

 **EURO**

**DEP**  
PUTTING EVIDENCE INTO PRACTICE

ADAPTED FOR EUROPEAN NURSES BY EONS

# Radiodermatitis (Radiation Skin Reactions)

Improving symptom management in cancer care  
through evidence based practice





## Welcome to the Euro PEPs

---

The European Oncology Nursing Society is pleased to present its first set of "Putting Evidence into Practice" guidelines to improve the care of cancer patients in Europe.

Improvement in patient care is an ongoing process. There is a gap between the evidence that is available and what is actually implemented. This knowledge gap impacts on patient's in poor or inappropriate care that is detrimental to cancer patients. Results from research studies reveal that nurses insufficiently put evidence into practice. The results indicate that there are multiple reasons for why nurses do not use the latest evidence. Firstly, that research is difficult to understand, overwhelming in the amount published and secondly that they feel they don't have the expertise to interpret the quality of the evidence. If we could put even a little of what we know about symptom management into practice we would improve patient experience.

This Euro PEP has been developed as a partnership with the Oncology Nursing Society and funded by the European Commission as part of the European Action Against Cancer. Many people have contributed to the development and expert review of these documents, both in Europe and in the USA. EONS thanks their dedication and great efforts.

This documentation provides you with a concise summary of the evidence, a synthesis of patient assessments, a summary of evidence based interventions, and expert opinions to help guide you in the interpretation of European standards along with the references and source material. You may wish to adapt the guidance for your own work setting, but the PEPs gives you the confidence that these topics were reviewed in 2012 through a rigorous process by some of the leading experts and practitioners in the field. On behalf of the review team we are confident that this information, coupled with your efforts and commitment to improve your practice, will help you achieve better, patient-centered outcomes based on scientific evidence. We wish you great success!







Sara Faithfull  
Anita Marguiles

Chair EPAAC Project  
Chair PEPs

---

## CONTENTS

---

Chapter icon explanations	page 5
How to use this guide	page 6
 Quick view	page 8
 Expert opinion	page 10
 Assessment tools	page 12
 Definitions	page 14
 References	page 18
 Evidence tables	(See separate section)

Putting Evidence into Practice (PEP) resources (evidence syntheses and weight of evidence categorization) are the work of the Oncology Nursing Society (ONS). Because translations from English may not always be accurate or precise, ONS disclaims any responsibility for inaccuracies in words or meaning that may occur as a result of the translation.

© European Oncology Nursing Society (2012). Authorized translation and adaptation of the English edition © 2009-2011 and open-access web materials by the Oncology Nursing Society, USA. This translation and adaptation is published and distributed by permission of the Oncology Nursing Society, the owner of all rights to publish and distribute the same.

This publication arises from the European Partnership for Action Against Cancer Joint Action, which has received funding from the European Union, in the framework of the Health Programme.



# Introduction to the Sections



## Quick view

The quick view provides very brief summary from the ONS PEP resources. A full copy of this is provided in the course documentation. ONS PEP information for this topic and description of the categories of evidence can be accessed at <http://www.ons.org>.



## Expert opinion

Expert Opinion: low-risk interventions that are (1) consistent with sound clinical practice, (2) suggested by an expert in a peer-reviewed publication (journal or book chapter), and (3) for which limited evidence exists. An expert is an individual with peer-reviewed journal publications in the domain of interest.



## Assessment tools

In general, no single tool measures all of the elements of a symptom. The choice of tool depends on the purpose of the assessment as well as the level of clinician and patient burden. Most symptoms are a subjective experience, thus self-report is the most reliable assessment method.



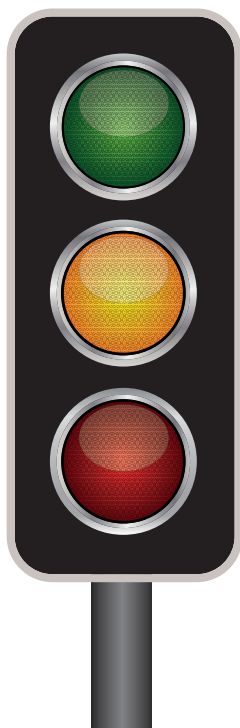
## Definitions

Within the documentation various terms may need further explanation which through better understanding, could improve the outcomes of chosen interventions. The following definitions are tailored to the content of the respective PEP document.

