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

Tracy K. Gosselin, RN, MSN, AOCN®, Susan M. Schneider, PhD, RN, AOCN®, FAAN, Mary Ann Plambeck, RN, MSN, OCN®, and Krista Rowe, RN, MSN, AOCNS®

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.

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. 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?

Literature Review

Since the 1980s, radiation technology and treatment techniques have evolved with better contouring and tissue penetration, thus minimizing dosage to the skin when possible. A review of the literature suggested that no standards of care exist related to the protection and prevention of treatment-related skin reactions from radiation therapy. Multiple studies have been conducted to evaluate the ability of skin care products to decrease the incidence or severity of an acute skin reaction. Historically, evidence-based guidelines in this area have been based on expert opinion, provider preference, patients' reported satisfaction, and product availability. Protective skin care products are believed to defend the epidermis by providing hydration and keeping the skin supple, whereas other products are thought to decrease pruritis, erythema, and dry desquamation.

Publications by Wickline (2004), McQuestion (2006), and Bolderston et al. (2006) provide a comprehensive review of individual studies; this article provides only an overview. Wickline (2004) reviewed 18 randomized, controlled trials (RCTs), one case report, and one unpublished study. The most commonly studied products included aloe vera, Biafine® RE (Laboratoire Medix), and sucralfate. Wickline (2004) noted challenges related to sample size and generalizability of results, as well as a lack of consistent scoring measures across studies. McQuestion (2006) reviewed 14 RCTs and one nonrandomized study, noting a lack of well-designed RCTs reported in the literature. McQuestion (2006) recommended additional examination of calendula cream because one study, to date, found a statistically significant difference ($p < 0.001$) in grade 2 or higher skin reactions. Bolderston et al. (2006) reviewed 28 trials and concluded that gentle washing of the skin and the use of an unscented, lanolin-free hydrophilic cream may be helpful in preventing a skin reaction, whereas low-dose corticosteroids also may be used to minimize itching.

The reviews shared many of the same RCTs and commonly used products such as aloe vera, Aquaphor, and Biafine RE, as well as less commonly used products such as calendula ointment, chamomile cream, almond oil, topical vitamin C, corticosteroid creams, sucralfate cream, and hyaluronic acid cream. Barrier products such as Dermafilm® (Vygon) and hydrocolloid dressings also have been studied in patients with desquamation. The authors suggest further study of aloe vera, calendula cream, corticosteroid cream, and various dressings because existing literature is inconclusive to guide practice.

To date, several studies have tested the efficacy of products, and results support the use of some products; however, gaps exist in this area of research and future studies should consider incorporating (a) a consistent and validated scoring mechanism, (b) an adequate sample size, (c) randomization or blinding, (d) diverse patient populations and treatment sites, and (e) additional outcome measures including patient comfort, symptom relief, ease of product application, and satisfaction. Researchers also might consider multisite studies for quicker accrual as well as comparing commonly available products to new agents. Finally, product initiation (two weeks before treatment, day of treatment, or once a reaction occurs) and frequency of application (once, twice, or three times daily) are areas of variability in the literature that need additional study, and participant adherence rates with product application are not reported consistently.

Framework

The framework used to guide the current study was the physiologic model of wound healing. The skin is the first line of defense against infection and is the largest organ of the body, accounting for about 15% of total body weight in the average adult (Sherwood, 1989). The skin is composed of three layers: epidermis, dermis, and subcutaneous tissue. The layers serve various intrinsic and extrinsic functions. Intrinsic factors that can affect healing include poor oxygenation, poor blood supply, anemia or other concurrent diseases (e.g., immunosuppression), diabetes mellitus, malignancies, edema, inadequate hydration, and the regulation of electrolytes. Extrinsic factors that can affect healing include pressure, shear, friction, excessive moisture, or repeated trauma.

