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A case-control, mono-center, open-label, pilot study to evaluate the feasibility of therapeutic touch in preventing radiation dermatitis in women with breast cancer receiving adjuvant radiation therapy

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Summary
Background: Therapeutic touch (TT) is a non-invasive commonly used complementary therapy. TT is based on the use of hand movements and detection of energy field congestion to correct imbalances. Improvement in subjective symptoms in a variety of clinical trials has been seen with TT. The effect of TT during radiotherapy for breast cancer is unknown.
Methods: Women undergoing adjuvant radiation for Stage I/II breast cancer post conservative surgery were recruited for this cohort study. TT treatments were administered three times per week following radiation therapy. Feasibility was defined as an a priori threshold of 15 of 17 patients completing all TT treatments. The preventive effectiveness of TT was evaluated by documenting the 'time to develop' and the 'worst grade of radiation' dermatitis. Toxicity was assessed using NCIC CTC V3 dermatitis scale. Cosmetic rating was performed using the EORTC Breast Cosmetic Rating. The quality of life, mood and energy, and fatigue were assessed by EORTC QLQ C30, POMS, and BFI, respectively. The parameters were assessed at baseline, and serially during treatment.
Results: A total of 49 patients entered the study (17 in the TT Cohort and 32 in the Control Cohort). Median age in TT arm was 63 years and in control arm was 59 years. TT was

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considered feasible as all 17 patients screened completed TT treatment. There were no side effects observed with the TT treatments. In the TT Cohort, the worst grade of radiation dermatitis was grade II in nine patients (53%). Median time to develop the worst grade was 22 days. In the Control Cohort, the worst grade of radiation dermatitis was grade III in 1 patient. However, the most common toxicity grade was II in 15 patients (47%). Three patients did not develop any dermatitis. Median time to develop the worst grade in the control group was 31 days. There was no difference between cohorts for the overall EORTC cosmetic score and there was no significant difference in before and after study levels in quality of life, mood and fatigue.

Conclusion*:* This study is the first evaluation of TT in patients with breast cancer using objective measures. Although TT is feasible for the management of radiation induced dermatitis, we were not able to detect a significant benefit of TT on NCIC toxicity grade or time to develop the worst grade for radiation dermatitis. In addition, TT did not improve quality of life, mood, fatigue and overall cosmetic outcome.

Introduction

Therapeutic Touch (TT) is the current term used for an ancient practice called the ''laying of hands'' commonly used in a variety of settings. However, this is a misnomer since the intervention does not necessarily require any direct patient touching. It is based on a belief that every living organism has an energy field around it that produces an aura. This energy field can go unbalanced when the living organism is sick and healers can feel and manipulate this energy field by movement of hands over the patient's body just like massaging the air few inches above the patient's body. This process usually lasts 10—20 min depending on the practitioner's ability to detect these imbalances and the amount of areas with energy congestion.[1] This primal life energy imbalance can be corrected according to TT practitioners. Furthermore, this channeling of vital energy can assist healing; a concept common in Ayurvedic medicine and healing systems found in India, China, Japan, and Greece where it is called prana, chi, ki, or pneuma, respectively.[1,2]

According to the Cochcrane Collaboration, TT was first popularized by Dr. Krieger, a research nursing professor at New York University. A literature search using the MESH heading 'therapeutic touch' identifies 847 articles with 178 published within the last 5 years.[3] TT at present is taught in 75 schools and universities and at 95 health care facilities in North America.[4] Training is available in over 70 countries through institutions such as The American Nurses Association.[4]

There are no known side effects related to the use of TT. Most of the previous trials on TT have demonstrated subjective symptom improvement in a variety of clinical situations, including anxiety, pain and other related symptoms. The rationale for this study stemmed from clinical trials, which demonstrated improvement in wound healing with TT.[2,5]

Relative to many alternative therapies, the demonstration of a quantifiable objective response is an interesting and impressive aspect of TT that calls for further investigation. Radiation induced dermatitis is a common problem in a significant proportion of patients treated with radiation. In addition, it is a quantifiable complication, easily observed and graded according to National Cancer Institute criteria for toxicity. Therefore, we opted to investigate TT to assess its ability to prevent radiation dermatitis associated with adjuvant radiation therapy for early breast cancer.

Patients and methods

Study design

Patient selection

A single institution, ethics review board approved, prospective case-cohort study was conducted in patients with histo-pathologically or cytologically confirmed diagnosis of breast cancer, scheduled to receive adjuvant tangent radiation therapy as outpatients at the London Regional Cancer Program, London, Ontario. Female patients between 18 and 80 years of age at the time of enrollment and who had completed lumpectomy and sentinel lymph node biopsy or axillary lymph node dissection were eligible. Patients requiring electron treatments or bolus were excluded. Patients were allowed to receive standard treatments for dermatitis as per institution guidelines. Patients had to be off of any homeopathic and/or herbal treatment intended for preventing or treating dermatitis 24 h prior to study entry and such treatments were not allowed during the study as well. A convenience sample comprising of 17 consecutive patients was recruited. Once this cohort had completed the study a sequential control cohort consisting of 32 patients was recruited subsequently. This control cohort of patients had the same inclusion and exclusion criteria for their eligibility to participate in the trial and followed the same study schedule as the experimental cohort, except that no TT was administered.

The primary outcome measurements were (1) feasibility of conducting TT treatment in a comprehensive cancer centre defined as an a priori threshold of 15 of 17 patients completing all treatments and (2) prevention of dermatitis defined by two objective variables: (i) the worst grade of radiation dermatitis experienced and (ii) time to develop the worst grade. Secondary objectives included evaluation of quality of life (EORTC QLQ C-30), fatigue (Brief Fatigue Inventory, BFI) and mood (POMS). The secondary outcomes were only measured in the experimental cohort.

Therapeutic touch treatment

Certified TT practitioners from Wellsprings, London, Ontario volunteered to perform TT on recruited patients. All practitioners had completed level 3 (basic therapeutic touch