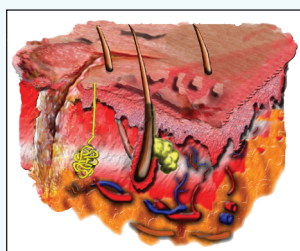


■ CNE Article

# A Feasibility Study of Low-Cost, Self-Administered Skin Care Interventions in Patients With Head and Neck Cancer Receiving Chemoradiation

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Current evidence for the management of radiation skin toxicities demonstrates equivocal outcomes using a variety of interventions, leaving substantial gaps in knowledge. Skin toxicities can lead to treatment delays, infection, pain, and increased costs for the patient. Patients with head and neck cancers receiving chemoradiation (N = 100), a population particularly vulnerable to disruptions in skin integrity, were enrolled into a prospective, descriptive study. Data collection was conducted and photographs were taken at baseline and weekly throughout treatment. Patients received skin care kits, instructions, and a diary to record adherence.

Skin toxicity was measured and validated by at least three observers using serial photographs with 100% interrater agreement. Data were analyzed using descriptive statistics, graphs, and bivariate analysis. Adherence to both washing and moisturizing was consistently high. Although a correlation existed between the radiation dose and skin toxicity at week 6, no correlation existed between skin toxicity and adherence. Given the rate of grade 3 toxicities at week 6 and product costs, this proved to be an affordable regimen to which patients could easily adhere. Positive patient outcomes can be promoted through teaching and reinforcement of self-care measures to reduce skin toxicity.

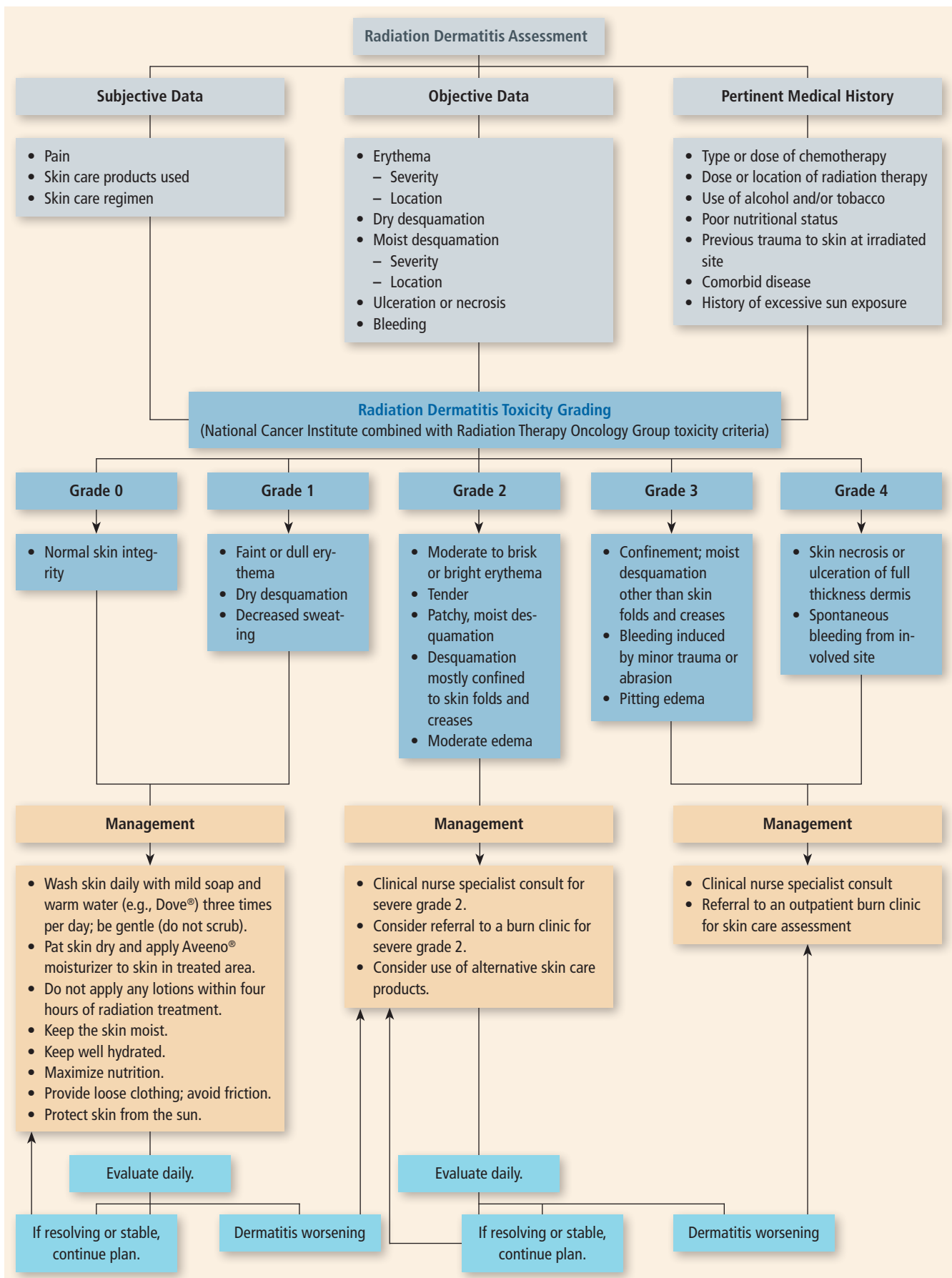
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**N**urses from radiation oncology, ambulatory infusion, and inpatient oncology units perceived an increase in skin toxicities in patients receiving chemoradiation within their respective clinical settings. The group formed a skin care task force (SCTF) and was joined by a nurse practitioner from the ambulatory burn clinic who had previously consulted on patients with treatment-related toxicities. The SCTF's preliminary work identified several areas for improvement. Nurses were using a variety of tools from the Radiation Therapy Oncology Group (RTOG) and National Cancer Institute (NCI), as well as descriptive documentation, to measure and describe grades of toxicity, including the RTOG skin toxicity tool and the NCI's Common Terminology Criteria for Adverse Events (CTCAE), version 3.0.