The wound healing process typically is classified as a cascade with overlapping phases. Historically, the process was considered to be composed of three to four phases but may now include five overlapping phases (Denham & Hauer-Jensen, 2002), based on new knowledge of cytokines and growth factors. The first phase is homeostasis, in which the coagulation system activates and vasoconstriction occurs. Next is the inflammation phase, often referred to as the defensive phase because it is the initial response to injury and is characterized by the attraction of neutrophils and macrophages. Capillary dilation, increased vascular permeability, and an increase in oxygen also may occur. The proliferation or regeneration phase is when angiogenesis occurs and a new extracellular matrix is developed by fibroblasts that lay a bed of collagen. Re-epitheliazation occurs of the epidermis, and macrophages are the dominant cell in this phase. During contraction, the injury starts to decrease in size. Finally, in the maturation-remodeling phase, the collagen is remodeled and the epidermis is restored. The process varies in people receiving radiation therapy as a result of the repetitive nature of the treatment.

Skin reactions occur when ionizing radiation affects rapidly growing cells and causes biochemical changes that can injure and kill proliferating cells in the basal layer of the epithelium. Basal cells are highly proliferative and sensitive to radiation and undergo rapid mitotic activity following injury. As basal cells multiply to

replace injured cells, the skin surface becomes dry and patients may experience dry desquamation. If new cells are not being produced fast enough as in areas of skin apposition, moist desquamation forms in response to shedding of the epidermis (Korinko & Yurick, 1997). Symptoms of a skin reaction and their severity vary based on the dose of radiation therapy. Epilation and erythema occur at doses of 2,000–4,000 centigray (cGy); pigmentation changes at 4,500 cGy, dry desquamation at doses higher than 3,000 cGy, and moist desquamation with doses higher than 4,000 cGy (Archambeau, Pezner, & Wasserman, 1995; Moore-Higgs, 2007; Sparks, 2007). In addition to visible skin changes, acute skin reactions can cause discomfort including pruritis and varying degrees of somatic pain (Moore-Higgs & Amdur, 2001).

The proposed trial was designed to build on existing knowledge and eliminate some methodologic issues of prior research. Conducting a double-blinded study that evaluates the outcomes of skin care products in patients with breast cancer can provide knowledge that will guide nursing intervention. Although the results of this study can be generalized only to patients with breast cancer, the design can be replicated easily in patients receiving radiation therapy for other types of cancer and with different study products. The current study tested the premise that use of a skin care product will reduce the incidence of a radiation therapy skin reaction by providing a protective barrier that promotes cellular regeneration.

Methods

Sample

This prospective, double-blinded, placebo-controlled study had a convenience sample of 301 women with a diagnosis of breast cancer who were to receive whole-breast

Table 1. Sample Characteristics

	Placebo (N = 49)		Aquaphor® (N = 53)		Biafine® RE (N = 53)		RadiaCare™ (N = 53)		
Characteristic	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**$\bar{X}$**	**SD**	**p**
Age (years)	55.8	11.9	54.8	10.6	56	10.8	55.6	8.15	0.88
Body mass index	28.1	6	29.1	7.6	28.8	7.1	28	7	0.69
Blood pressure (mmHg)									
Systolic	130	19.1	129	18.1	130	18.2	129	19	0.98
Diastolic	74	9.7	74	10.3	76	10	76	9	0.39
Characteristic	**n**	**%**	**n**	**%**	**n**	**%**	**n**	**%**	**p**
Race									0.67
Caucasian	39	80	43	81	44	83	46	87	
African American	9	18	10	19	9	17	7	13	
Asian	1	2	–	–	–	–	–	–	
Skin complexion									0.14
Light	19	39	26	49	21	40	34	64	
Medium	21	43	18	34	23	43	11	21	
Dark	9	18	9	17	9	17	8	15	
Bra size[a]									0.94
A	3	6	3	6	2	4	3	6	
B	12	24	17	32	15	28	19	36	
C	24	49	19	36	21	40	18	34	
D	10	20	14	26	13	25	13	25	
Prior chemotherapy									0.37
Yes	15	31	24	45	20	38	24	45	
No	34	69	29	55	33	62	29	55	
Menopausal status									0.8
Premenopausal	10	20	10	19	7	13	9	17	
Postmenopausal	37	76	41	77	41	77	40	75	
Perimenopausal	2	4	2	4	5	9	4	8	
Tobacco use									0.96
Yes	7	14	9	17	8	15	7	13	
No	42	86	44	83	45	85	46	87	
Education level									0.06
Less than high school	2	4	5	9	1	2	–	–	
High school	9	18	12	23	9	17	5	9	
More than high school	38	78	35	66	39	74	45	85	
More than 16 years of school	–	–	1	2	4	8	3	6	

[a] Data are missing for the Biafine RE group.