## How to use this guide

- Review the Euro - PEP resources and consider the applicability in your own practice and your patient situation.
- Do a thorough patient assessment of the relevant clinical problem(s). Examples of measurement tools are provided by the evidence-based measurement summaries, located on the individual PEP topic pages.
- Identify interventions with the highest category of evidence and integrate them into the plan of care. Consider the patient's preferences, lifestyle, and the cost and availability of the interventions.
- Evaluate and document the patient's response to the interventions. If indicated, consider implementing other interventions supported by a high level of evidence.
- Educate patients that their care is based on the best available evidence.
- The Weight of Evidence Table (traffic light ) provides information about how the evidence was weighed.

Adapted for Euro PEP Resources from [www.ons.org/Research/PEP](http://www.ons.org/Research/PEP)



### Green = Go!

The evidence supports the consideration of these interventions in practice.

### Yellow = Caution!

There is not sufficient evidence to say whether these interventions are effective or not.

### Red = Stop!

The evidence indicates that these interventions are either ineffective or may cause harm.

### Recommended for practice

Interventions for which effectiveness has been demonstrated by strong evidence from rigorously designed studies, meta-analysis, or systematic reviews, and for which expectation of harm is small compared to the benefits.

### Likely to be Effective

Interventions for which effectiveness has been demonstrated from a single rigorously conducted controlled trial, consistent supportive evidence from well-designed controlled trials using small samples, or guidelines developed from evidence and supported by expert opinion.

### Benefits Balanced with Harm

Interventions for which clinicians and patients should weigh the beneficial and harmful effects according to individual circumstances and priorities.

### Effectiveness Not Established

Interventions for which insufficient or conflicting data or data of inadequate quality currently exist, with no clear indication of harm.

### Effectiveness Unlikely

Interventions for which lack of effectiveness has been demonstrated by negative evidence from a single rigorously conducted controlled trial, consistent negative evidence from well-designed controlled trials using small samples, or guidelines developed from evidence and supported by expert opinion.

### Not Recommended for Practice

Interventions for which lack of effectiveness or harmfulness has been demonstrated by strong evidence from rigorously conducted studies, meta-analyses, or systematic reviews, or interventions where the costs, burden, or harm associated with the intervention exceed anticipated benefit.

# Radiodermatitis (Radiation Skin Reactions) Quick View

## Definition and Incidence:

*Radiodermatitis* or *Radiation skin reactions* are the response of the integumentary system to planned exposure of ionizing radiation. Skin reactions can become a source of significant discomfort and cause treatment interruptions, or in very severe cases, treatment cessation. As many as 95 % of patients will experience some degree of reaction of the integumentary system with radiation therapy.

## Recommended for practice

- Intensity modulated radiation therapy
- Continuation of usual hygiene practices. Daily use of washing with clean water and mild soap should be recommended (European recommendation).
- Use of deodorants is allowed if the skin is intact.
- Smoking should be avoided. (European recommendation)

## Likely to be Effective

- Calendula cream\*
- \*level of evidence as rated by ONS; please note EONS rating as yellow

## Benefits Balanced with Harm Effectiveness Not Established

### Topical Agents

- Aloe vera
- Anionic polar phospholipid cream
- Bepanthen
- Calendula cream\*





- Chamomile cream
- Glutathione and anthocyanin
- Hyaluronic acid/sodium hyaluronate
- Lipiderm® (Not available in Europe)
- Sodium sucrose octasulfate
- Steroid creams
- Sucralfate
- Theta cream
- Vitamin C
- Urea lotion
- Hydrolipid cream (e.g. XClair®)

\*level of evidence as rated by EONS: (based on Sharp et al 2013, Pommier et al 2004); please note ONS rating as green

#### **Dressings**

- GM-CSF impregnated gauze
- Honey impregnated gauze
- Hydrogel & Hydrocolloid dressing
- No-Sting barrier film (e.g. Cavilon®)
- Silver leaf dressing
- Silicone coated dressings (European recommendation)

#### **Oral Medications/Agents**

- Proteolytic enzymes
- Red wine
- Sucralfate
- Zinc

#### **Effectiveness Unlikely**

- Trolamine/triethanolaminum (e.g. Biafine®)

#### **Not Recommended for Practice**

- Gentian violet
- Products containing Chlorhexidine (European recommendation)

## Expert Opinion

**Low-risk interventions that are:**

- consistent with sound clinical practice
- suggested by an expert in a peer-reviewed publication (journal or book chapter) and
- for which limited evidence exists.