No standard skin care regimen was used to minimize or prevent treatment-related skin toxicities. This resulted in inconsistent management and prevention of treatment-related skin toxicities. The SCTF also surveyed staff regarding the wide range of skin care products used and found that the products varied in cost, availability, and evidence of efficacy.

To address these problems, the SCTF proposed using a standardized tool (see Figure 1) that would promote consistent skin toxicity grading across settings, implement an algorithm for management of skin toxicities to establish guidelines, and encourage consistent skin care across settings. In addition, an evidence-based literature review was conducted to determine best practice. The literature review revealed insufficient and inconclusive evidence supporting use of specific products;



**FIGURE 1. Skin Care Algorithm**

Note. Courtesy of Mimi Bartholomay, RN. Used with permission.

however, it did identify skin care principles, which included washing, moisturizing, and injury prevention (Bolderston, Lloyd, Wong, Holden, & Robb-Blenderman, 2006; McQuestion, 2006; Roy, Fortin, & Larochelle, 2001). The SCTF developed a rationale for use of skin care products that were fast absorbing, non-greasy, widely available, and low cost. Six months after instituting this process, a consensus existed among the multidisciplinary SCTF that the level of skin toxicity in patients receiving chemoradiation had improved, with fewer patients being referred to the nurse practitioner in the burn clinic.

A formal research study resulted from this preliminary work and focused on patients diagnosed with head and neck malignancies receiving combined chemoradiation treatments. The overall purpose of this study was to evaluate a low-cost, patient-administered skin care regimen focusing on efficacy, patient adherence, and affordability. The primary research questions were

- Can a low-cost, patient-administered skin care intervention minimize the grade of skin toxicity in patients with head and neck cancer receiving chemoradiation?