Note. Because of rounding, not all percentages total 100.

radiation therapy. Women were accrued after they were seen by a radiation oncologist and radiation therapy was documented as part of their treatment plan. Inclusion criteria were female gender, a diagnosis of breast cancer, older than 18 years of age, Karnofsky performance status of 80 or higher, and the ability to read and write in English. Exclusion criteria were active skin lesions on either breast, being pregnant, mastectomy, concurrent chemotherapy, concurrent hyperthermia, prior radiotherapy to the same breast, and history of allergic reaction to the products used in the study.

Instruments

Clinician assessment: A skin care data tool was initiated for all participants at the time of initial consent. The tool was developed by the nurses in the radiation oncology department and was pilot tested in the department prior to study implementation. Documentation of skin condition was added to the form during the weekly treatment check. The Radiation Therapy Oncology Group (RTOG) acute radiation morbidity scoring criteria were used to provide consistency in measuring the severity of the skin reaction and to provide consistency in data collection. The RTOG scale has no formal published reliability or validity testing; however, the scale is used widely to assess skin reactions (Fisher et al., 2000; Halperin, Gaspar, George, Darr, & Pinnell, 1993; See, Wright, & Denham, 1998). The acute radiation morbidity scoring criteria were developed in 1985 as complimentary to the late effects scoring criteria (Cox, Stetz, & Pajak, 1995). The RTOG scoring criteria are used regularly as a standard tool in the clinic to measure acute and late side effects. Each nurse was asked to rate 10 different standardized skin reactions, and reliability was found to be greater than 90% prior to study initiation with the scale. Data collected included changes noted in the skin, severity of the skin reaction, and other symptom measures. Weekly evaluation and data collection were estimated to take about five minutes. Inter-rater reliability for the RTOG scoring criteria was 0.96 prior to study initiation.

Participant self-assessment: Participants were asked to complete a home journal that was developed by the principal investigator. The journal documented participants' application, satisfaction, and ease of use with the product and the effect of a skin reaction on the patient if one occurred. The journal also served as a reminder not to apply any other products to the area. Williams et al. (1996) were unable to follow compliance with skin regimens in their study participants who did not use a home journal. The journal contained daily boxes for the patient to check off each application over the course of radiation therapy and was pilot tested with a group of women for readability and ease of use. Responses were measured on a scale of 0–4. During their last week of treatment, participants were asked three additional questions: two related to the product that they were given and another that asked them to confirm that they did not use any other skin product in the treatment area. The responses provided the principal investigator with subjective information from the participants on the severity and effect that the skin reaction had on them.

Table 2. Disease-Related Characteristics

Characteristic	n	%
Breast		
Left	113	54
Right	95	46
Stage		
0	53	25
I	76	37
II	62	30
III	17	8
Estrogen-receptor status		
Positive	157	75
Negative	43	21
Borderline	2	1
Not tested	6	3
Progesterone		
Positive	154	74
Negative	42	20
Borderline	6	3
Not tested	6	3
HER2/neu status		
Positive	53	25
Negative	93	44
Triple negative	17	8
Not tested	45	22
Comorbid diseases		
Skin allergies	44	21
Diabetes mellitus	20	10
Rheumatoid arthritis	4	2
Systemic lupus erythematosis	3	1
Bloom syndrome	2	1
Other	5	2

N = 208

Note. Because of rounding, not all percentages total 100.