**An expert is an individual who has authored articles published in a peer-reviewed journal in the domain of interest.**

**Personal Hygiene Habits and Recommendations for Care by Skin Toxicity Grade: Radiation Therapy and Epidermal Growth Factor Receptor Inhibitors**

**Prophylaxis:**

No evidence supports any agents to prevent radiation dermatitis.

**General management guidelines:**

- Gentle washing and drying
- pH-neutral synthetic detergent or cleanser preferred over soap
- Topical moisturizers, gels, and emulsions should not be applied directly before radiation therapy (risk for bolus effect).
- Establish that reaction is not caused by other concomitant medications (other than the EGFR inhibitor).
- Verification of radiation dose and distribution are correct.
- Institutions should have policies in place for skin preparations; good hygiene is imperative both before and during therapy.



### **General Recommendations:**

- Use only mild soap and pat dry with a soft towel.
- May use unscented, lanolin-free, water-based lubricant or moisturizing cream.
- Avoid use of cosmetic or perfumed products on irradiated skin.
- May use deodorant during treatment, but only on intact skin. (See reference – Watson CL et al – European recommendation).
- Do not use cornstarch or baby powder, especially in areas with skin folds.
- Wear loose clothing made from a soft fabric or cotton.
- Protect skin from sun or cold wind. Cover the area.
- Avoid use of tapes and other adhesives within the treatment field to avoid mechanical skin injury.
- Do not use ice or heating pads on the skin in the area being treated.
- Use only an electric razor if shaving is needed.
- Avoid swimming in lakes or chlorinated pools, using hot tubs, or using saunas.
- Avoid sun exposure following radiation treatment for lifetime. Use sunscreen with a protection factor of at least 30 at all times.

### **Recommendations for management of moist desquamation:**

- Consider use of specialized dressings for moist desquamation, bleeding, exudates, or drainage.
- When selecting a dressing, consider the principles of wound healing, patient comfort, need for and frequency of dressing changes, product evaluation and cost.
- Topical or systemic antimicrobials should be considered in the presence of positive cultures and documented infection.

### **Issues for future recommendations:**

- Adopt NCI CTCAE toxicity scale for uniformity.
- Taking photographic documents may be of use to decrease subjectivity of rater.
- The RTOG/EORTC scale in combination with patient reported symptoms is more relevant for Europe.

## Assessment Tools

**The assessment tool can be used to identify grades or degrees of skin reactions. Skin should be assessed before the initiation of treatment and regularly thereafter.**

The skin assessment should include changes in color, level of desquamation, drainage, odor and signs of infection.

Symptoms and/or impact are not included in the majority of the tools. Therefore the patients symptoms e.g. dryness, pruritus or pain must also be taken into consideration. The distress and impact on quality of life, daily living, self-care ability and financial impact of caring for the skin are also important areas of assessment.

Commonly used grading or scoring tools for the assessment and documentation of radiodermatitis include the Radiation Therapy Oncology Group (RTOG) Acute Radiation Morbidity Scoring Criteria (Cox, Stetz & Pajak, 1995), the RTOG/EORTC (European Organization for Research and Treatment of cancer) Late Radiation Morbidity Scoring Scheme (Cox et al., 1995), the National Cancer Institute (NCI) Cancer Therapy Evaluation Program (2010) Common Terminology Criteria for Adverse Events, the Skin Toxicity Assessment Tool (Berthelet et al., 2004), the Oncology Nursing Society (Catlin-Huth, Pollock & Haas, 2002) Acute Skin Toxicity Scale using NCI's common toxicity criteria, and the Radiation-Induced Skin Reaction Assessment scale (Noble-Adams, 1999a, 1999b).