- What are the sociodemographic and clinical effect modifiers that influence a low-cost, patient-administered skin care intervention in terms of skin toxicity and adherence?
- Will patients adhere to a self-administered intervention?

## Literature Review

To date, research for the management of skin reactions related to radiation treatment is limited by use of varying patient populations, interventions, methodologies, and relatively small sample sizes (Kumar, Juresic, Barton, & Shafiq, 2010). The equivocal outcomes make evidence-based interventions difficult to determine. The variety of both treatment regimens and outcome measurements found in the literature contribute to the substantial gaps in knowledge regarding radiation skin reactions.

Patients with head and neck malignancies receiving chemoradiation are particularly vulnerable to disruptions in skin integrity, which may result in treatment delays, increased risk for infection, and pain for the patient. Impaired skin integrity

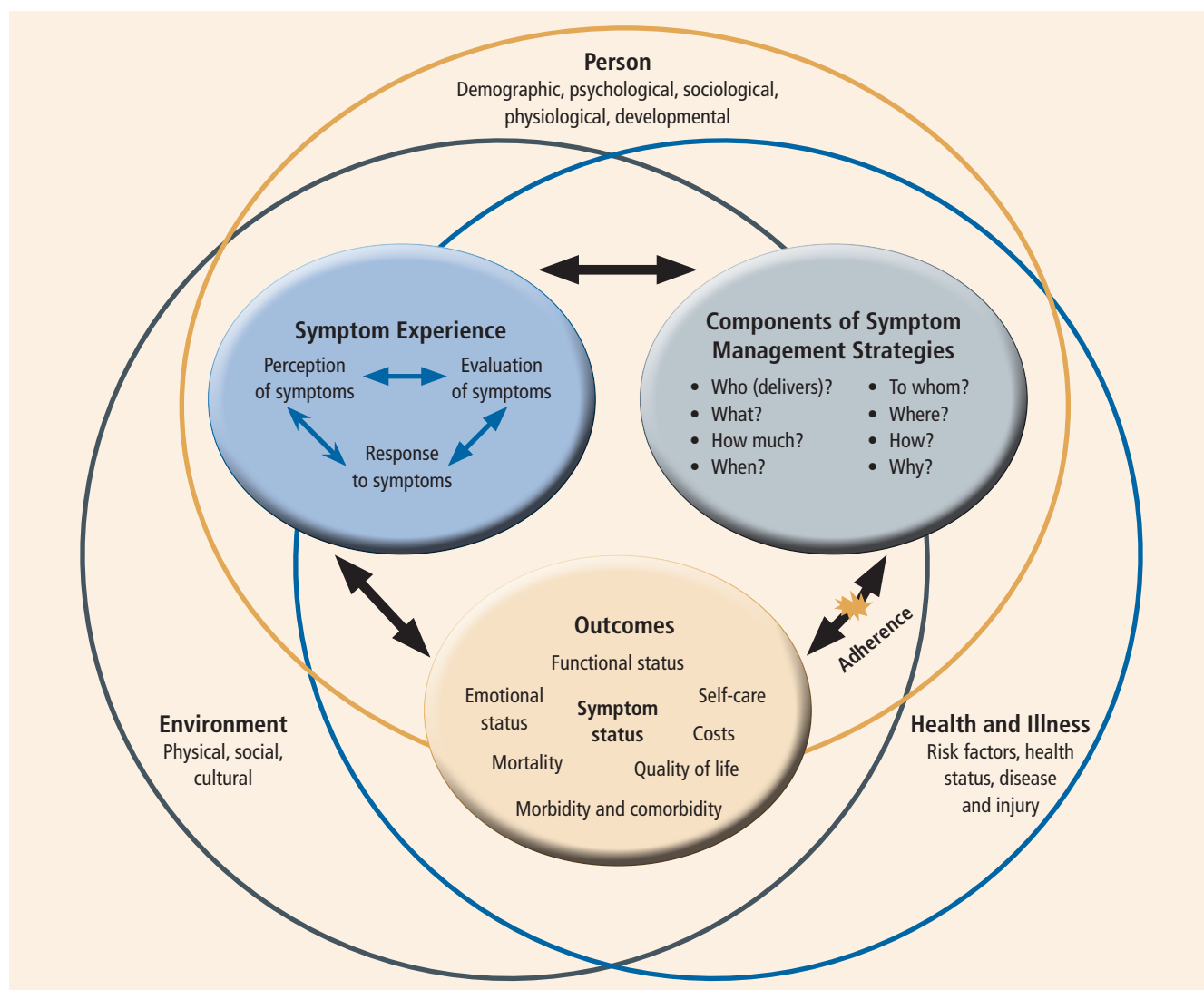


FIGURE 2. Model of Symptom Management

Note. From "Advancing the Science of Symptom Management," by M.J. Dodd, S. Janson, N. Facione, E.S. Faucett, J. Froelicher, J. Humphreys, . . . D. Taylor, 2001, *Journal of Advanced Nursing*, 33, p. 670. Copyright 2001 by John Wiley and Sons. Reprinted with permission.

**TABLE 1. National Cancer Institute Grading Scale for Dermatitis Associated With Chemoradiation**

Adverse Event	Short Name	Grade 1	Grade 2	Grade 3	Grade 4	Grade 5
Rash: dermatitis associated with chemoradiation	Dermatitis	Faint erythema or dry desquamation	Moderate to brisk erythema; patchy moist desquamation, mostly confined to skin fold areas	Moist desquamation other than skin folds and creases; bleeding induced by minor trauma or abrasion	Skin necrosis or ulceration of full thickness dermis; spontaneous bleeding from involved site	Death