Procedures

The clinical trial was approved by the institutional review board for the protection of human subjects before study accrual. Participants were identified by the radiation oncologists or radiation nurses on the day of consultation and then were invited to participate. After hearing an explanation of the study and giving informed consent, women were randomly assigned by using a table of random numbers to a study arm to receive placebo (sterile water mist), Aquaphor (ointment), Biafine RE (cream), or RadiaCare™ (Carrington Laboratories, Inc.) (gel). The products were selected because they are used commonly by patients and each represents a different type of topical application. Patients were enrolled from 2002–2006.

Products were supplied by the investigational pharmacy in containers labeled 4, 5, 6, or 7, with a sealed envelope that indicated the code number of each skin

Table 3. Radiation Therapy Characteristics

Characteristic	$\bar{X}$
Total number of treatments	31
Daily fraction dose (centigray)	199
Total dose (centigray)	6,200
Number of boost treatments	8
Boost dose (centigray)	1,611

Characteristic	n	%
Boost		
Yes	205	99
No	3	1
Tangent fields	208	100
Axilla field		
Yes	21	10
No	187	90
Supraclavicular field		
Yes	50	24
No	158	76
Breast ring		
Yes	4	2
No	204	98

N = 208

care product. Products were given to participants in a brown bag along with instructions for application. Participants were able to bathe because bathing has not been associated with increased toxicity (Campbell & Illingsworth, 1992; Roy, Fortin, & Larochelle, 2001). Patients were instructed to start the product on the first day of treatment and apply it twice a day (morning and night) every day of the week until treatment was complete, document the application in the journal, wash hands before and after product use, and avoid applying any other skin care product to the breast or applying the study product four hours before treatment. If radiation therapy was received in the morning, patients were instructed to apply the product after treatment. The radiation nurses and oncologists were blinded to group assignment. Participants were provided additional product as needed throughout their course of radiation therapy by the principal investigator. Upon completion of the study, women were provided a complimentary bottle of sunscreen.

The radiation nurse assessed the control and intervention groups weekly and reminded participants to complete their home journal. Journals were collected at the completion of radiation therapy. If the journal was not returned, the principal investigator sent participants a self-addressed stamped envelope in which to return it. If participants did not have the journal, they were asked three questions related to product application, satisfaction, and ease of use.

To ensure reliability in patient assessment, the principal investigator randomly reviewed participants' charts with the nurses weekly and when patients were on the treatment machine. The principal investigator randomly conducted an independent skin assessment on 10% of participants each week to establish interrater reliability. In addition, several practice cases were used to educate the nurses regarding skin care assessment procedures.

Data Analysis

Data were analyzed with SAS/STAT® version 9.1. Descriptive statistics were used to describe the sample, and analysis of variance was used to detect differences among study groups.

Results

Three hundred and one women were approached to participate in the clinical trial, of which 208 (69%) consented. Commonly stated reasons for not participating included not wanting a placebo, not interested, already having a product to use, wanting to keep options open, not wanting to incur additional costs, allergies, and emotional issues related to feeling overwhelmed or scared. The groups were equivalent in regard to age, body mass index, blood pressure, race, skin complexion, bra size, menopausal status, having received prior chemotherapy, tobacco use, and education level, demonstrating the effectiveness of randomization (see Table 1). In previous studies, some of those variables were found to influence skin reactions (Fisher et al., 2000; Heggie et al., 2002; Pommier et al., 2004; Wells et al., 2004).

Baseline disease-related factors demonstrated that most women had early stage disease (Tis and T1), were estrogen-receptor and progesterone-receptor positive, and had no metastasis (see Table 2). Women received an average of 31 external beam treatments with a mean

