



## Longitudinal trends in skin-related and global quality of life among women with breast radiodermatitis: A pilot study<sup>☆</sup>



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### A B S T R A C T

**Purpose:** The purpose of this pilot study was to explore the relationship between skin-related quality of life (SR-QOL) and global quality of life (G-QOL) among women experiencing breast radiodermatitis, measure change in SR-QOL and G-QOL between the start and fifth week on radiotherapy, and examine the trend in SR-QOL and severity of radiodermatitis over time on treatment.

**Methods:** A descriptive longitudinal study using repeated measurements was implemented. Forty women undergoing whole breast 3-dimensional conformal radiotherapy at a comprehensive community cancer center completed the Dermatology Life Quality Index (DLQI) weekly and Quality of Life-Breast Cancer Patient Version at baseline before and at five weeks on radiotherapy. Skin toxicity was measured weekly using the Radiation Therapy Oncology Group (RTOG) Acute Radiation Morbidity Scoring Criteria-Skin scale. A Kendall's tau correlation explored the relationship between measures of SR-QOL and G-QOL. Paired t-tests measured the change in SR-QOL and G-QOL from baseline to fifth week on radiotherapy. The mean of the baseline and weekly total DLQI and RTOG scores was calculated and plotted on a graph.

**Results:** In general, SR-QOL and G-QOL were highly correlated. SR-QOL changed profoundly ( $p < .001$ ) while G-QOL did not change ( $p = .55$ ) between baseline and five weeks on radiotherapy. SR-QOL and radiodermatitis steadily worsened over time.

**Conclusions:** Radiation-induced skin toxicity has a major impact on SR-QOL but not G-QOL. This study provides much-needed scientific evidence to inform a larger future study in a community setting. Recommendations for future studies include inclusion of a skin-sensitive survey of radiodermatitis; larger, more diverse community-dwelling sample.

### 1. Introduction

Skin toxicity (i.e., radiodermatitis) is a common issue among women receiving radiotherapy for breast cancer. The incidence of radiodermatitis of the breast ranges up to 100% (Berthelet et al., 2004; Knobf and Sun, 2005). Radiodermatitis develops in a continuous cycle during treatment. The skin is an “innocent bystander” (i.e., not the intended target) during radiotherapy (Hymes et al., 2006). Radiation damages the epidermal and dermal layers of the skin tissue and vasculature supporting the skin at the cellular level including DNA (Singh et al., 2016). Inflammatory cells are recruited (Salvo et al., 2010; Singh et al., 2016). Each subsequent fraction of radiotherapy leads to

additional tissue damage and inflammatory response; continuing the cycle. The local manifestations of acute radiodermatitis include erythema, increased pigmentation, epilation, dry desquamation, and moist desquamation (Archambeau et al., 1995). The RTOG, CTCAE and WHO criteria are 3 established instruments used to measure radiation-induced skin toxicity (Huang et al., 2015). Acute radiodermatitis occurs during or near the time of therapy (Seité et al., 2017). Evidence to reliably prevent or manage radiodermatitis is lacking (Singh et al., 2016).

A few studies have examined the impact of breast radiodermatitis on health-related quality of life (HRQOL) as a primary outcome. Schnur et al. found in their 2009 pilot study that breast cancer patients receiving radiotherapy perceived there is a time when symptoms should

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appear and a time when those symptoms should resolve; the patients feared cancer recurrence, receiving the wrong treatment, or the symptoms may never end; the patients perceived themselves as physically repulsive and felt guilty about not being able to do everything they did before the breast cancer diagnosis. The pilot study was followed with a larger study in 2011. In this second study, breast cancer patients commented that sunburns go away, but radiation burns keep getting worse; they were anxious for their skin's appearance to return to normal; they often needed to adapt their clothing and this impacted their social activities (Schnur et al., 2011). In another study, women receiving external whole breast radiotherapy reported worsened perception of body image and more financial concerns than women receiving interstitial multicatheter brachytherapy (i.e., internal radiotherapy; Wadasadawala et al., 2009), (Knobf and Sun 2005) found women undergoing radiotherapy for breast cancer reported experiencing pain, twinges, skin changes, fatigue, sleep disturbances, and breast edema. Comparably, women in the study by Wengström et al. (2000) described having pain, skin changes, and fatigue at the end of breast radiotherapy. All the participants in Knobf and Sun (2005) study experienced a skin change by the fifth week of radiotherapy. Similarly, 100% of the breast cancer patients in a study by Berthelet et al. (2004) developed skin toxicity during external radiotherapy. The results of these studies demonstrate that women receiving external radiotherapy for breast cancer are likely to develop radiodermatitis and experience a detrimental effect on their HRQOL. The term skin bother is sometimes used to describe and quantify the impact of skin conditions on quality of life (Chren, 2012). Skin bother includes one or more of the following discomfort, difficulty, trouble, interruption, and irritation (Gawlicki et al., 2014).