*Note.* From *Common Terminology Criteria for Adverse Events (CTCAE)*, version 3.0, by the National Cancer Institute Cancer Therapy Evaluation Program. For the most up to date CTCAE version, visit [http://ctep.cancer.gov/protocolDevelopment/electronic\\_applications/ctc.htm](http://ctep.cancer.gov/protocolDevelopment/electronic_applications/ctc.htm).

can require intensive wound management that may be costly to the patient in terms of time and money.

The skin toxicities of external beam radiation therapy alone range from erythema and dry desquamation (NCI grade 1), moderate to brisk erythema or patchy moist desquamation (NCI grade 2), to moist desquamation (NCI grade 3) and skin necrosis or ulceration (NCI grade 4) (NCI Cancer Therapy Evaluation Program, 2006). Despite the fact that these skin side effects have been recognized as problematic for this population, little definitive research has been conducted on this topic and the results have been equivocal. Treatments range from mild soaps and aloe vera gels to Aquaphor®, Eucerin®, Biofene®, Xenaderm®, and various dressings, such as hydrogels. No conclusive evidence or data support specific products or skin care intervention protocols (Blevins, 2006; Bolderston et al., 2006; Fenig et al., 2001; Gosselin, Schneider, Plambeck, & Rowe, 2010; McQuestion, 2010, 2011; Naylor & Mallett, 2001; Nystedt et al., 2005); however, a randomized study of patients with breast cancer undergoing a course of radiation treatment demonstrated that use of a topical agent resulted in less erythema in the treatment field compared to those patients who did not use any topical agent. This study also noted an increase in skin toxicity in the no-topical agent group after two weeks of treatment, peaking between weeks 4 and 6 (Rizza, D’Agostino, Girlando, & Puglia, 2010).