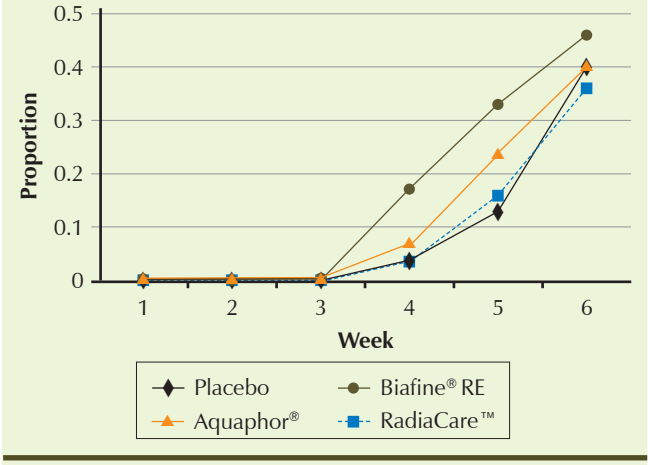

Figure 1. Proportion of Patients With a Grade 2–4 Skin Reaction

Placebo
- I thought I had water, the placebo, and sure enough that is what it tasted like.
- Hard to know if I covered all areas.
- A spray is not my choice but I can still rub if I need to. Would prefer a spray for comfort though.

Aquaphor®
- Rubbed off the markings and they had to be reapplied.
- I'm not sure if it was the product or the diligence in applying it—that prevented skin problems.
- The greasy formula was uncomfortable in daily life—messy.
- My skin is very sensitive to lotions and tape, but I had no problems with this product.

Biafine® RE
- Doesn't absorb into the skin very well.
- I found the product to be very soothing and moisturizing and used it on unaffected areas.
- In general a very nice product that eradicated my itching. Nice texture and it appears to "stay with you."
- My skin peeled and bled. This cream lasted for a little while but didn't last.

RadiaCare™
- Too sticky.
- Can't tell if it helped.
- Took 20 minutes to dry and stuck to clothes, but very soothing.
- I have sensitive skin and did well with this.

General
- Really have no idea of what to compare/how to compare.

Figure 2. Patient Comments Related to Study Products

daily dose of 199 cGy (median dose 200 cGy), eight of which were boost treatments to the scar with electrons (see Table 3). A total dose of 6,200 cGy was found to be most common.

A major finding of the study was that 95% of women who received radiation therapy for breast cancer treatment experienced a skin reaction. Time was a major predictor in the occurrence of skin reactions, with most women beginning to experience them by week 4. Time was found to be a significant factor in initial analyses and was retained in final models. An unstructured matrix provided the best fit to the data and was used to model within-person residual correlations over time. Significance tests were based on changes to the likelihood-ratio chi-square across nested models and indicated that increases in skin reaction over time did not vary with treatment group. The finding was true for linear ($p = 0.16$) and nonlinear ($p = 0.94$) effects of time and for both time components tested together ($p = 0.41$).

Figure 1 shows the proportion of participants with clinically significant (grade 2–4) skin reactions during each week of the study. None of the skin care products demonstrated a statistically significant difference in minimizing the incidence of a grade 2–4 skin reaction compared to placebo. Subsequent increases in the proportion with a skin reaction appeared similar for placebo and for participants using Aquaphor and RadiaCare. Increases were greatest among participants using Biafine RE.

In addition, understanding patient perspectives regarding the products was important because attitudes could potentially affect adherence to product use (see Figure 2). Product assignment did not seem to have an effect on patient adherence to the twice-a-day application schedule as outlined. One hundred and ninety one patients (92%) completed the journal as requested; of the 208 respondents, 90% (n = 187) recorded product application adherence higher than 80% for the duration of the study. From an ease of application standpoint, patients clearly preferred Biafine RE (see Table 4) and were more satisfied with Biafine RE over the other products (see Table 5), although the proportion of patients with skin reactions was highest in that group. The results are not surprising because Biafine RE is a cream-based product that is easy to apply whereas Aquaphor is a thick ointment and RadiaCare is a gel that often can make the skin feel tight once it dries.

Discussion

The purpose of this study was to prospectively evaluate three skin care products that may decrease the incidence of acute skin reactions or reduce the severity of skin reactions from radiation therapy in women with breast cancer. Findings demonstrate that none of the three skin care products tested was superior to the placebo of sterile water mist.

