatment group. A positive score denotes an improvement in fatigue from baseline. The nonparametric Kruskal-Wallis H Exact Test for independent samples was used to compare groups. At week 1, groups 2 and 3 were combined as each had a single polarity treatment at that assessment point.*

week 1 and baseline to week 2 (see Figure 2). Analyses showed a statistically significant difference on "improvement in HRQL" between the 10 patients who had a polarity treatment compared to the 5 patients who did not at week 1 (mean change score: 1 polarity treatment = 3.8, SD = 13.5; no polarity treatment = –8.0, SD = 5.6; P = .02). The "improvement in HRQL" between the 3 treatment groups at week 2 was not statistically significant (mean change score: 2 polarity treatments = 13.2, SD = 14.9; 1 polarity treatment = 7.1, SD = 11.1; no polarity treatment = 1.7, SD = 17.5; P = .68).

Intervention feedback. Four of the 10 women who received PT found it to be "very useful" in reducing CRF, while 3 women gave it a rating of "somewhat useful" and 2 said it "works a little." Two patients reported that it "doesn't seem to help." Six of the 10 patients said they would highly recommend PT or a similar therapeutic intervention to other women receiving radiation treatment for breast cancer. One woman would "strongly not recommend" PT, and 3 women gave intermediate responses to the question of whether they would recommend the intervention to other patients.

Discussion

The purpose of this pilot study was to gather efficacy and feasibility data in preparation for a larger study examining the efficacy of PT for reducing CRF and improving HRQL in women receiving radiation treatments for breast cancer. The results from this preliminary investigation suggest that PT may have a significant positive influence on CRF in women diagnosed with breast cancer while undergoing radiation therapy. It is interesting that 80% of the women who received PT reported a decrease in CRF levels after the first PT session (week 1 assessment), while 80% of the women who did not receive PT reported an increase in CRF. Furthermore, this assessment of CRF typically occurred during the patients' fourth week of radiation therapy, a time when patients usually report an increase in CRF.[1,27-29] As such, these data suggest that PT benefits are present after only 1 treatment and are positive for the patient within 3 days (assessments were on Friday after receiving PT on the previous Tuesday). In addition, there was a statistically significant difference among the 3 treatment groups in improvement in CRF at the week 2 assessment. This finding, coupled with a visual inspection of the means, supports the plausibility of a dose response concerning PT. Taken together, these data support our hypothesis that PT is helpful in managing fatigue.

The results regarding HRQL were similarly positive and provide additional evidence that PT is beneficial to patients receiving radiation treatment for breast cancer. At the week 1 assessment, the 10 women receiving PT reported a statistically significant improvement in HRQL compared to the 5 women who did not receive PT, with the former patients reporting an overall improvement in HRQL and the latter reporting an overall decline. In addition, although not statistically significant, the 8% to 12% improvement in HRQL observed at the week 2 assessment in patients who received 2 polarity treatments compared to the other study participants is substantial and, as in the analysis examining CRF at week 2, provides preliminary evidence of a dose response.

Although these results are positive, we recognize this study has several limitations. The very small, homogenous sample of participants, while providing statistically analyzable data, prohibits generalization of the results to the larger cancer patient population (eg, men, children, those with disease at other sites, or those undergoing differing treatment regimens). In addition, participants may also have been individuals who were more receptive to or curious about complementary and alternative interventions, and results may not generalize to those less amenable to these healing modalities. Furthermore, the fact that we used 1 PT practitioner controlled for provider variability but does not control for the specific provider-patient interaction. Last, since this study was not blinded or placebo controlled, it is possible that the benefits reported from the intervention were due to

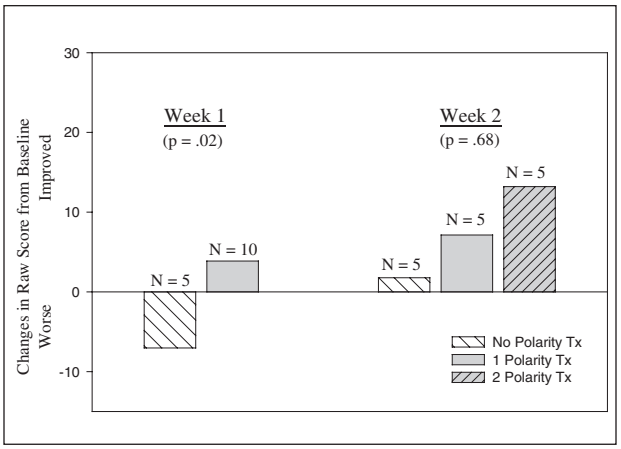

Figure 2 Raw change in health-related quality of life (HRQL; Functional Assessment of Chronic Illness Therapy–Fatigue) at 1 and 2 weeks following baseline by polarity treatment group. A positive score denotes an improvement in HRQL from baseline. The nonparametric Kruskal-Wallis H Exact Test for independent samples was used to compare groups. At week 1, groups 2 and 3 were combined as each had a single polarity treatment at that assessment point.

experimenter bias, expectancy effects, or nonspecific treatment effects (eg, increased patient attention). Despite these limitations, the results of this pilot study are very positive and provide preliminary evidence that PT is effective in alleviating CRF and improving HRQL.

Conclusion

There are several avenues yet to be explored regarding the use of PT with CRF. Future studies should include larger sample sizes that consist of more diverse participants and be designed to control for experimenter bias, expectancy, and nonspecific treatment effects. Future studies also need to control for other comorbidities that could affect fatigue, such as anemia and chronic fatigue syndrome. In addition, environmental issues that may influence the efficacy of the PT treatment should be explored, such as examining the impact of providing PT at the patient's home. Furthermore, dose-response levels and costs-benefits analyses might provide useful information.

In summary, PT may offer an efficacious, noninvasive, nonpharmacological intervention for CRF, one with the benefits of a formal training and regulatory system for practitioners, ease of access for patients, and having no known side effects. Future research to confirm and expand these initial positive findings is warranted.

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