In addition, a randomized, controlled study of 99 patients receiving breast irradiation compared washing with mild soap and tepid water to no washing in the treatment area. Patients experienced worse skin reactions in the no washing arm. Roy et al. (2001) concluded that washing does not increase skin toxicity and suggested this be part of routine care for patients receiving radiation. In addition, Dove® soap has been classified as a mild soap (Frosch & Kligman, 1979) and is recommended for use on sensitive skin. The study was guided by the theoretical and conceptual underpinnings of Dodd, Miaskowski, and Paul’s (2001) Model of Symptom Management (MSM) used to study symptoms in patients with cancer from a subjective symptom experience (Dodd, Janson, et al., 2001; Larson et al., 1994). The MSM has been used with patients undergoing chemotherapy and radiation treatment (see Figure 2).

## Methods

### Design, Setting, and Sample

The study was an institutional review board-approved prospective, descriptive study in a population of patients diagnosed

with head and neck malignancies receiving concurrent chemoradiation. Data collection occurred at baseline and at weekly intervals throughout the course of radiation treatment. Data were collected from patient diaries and chart review. Descriptive statistical analysis was conducted using SPSS®, version 17.0.

Patients were recruited from a radiation oncology department in a large, urban academic medical center. Eligibility criteria included being aged 21 years or older, having a diagnosis of a head and neck cancer, and receiving concurrent chemoradiation treatment. The sample was limited to English-speaking patients because of the limited number of non-English-speaking patients. Eligibility was not limited to any particular treatment regimen or disease stage. A convenience sample of 100 patients met the eligibility criteria and provided consent. Sample size was driven by available patient volume.

### Instruments

The demographic data collection form and weekly skin care diary were instruments developed by the investigators for data capture. A review of patient adherence studies, primarily on pharmacoadherence, supported the use of a diary as an indirect, subjective method for measuring patient adherence (Vermiere, Hearnshaw, & Van Royen, 2001). The weekly diary recorded daily washing and frequency of daily moisturizing, as well as comments and use of other skin care products. Skin grading was conducted on a weekly basis using the NCI’s CTCAE, version 3.0, grading scale for dermatitis associated with chemoradiation by staff nurses in radiation oncology (see Table 1). Despite training and education in NCI skin grading, an inherent potential for variation existed in the assessment of skin toxicity grading. To maintain reliability and validity of weekly skin assessment and grading, serial digital photographs were taken to document the skin integrity and level of skin reaction and were used to confirm the assigned NCI skin toxicity grade. Digital photographs were compared to documented NCI skin grade and reviewed by a minimum of three clinicians to reach 100% inter-rater agreement.

### Skin Care Intervention and Patient Education

After obtaining consent, patients were given specific skin care instructions on laminated cards, with verbal reinforcement. Patients were instructed to wash daily and moisturize three times per day with the products provided and to record the times in the weekly diary. The provided skin care kit included Dove soap, moisturizing lotion containing avena sativa,

TABLE 2. Sample Characteristics

Characteristic	$\bar{X}$	Range
Age (years)	57.4	21–90
Years of education	15	8–25
Characteristic	n	
<b>Gender</b>		
Male	87	
Female	13	
<b>Marital status</b>		
Married	64	
Single	23	
Divorced	13	
<b>Race</b>		
Caucasian	82	
African American	5	
Asian	5	
Hispanic	1	
Unknown	7	
<b>Smoking history</b>		
Former	55	
Current	8	
Never	37	
<b>Ethanol use</b>		
Current use	69	
No ethanol	30	
Unknown	1	
<b>Chemotherapy and biotherapy regimens (N = 90)</b>		
Carboplatin	17	
Carboplatin and paclitaxel	34	
Carboplatin and etoposide	21	
Carboplatin, paclitaxel, and panitumumab	4	
Cetuximab	4	
Cisplatin and doxorubicin	1	
Other	9	
<b>Radiation treatment regimens (N = 90)</b>		
Photon	67	
Proton	12	
Photon and proton	11	
N = 100, unless otherwise noted		

sunscreen with sun protection factor 30, and lip balm with sunscreen. The rationale for using these products was based on the principles of fast absorbing, non-greasy, hypoallergenic, widely available, and low cost. Dove soap was chosen based on the work of Frosch and Kligman (1979).