Findings are consistent with those previously reported by other researchers who tested single substances such as ascorbic acid, aloe vera gel, or Biafine (Fisher et al., 2000; Halperin et al., 1993; Williams et al., 1996). The current study addressed limitations identified in literature reviews by Bolderston et al. (2006), McQuestion (2006), and Wickline (2004). Despite the use of a prospective

Table 4. Participant Ratings: Ease of Product Application

	Not at All		A Little Bit		Somewhat		Quite a Bit		Very Much	
Product	n	%	n	%	n	%	n	%	n	%
Placebo (N = 49)	5	10	2	4	3	6	9	19	30	61
Aquaphor® (N = 53)	5	9	3	6	5	9	11	21	29	55
Biafine® RE (N = 53)	1	2	–	–	3	6	11	21	38	72
RadiaCare™ (N = 53)	2	4	2	4	2	4	18	34	29	55

Note. Because of rounding, not all percentages total 100.

Table 5. Patient Satisfaction With Product

Product	Not at All		A Little Bit		Somewhat		Quite a Bit		Very Much	
	n	%	n	%	n	%	n	%	n	%
Placebo (N = 49)	17	35	3	6	13	27	2	4	14	29
Aquaphor® (N = 53)	6	11	3	6	18	34	13	25	13	25
Biafine® RE (N = 53)	4	8	2	4	7	13	18	34	22	42
RadiaCare™ (N = 53)	3	6	3	6	13	25	18	34	16	30

Note. Because of rounding, not all percentages total 100.

double-blind design, a larger sample (n = 208), and consistent measurement for skin reactions, the current study did not identify a product that was effective at preventing skin reactions. Congruent with the findings from the existing literature reviews, the data from this study did not provide conclusive evidence that could guide clinical practice.

Strengths and Limitations

Strengths of the study were that it explored the effectiveness of skin care products in reducing the incidence of radiation-induced skin reactions prophylactically, had a large sample size, used a randomized double-blind design, and used available products that patients commonly use. Limitations were conducting the study at a single site, the self-report of product application, and the inability to control for intermittent use of other skin products. Although the results of this study can be generalized only to patients with breast cancer, the design can be replicated easily for patients receiving radiation therapy for other types of cancer and for testing other skin care products in the radiation therapy setting.

Selection of the placebo was problematic. After consulting with pharmacists and dermatologists, the authors determined that no lotion- or gel-type products would be neutral and lack the ability to provide a therapeutic effect. The authors decided to use a sterile water spray as the placebo because it allowed women to apply something but was not likely to interfere with any of the measurable effects that could be obtained from the lotion- and gel-type products. In addition, the authors were careful to plan twice daily dosing for women in all study arms to accommodate the schedule of the majority of the proposed population, who were employed women.

Clinical Implications

Skin reactions occurred in 95% of the women undergoing radiation therapy for breast cancer. Women facing a course of radiation therapy should be educated about what to expect as well as how to manage an acute skin reaction appropriately. The development of guidelines to support patient care is encouraged.

The current study was the first to demonstrate that no product was found to be more effective than placebo in preventing skin reactions. With the nurses providing supportive care, more data are needed to support evidence-based guideline development because this study and others do not support the recommendation of one product over another. If a woman should choose to use a product, healthcare providers should emphasize that the use of a skin product is not likely to prevent a skin reaction. Nurses will want to consider personal preferences such as ease of application, risk for an enhanced skin reaction, and product cost carefully before they recommend use. Aquaphor currently is available over the counter, whereas RadiaCare and Biafine RE require prescriptions, and the cost associated with each product is different.

The current study demonstrated that frequent skin assessments can be incorporated easily into routine care in the radiation oncology department. In addition, the study shows that the RTOG instrument was helpful for clinical assessments and using research data. Inter-rater reliability of the instrument was greater than 90%.

Education Implications

Educational materials for patients based on the best available evidence should be developed. Clinicians should emphasize that evidence does not support the use of a product to prevent skin reactions. The current study demonstrated that many patients chose not to participate in the study because they did not want to receive a placebo. Women clearly want to participate in their care; therefore, educational materials describing basic skin care (e.g., bathing instructions, avoiding sun exposure) could be provided.

