

# A Prospective Randomized, Placebo-Controlled Skin Care Study in Women Diagnosed With Breast Cancer Undergoing Radiation Therapy

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Each year in the United States, about 207,090 women are diagnosed with breast cancer (American Cancer Society, 2010); of them, a subset will receive radiation therapy for cure, control, or palliation. Women undergoing radiation therapy can expect to experience certain acute or late effects. One of the most common side effects along with fatigue is an acute skin reaction that can occur as early as one to two weeks into treatment and take up to one month post-treatment to heal. The challenge for healthcare providers is twofold: (a) patients can access and choose from a variety of skin care products (e.g., Aquaphor®, Beiersdorf, Inc.) and (b) no evidence-based practice guidelines exist.

Acute skin reactions arise from the interaction of ionizing radiation on the normal epithelium. Patients undergoing treatment typically have an entry and exit site from the radiation beam, and the skin becomes irradiated by treatment necessity. Although the reactions are considered a normal part of the treatment experience, they can cause discomfort, pain, and difficulty in performing activities of daily living, as well as interfere with patients' quality of life. Severe skin reactions may be painful, lead to localized and occasionally systemic infection, and cause permanent scarring (Williams et al., 1996). Other acute effects associated with whole-breast irradiation include transient pain or discomfort in the breast, nipple tenderness or sensitivity, and mild breast edema (Mazanec, 1997).

Women commonly develop skin reactions during radiation therapy. About 87% of women will develop some degree of radiation-induced dermatitis, varying from mild to brisk erythema or moist desquamation (Fisher et al., 2000). The reactions vary in incidence and severity based on the total dose of radiation, treatment volume, daily fraction size, energy and type of radiation, total treatment time, and other individual factors.

The purpose of the current study was to evaluate three commonly used skin care products for women receiving whole-breast radiation therapy against a placebo.

**Purpose/Objectives:** To compare the effectiveness of three different skin care products versus a placebo in reducing the incidence of radiation therapy-induced skin reactions prophylactically.

**Design:** Prospective randomized, double-blinded, placebo-controlled study.

**Setting:** A radiation oncology department at a National Cancer Institute-designated comprehensive cancer center in the southeastern United States.

**Sample:** 208 women with breast cancer who were to receive whole breast radiation therapy.

**Methods:** Patients were invited to participate after radiation therapy was documented as part of their treatment plan. Patients applied a skin care product starting on the first day of treatment and were assessed weekly by their radiation oncology nurse.

**Main Research Variables:** Skin reaction score and skin product.

**Findings:** None of the products were statistically better than placebo in preventing skin reactions. Increases in skin reaction over time did not vary with treatment group for the linear ( $p = 0.16$ ) and nonlinear ( $p = 0.94$ ) effects of time and for both time components tested together ( $p = 0.41$ ).

**Conclusions:** Ninety-five percent of women participating in this study experienced a radiation therapy-induced skin reaction.

**Implications for Nursing:** The development of guidelines to support safe patient care is encouraged because patients prefer to take action rather than do nothing. However, the findings do not demonstrate improved clinical outcomes with the use of skin care products. Healthcare providers should proactively educate patients about acute skin reactions and self-care strategies to minimize skin breakdown.

The study addressed the following questions: (a) What percentage of women who undergo radiation therapy for breast cancer treatment experience a skin reaction? (b) Does a skin care product compared to placebo reduce the incidence of an acute skin reaction in women receiving radiation therapy for breast cancer?