### Data Collection and Analysis

All staff nurses in radiation oncology completed the institutional review board human research subjects training course and specific training regarding the study protocol. Patients were screened by the nurses, and those meeting eligibility criteria were given study information. Consent was obtained prior to the start of radiation treatment. Baseline data included demographic information, NCI skin grade, and a digital photograph of the treatment fields. Weekly data collection consisted

of documented NCI skin grade, digital photographs of the treatment fields, and a patient-completed diary.

The investigators established the following definitions for the levels of adherence.

- **Washing:** fully adherent (once per day), partially adherent (missed one day per week), and nonadherent (missed more than one day per week)
- **Moisturizing:** fully adherent (at least two times per day, every day), partially adherent (missed 1–2 days of moisturizing at least two times per day), and nonadherent (missed more than three days per week of moisturizing at least two times per day)

Although the skin care instructions were to moisturize three times daily, the definition for adherence was adjusted to twice daily to account for travel time and time in clinic, which did not always allow for moisturizing three times per day. The definitions for full and partial adherence were collapsed into one group, resulting in an adherent and a nonadherent group for data analysis.

## Results

### Sample

The sample (N = 100) was predominantly men, Caucasian, and married, with a mean age of 57 years and 15 years of education. After providing consent, and prior to beginning treatment, 10 patients dropped out for the following reasons: refused chemotherapy (n = 4), went to hospice (n = 3), conflicted with another study (n = 2), and “felt overwhelmed” (n = 1) (see Table 2).

Variations in sample size and total radiation dose occurred during the course of the study because of the differences in length of radiation treatment. The investigators focused the analysis on specific points of time during the last weeks of radiation treatment: week 6 because it included the most patients on treatment (n = 89), and week 7 (n = 74) because of the slightly higher radiation dose in the final week of treatment. Because no consistent timeframe was in place for the initial post-treatment follow-up examination, post-treatment evaluation was not included in this study.

### Skin Toxicity and Adherence

During week 6, 93% of patients (n = 89) had NCI grade 2 or less, with a mean grade of 1.74. In week 7, 81% of patients (n = 74) maintained NCI grade 2 skin toxicity or less, with a mean grade of 1.93. A significant correlation was noted between the radiation dose at week 6 and the grade of skin toxicity observed (p = 0.003). At week 7, the correlation between the radiation dose and skin grade was small and not significant (p = 0.95), possibly because of the fewer patients in treatment in week 7.

Overall adherence to washing and moisturizing was consistently high throughout the course of treatment. In weeks 6 and 7, adherence to washing was greater than 85%, moisturizing 89%, and combined adherence to both washing and moisturizing was greater than 80%. At week 6, the adherent group experienced less grade 2 (63%) and 3 (4.4%) skin toxicities than the nonadherent group (74% and 11%, respectively). Twenty-eight percent of adherent patients had a grade 1 toxicity compared to 11% in the nonadherent group. At week 7, patients in the adherent group had fewer grade 2 skin toxicities

(55%) compared to the nonadherent group (65%). No statistical significance was noted between the levels of adherence in relation to the NCI skin grade in either week 6 or 7. Given the high level of adherence throughout treatment, it was difficult to make a comparison given the low numbers in the nonadherent group (see Figure 3).

### Sociodemographic and Clinical Effect Modifiers

No significant relationships were noted between sociodemographic modifiers (i.e., age, gender, years of education, and marital status) or clinical effect modifiers (i.e., chemotherapy or biotherapy regimens) that influenced skin toxicity or adherence, although a correlation did exist between the radiation dose and level of skin toxicity at week 6 ( $p = 0.003$ ). Of note, all of the grade 3 skin toxicities in week 6 occurred in patients receiving platinum-based regimens.