Research Implications

Ongoing skin care research in radiation therapy is warranted because many products have been implemented in practice since the current study was initiated. Consistent use of a scoring mechanism and appropriate sample size should be taken into account when designing a study. In addition, other symptom measures such as pruritis, infection, or pain should be considered because a product might be able to influence other treatment-related symptoms versus the skin reaction itself.

Conclusion

The current study evaluated three commonly available products versus placebo in women undergoing radiation

therapy. The ability to determine which women are at risk for acute and late skin reactions pretreatment remains unclear. Findings from the current study and others demonstrate that additional research is warranted in this area before a definitive gold standard can be recommended. Nurses should evaluate the pros and cons of over-the-counter products compared to prescriptive products in relation to cost, efficacy, and composition because proactive education is essential for patients who prefer to take action rather than do nothing.

Tracy K. Gosselin, RN, MSN, AOCN®, is the associate chief nursing officer for Oncology Services at Duke University Health System; Susan M. Schneider, PhD, RN, AOCN®, FAAN, is an associate professor and director of the Graduate Oncology Nursing Specialty in the School of Nursing at Duke University; Mary Ann Plambeck, RN, MSN, OCN®, is the nurse manager of the Department of Radiation Oncology at Duke University Hospital; and Krista Rowe, RN, MSN, AOCNS®, is a clinical specialist in the Division of Cellular Therapy at Duke University Medical Center, all in Durham, NC. No financial relationships to disclose. Mention of specific products and opinions related to those products do not indicate or imply endorsement by the *Oncology Nursing Forum* or the Oncology Nursing Society. Gosselin can be reached at gosse001@mc.duke.edu, with copy to editor at ONFEditor@ons.org. (Submitted October 2009. Accepted for publication January 15, 2010.)

Digital Object Identifier: 10.1188/10.ONF.619-626

References

American Cancer Society. (2010). *Cancer facts and figures 2010*. Atlanta, GA: Author.

Archambeau, J.O., Pezner, R., & Wasserman, T. (1995). Pathophysiology of irradiated skin and breast. *International Journal of Radiation Oncology, Biology, Physics, 31,* 1171–1185. doi: 10.1016/0360-3016(94)00423-I

Bolderston, A., Lloyd, N.S., Wong, R.K., Holden L., Robb-Blenderman, L., & Supportive Care Guidelines Group of Cancer Care Ontario Program in Evidence-Based Care. (2006). The prevention and management of acute skin reactions related to radiation therapy: A systematic review and practice guideline. *Supportive Care in Cancer, 14,* 802–817. doi: 10.1007/s00520-006-0063-4

Campbell, I.R., & Illingsworth, M.H. (1992). Can patients wash during radiotherapy to the breast or chest wall? A randomized controlled trial. *Clinical Oncology, 4,* 78–82. doi: 10.1016/S0936-6555(05)80971-9

Cox, J.D., Stetz, J., & Pajak, T.F. (1995). Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organisation for Research and Treatment of Cancer (EORTC). *International Journal of Radiation Oncology, Biology, Physics, 31,* 1341–1346. doi: 10.1016/0360-3016(95)00060-C

Denham, J.W., & Hauer-Jensen, M. (2002). The radiotherapeutic injury—A complex "wound." *Radiotherapy and Oncology, 63,* 129–145. doi: 10.1016/S0167-8140(02)00060-9

Fisher, J., Scott, C., Stevens, R., Marconi, B., Champion, L., Freedman, G.M., . . . Wong, G. (2000). Randomized phase III study comparing best supportive care to Biafine as a prophylactic agent for radiation–induced skin toxicity for women undergoing breast irradiation: Radiation Therapy Oncology Group (RTOG) 97–13. *International Journal of Radiation Oncology, Biology, Physics, 48,* 1307–1310. doi: 10.1016/S0360-3016(00)00782-3

Halperin, E.C., Gaspar, L., George, S., Darr, D., & Pinnell, S. (1993). A double-blind, randomized, prospective trial to evaluate topical vitamin C solution for the prevention of radiation dermatitis. *International Journal of Radiation Oncology, Biology, Physics, 26,* 413–416. doi: 10.1016/0360-3016(93)90958-X