Many studies of radiodermatitis focus on testing agents to prevent or manage skin toxicity and measure HRQOL as a secondary outcome. The global impact of radiodermatitis on HRQOL includes changes to body image, clothing selection, and ability to engage in activities of daily living (Schnur et al., 2009, 2011). Studies that explore skin-related and global QOL in the presence of radiodermatitis are few. We sought to help fill that knowledge gap.

## 2. Methods

### 2.1. Study aims

The aim of this pilot study was to investigate the impact of breast radiodermatitis on skin-related and global QOL. More specifically, we sought to (1) explore the relationship between skin-related and global quality of life among women experiencing breast radiodermatitis, (2) measure change in skin-related and global quality of life before the start of and at week five on radiation therapy when radiodermatitis was expected to begin to reach peak level, and (3) examine the weekly change in skin-related QOL and severity of radiodermatitis.

### 2.2. Design

A descriptive longitudinal study using repeated measurements was implemented to explore the study aims.

### 2.3. Sample size

We desired sufficient power to accurately detect significant differences in our pilot study. Lacking an a priori estimate of effect, a sensitivity analysis was conducted using G\*Power version 3.1.9.1, with a sample size of 40 participants in one group, .10 alpha level of significance, power of .80, epsilon of 1.0, correlation of .50, and six repeated measurements (Buchner et al., 2017). Using these parameters, we could expect to detect an effect size of .15 which is a small effect size using Cohen's criteria (Cohen, 1992). Since we planned to conduct a descriptive pilot study, a slightly relaxed level of significance was

acceptable in that it helps us avoid missing small but clinically significant differences.

### 2.4. Sample and setting

A purposive sample of 41 women undergoing 3-dimensional conformal radiotherapy for breast cancer was recruited starting May 2014 through May 2015. Eligibility criteria included women over 18 years old with stage 0-III breast cancer; invasive ductal or lobular, or DCIS histology; receiving adjuvant external beam radiotherapy (EBT), and status post mastectomy or segmentectomy. One woman withdrew from the study before completing all the baseline measurements.

The study was conducted in a single radiation department in an American College of Surgeons Commission on Cancer-accredited Comprehensive Community Hospital Cancer Program in northern Illinois, United States of America. Catchment area for the cancer program includes several counties in northern Illinois and southern Wisconsin. The cancer program had 216 analytic cases of breast cancer during calendar year 2013 (Sebastian and Moerschbaeche, 2015).

## 3. Study measures

### 3.1. Dermatology Life Quality Index (DLQI)

The DLQI is a 10-question instrument that explores the participant's perception of skin condition impact on quality of life. It was designed to minimize survey burden when used weekly. Weighted scores range from 0 to 30 with higher scores indicating worsening quality of life (Department of Dermatology, Cardiff University). The independently investigated and reported reliability of the DLQI for use among individuals with psoriasis and eczema was a Cronbach's alpha of .83 (Badia et al., 1999). Participants in our study completed the DLQI at baseline and weekly during radiotherapy.

### 3.2. Quality of Life-Breast Cancer Patient Version (COH-QOL-breast)

The City of Hope Quality of Life-Breast Cancer Patient Version is an instrument consisting of 47 ordinal scale items that measure the participant's perception of breast cancer impact on global health-related quality of life (Ferrell et al., 1996). This instrument includes 4 subscales: physical wellbeing, psychological well-being, social concerns and spiritual well-being (City of Hope Quality of Life Instrument - Breast Cancer Patient Version). Results are generally reported in relation to mean scores for each of the four subscale scores and the total score. Scores can range from 0 to 10 usually based on a scale of 0 = worst outcome to 10 = best outcome.

For the purpose of this study, scores were reversed for part of the analysis, to match the scoring on the DLQI and the RTOG so that 0 = the best outcome and 10 = the worst outcome. The Quality of Life Breast Cancer Version instrument was developed from the 41-item Quality of Life Patient/Cancer Survivor instrument (QOL-CS). The reported overall Cronbach's alpha for the QOL-CS is  $r = 0.89$  and is  $r = 0.81$  for the social concerns,  $r = 0.88$  for the physical well-being,  $r = 0.88$  for the psychological wellbeing, and  $r = 0.90$  for the spiritual well-being subscales (Ferrell et al., 1996). A comparison of the DLQI and COH-QOL-Breast instruments is provided in Table 1.

### 3.3. RTOG Acute Radiation Morbidity Scoring Criteria-Skin (RTOG score)

The Radiation Therapy Oncology Group (RTOG) score is measured using an ordinal scale with a range of 0–4. The number represents level of skin toxicity and increases with severity of radiodermatitis grade (i.e., 0 = “no change from baseline;” 1 = “follicular, faint, or dull erythema/epilation/dry desquamation/decreased sweating;” 2 = “tender or bright erythema, patchy moist desquamation/moderate edema;” 3 = “confluent, moist desquamation other than skin folds,

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