### Discussion

This study builds on previous skin care research while also addressing the issue of patient adherence. Although this was not a comparative study of products, the results suggested a benefit. At weeks 6 and 7, 93% and 81% of patients, respectively, had a skin toxicity of grade 2 or less. In addition, several patients had grade 0 toxicity at weeks 6 and 7 (4.5% and 2.7%, respectively). The incidence of grade 3 skin toxicity in this study was relatively low compared to other studies, which have reported grade 3 skin toxicities ranging from 20% (Bernier et al., 2008) to 73% (Merlano et al., 2010).

The initial literature review identified a knowledge gap related to adherence. A meta-analysis of three decades of compliance and adherence research demonstrated that poor adherence could be expected among 30%–50% of patients (Vermiere et al., 2001). This study revealed an unusually high level of adherence to both washing and moisturizing (80% or greater). Although a statistically significant relationship was not noted between level of adherence and skin toxicity, this could be related to the small number of patients in the nonadherent group (low power).

In addition, a significant relationship between the sociodemographic variables and adherence was not found, which is consistent with Vermiere et al.'s (2001) meta-analysis. Although the adherence literature does not support any one strategy as being better than another, a meta-analysis by Haynes, McKibbon, Kanani, Brouwers, and Oliver (1997) showed improved adherence through use of a combination of approaches. This study used a multifaceted approach to enhance adherence: a standardized kit, written instructions, weekly diary, and routine reinforcement. The low-cost skin care kit provided to patients in this study likely did contribute to the high level of adherence seen in the results. Vermiere et al. (2001) suggested that treatment factors, such as cost, may impact level of adherence (i.e., increased cost may decrease adherence). Specialty products marketed for radiation dermatitis may be costly to patients and may not be readily accessible. The products used in the current study were readily available and low cost. The average cost of the soap and moisturizer was less than \$11 per patient for the course of treatment. Given the low cost of the kit, providing these to patients undergoing chemoradiation as adherence aides to enhance proactive skin care management should be considered.

The increased patient-provider interaction at weekly skin assessments also served to enhance adherence, as this provided an opportunity for teaching reinforcement. Use of patient diaries for follow-up at weekly status checks supports this process, has many benefits (e.g., fostering patient involvement in care, encouraging patient adherence), and is an easy intervention for a radiation nurse to implement. In addition, the use of a consistent skin care kit, written instructions, patient diary, and skin grading tool (e.g., CTCAE) served to enhance the uniformity of information provided to the patient, patient assessment, and documentation of skin reactions by the team of radiation oncologists, nurses, and therapists. Inconsistent patient instructions can be confusing for patients and lead to reduced adherence.

Assessing level of adherence to a prescribed regimen is essential, whether it be a medication or skin care regimen, as the literature supports that patients who adhere to prescribed medication regimens tend to have better treatment outcomes