Heggie, S., Bryant, G., Tripcony, L., Keller, J., Rose, P., Glendenning, M., & Heath, J. (2002). A phase III study on the efficacy of topical aloe vera gel on irradiated breast tissue. *Cancer Nursing, 25,* 442–451. doi: 10.1097/00002820-200212000-00007

Korinko, A., & Yurick, A. (1997). Maintaining skin integrity during radiation therapy. *American Journal of Nursing, 97,* 40–44. doi: 10.2307/3465498

Mazanec, S.R. (1997). Breast cancer. In K. Hassey-Dow, J. Bucholtz, R. Iwamoto, V. Fieler, & L. Hilderley (Eds.), *Nursing care in radiation oncology* (pp. 101–135). Philadelphia, PA: W.B. Saunders.

McQuestion, M. (2006). Evidence-based skin care management in radiation therapy. *Seminars in Oncology Nursing, 22,* 163–173. doi: 10.1016/j.soncn.2006.04.004

Moore-Higgs, G.J. (2007). Breast cancer. In M.L. Haas, W.P. Hogle, G.J. Moore-Higgs, & T.K. Gosselin-Acomb (Eds.), *Radiation therapy: A guide to patient care* (pp. 142–165). St. Louis, MO: Mosby Elsevier.

Moore-Higgs, G.J., & Amdur, R.J. (2001). Sustaining integrity of protective mechanisms (skin, oral, immune system). In D. Watkins-Bruner, G. Moore-Higgs, & M. Haas (Eds.), *Outcomes in radiation therapy* (pp. 493–518). Boston, MA: Jones and Bartlett.

Pommier, P., Gomez, F., Sunyach, M.P., D'Hombres, A., Carrie, C., & Montbarbon, X. (2004). Phase III randomized trial of *Calendula officinalis* compared with trolamine for the prevention of acute dermatitis during irradiation for breast cancer. *Journal of Clinical Oncology, 22,* 1447–1453. doi: 10.1200/JCO.2004.07.063

Roy, I., Fortin, A., & Larochelle, M. (2001). The impact of skin washing with water and soap during breast irradiation: A randomized study. *Radiotherapy and Oncology, 58,* 333–339. doi: 10.1016/S0167-8140(00)00322-4

See, A., Wright, S., & Denham, J. (1998). A pilot study of Dermofilm in acute radiation-induced desquamative skin reactions. *Clinical Oncology, 10,* 182–185. doi: 10.1016/S0936-6555(98)80064-2

Sherwood, L. (1989). Defense mechanisms of the body. *Human Physiology: From cells to systems* (pp. 362–405). New York, NY: West Publishing.

Sparks, S.G. (2007). Radiodermatitis. In M.L. Haas, W.P. Hogle, G.J. Moore-Higgs, & T.K. Gosselin-Acomb (Eds.), *Radiation therapy: A guide to patient care* (pp. 511–522). St. Louis, MO: Mosby Elsevier.

Wells, M., MacMillan, M., Raab, G., MacBride, S., Bell, N., MacKinnon, K., . . . Munro, A. (2004). Does aqueous or sucralfate cream affect the severity of erythematous radiation skin reactions? A randomized controlled trial. *Radiotherapy and Oncology, 73,* 153–162. doi: 10.1016/j.radonc.2004.07.032

Wickline, M.M. (2004). Prevention and treatment of acute radiation dermatitis: A literature review. *Oncology Nursing Forum, 31,* 237–247. doi: 10.1188/04.ONF.237-247

Williams, M., Burk, M., Loprinzi, C., Hill, M., Schomberg, P., Nearhood, K., . . . Eggleston, W.D. (1996). Phase III double-blind evaluation of an aloe vera gel as a prophylactic agent for radiation-induced skin toxicity. *International Journal of Radiation Oncology, Biology, and Physics, 36,* 345–349. doi: 10.1016/S0360-3016(96)00320-3