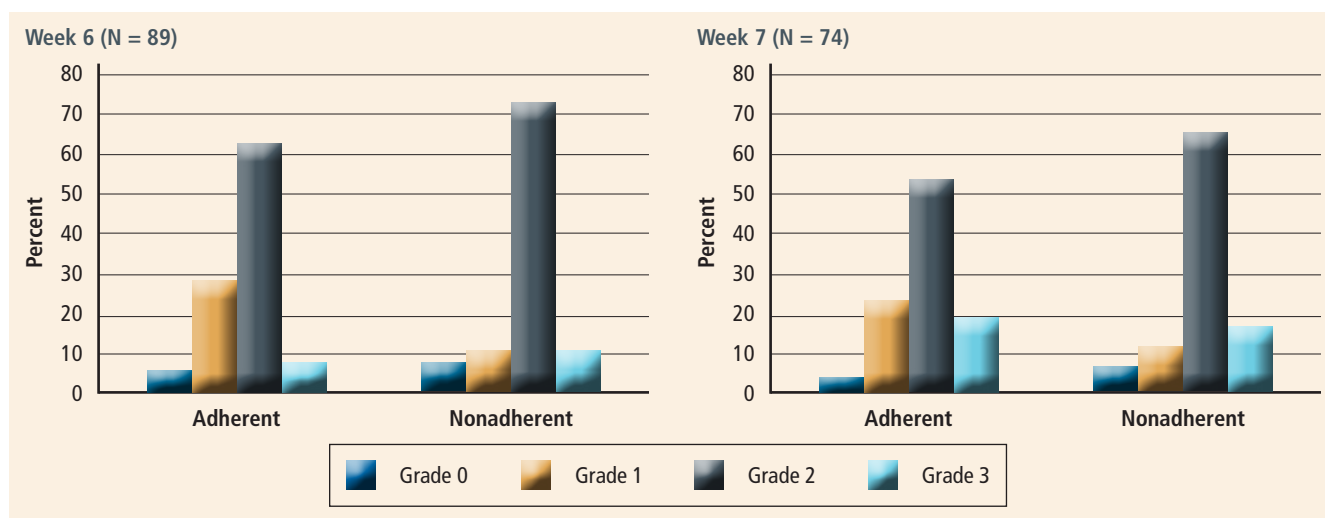


FIGURE 3. Skin Toxicity and Adherence to Washing and Moisturizing

## Implications for Practice

- ▶ Proactive patient education, early initiation of a skin care regimen, and ongoing reinforcement may be beneficial in minimizing skin toxicities.
- ▶ Empowering patients to become active participants in their care may contribute to positive outcomes.
- ▶ The use of a single skin toxicity measurement tool by all providers may improve patient assessment, documentation, and management of skin toxicities.

(Vermiere et al., 2001). In addition, poor patient adherence in research can lead to diminished power of results, and potentially yield negative outcomes for the patient and the research data.

## Limitations

This study included patients undergoing different courses of treatment, both in terms of radiation treatment type and dose, as well as various concurrent chemotherapy/biotherapy regimens. Because of inconsistent timeframes for patient follow-up, no post-treatment skin toxicity data are available. Products were provided free of charge to all patients, which may have increased patient adherence. Some patients reported using other moisturizing products during treatment, which may have potentially influenced outcomes. In addition, a self-administered intervention may inevitably have inconsistencies in application, and self-report diaries may not provide reliable information because of under- or overreporting. Although not necessarily a limitation, the high percentage of adherence may be related to the continuous reinforcement by the nurse. The possibility of a Hawthorne effect (a phenomenon in which participants alter or modify their behavior when they know they are being observed or studied) must also be considered. The generalizability of the study is limited by the patient sample, which primarily consisted of Caucasian men. Other limitations include the lack of a nontreatment control group and the lack of a power analysis for the sample size.

## Future Research

Additional research is needed comparing skin toxicities among the various chemotherapy/biotherapy regimens used with chemoradiation. Further research comparing the low-cost skin care products used in this study with specialty products is also recommended. Research efforts should use a consistent skin toxicity measurement tool, such as the NCI's CTCAE. Replication studies might consider including longitudinal skin toxicity grading data.

## Implications for Clinical Practice

Proactive patient education, early initiation of a skin care regimen, and ongoing reinforcement may be beneficial in minimizing skin toxicities in patients. Empowering patients to be active participants in their care may also contribute to more positive

outcomes. Given the lack of evidence to support the use of one skin care product over another, it may be the level of patient adherence to a skin care regimen, rather than the product itself, that contributes to more positive patient outcomes. This multidisciplinary effort enhanced consistency in patient education among and between the various providers. The use of a single skin toxicity measurement tool by all providers improved patient assessment, documentation, and management of skin toxicities. This study also identified a subgroup of patients, those receiving platinum-based therapies, who, because of their increased skin toxicities, may benefit from additional proactive interventions.

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