Each assessment tool can be used to identify grades or degrees of skin reactions, including erythema, dry desquamation, and moist desquamation. The majority of tools are assessments that the practitioner or observer completes and, thus, do not capture the symptoms or impact of the skin reaction (see Table 4-1). Skin should be assessed as a baseline prior to the initiation of treatment and, at a minimum, at weekly review appointments. The skin assessment should include changes in color, appearance of patchy dry desquamation, patchy or confluent moist desquamation, presence or absence of drainage, presence or absence of odor, and signs of infection. The patient's symptoms, such as the sensation of dryness, pruritus, or pain, must also be taken into account. The distress and impact associated with the radiodermatitis on quality of life, daily living, self-care ability and financial impact of caring for the skin reaction are also important areas of assessment.



## Clinical Measurement Tools for Radiodermatitis

Tool	Description	Benefits and/or limitations
Radiation Therapy Oncology Group Acute Radiation Morbidity Scoring Criteria (1985) (Cox et al 1995)	Assesses intensity or severity of reaction Ordinal scale 0-4	No reliability or validity data published. Observation of physical changes. Does not address symptoms or patient perspective. Commonly used in clinical trials.
Radiation Therapy Oncology Group/ European Organisation for Research and Treatment of Cancer toxicity criteria (Cox et al 1995)	Assesses late complications Ordinal scale 0-4 Acute: less than 90 days after first treatment Late: after day 90 Also assesses for fibrosis, induration, skin contracture and necrosis	No reliability or validity data published. Observation of physical changes. Does not address symptoms or patient perspective
Common Terminology Criteria for Adverse Events (v4.03)	Adverse events reporting tool Severity scale Rash: Dermatitis associated with radiation. Ordinal scale 0-5 Grades of desquamation	No reliability or validity data published. Observation of physical changes. Does not address symptoms or patient perspective
Skin Toxicity Assessment Tool (STAT) (Berthelet et al, 2004)	Three areas of assessment Patient and treatment factors affecting incidence and intensity of radio-dermatitis Objective scoring of grades of desquamation Patient symptoms	Preliminary reliability and validity results reported (Berthelet et al, 2004) Easy to use in the clinical setting Quickly administered
Radiation-Induced Skin Reaction Assessment Scale (RISRAS) (Noble-Adams, 1999)	Weighted categories (e.g. moist desquamation weighted higher than dry desquamation) for overall score that incorporates effect on patient Symptom scale (e.g. tenderness, itching, burning, warmth, effect on activity) Observer assessment (e.g. erythema, dry desquamation, moist desquamation, necrosis)	Nursing assessment tool Objective observer assessment and patient's perspective of symptoms Reliability and validity scores have been reported Has not been widely used in practice or research.

Adapted from: PEP – Putting Evidence into Practice, Vol. 2 Oncology Nursing Society

# Radiodermatitis (Radiation Skin Reactions)

## Definition List

### **Accelerated fractionation**

A shortened overall treatment time in which standard total doses are given in a shorter period of time by increasing the number of standard fractions per day. (Moore-Higgs, 2005)

### **Acute radiation dermatitis or Radiation skin reactions (European term)**

An inflammatory skin reaction associated with epidermal basal cell and endothelial cell damage. It is the most frequently encountered side effect in radiotherapy. (Bostrom et al., 2001; Fenig et al., 2001)

### **Adjuvant radiotherapy**

Radiotherapy given after definitive treatment (surgery or chemotherapy) to improve local control. (Campbell & Illingworth, 1992)

### **Aqueous creams**

Water-based moisturizing creams that are emulsions of oil in water, water washable, and completely absorbed into the skin. They supply humectants and increase the capacity to retain water, thus increasing skin pliability and flexibility while lubricating the skin, reducing friction, and helping retain normal skin pH. (Heggie et al., 2002)

### **Bolus**

A tissue equivalent material that is put directly on the patient's skin to even the irregular contours and to create a flat surface that normalizes the radiation beam and intentionally pulls the radiation dose more superficially. (Burch et al., 1997; Elliott et al., 2006)

### **Bolus effect**

Increased surface dose in the treatment field (Bieck & Phillips, 2010) Boost Dose of radiation specifically directed to the area in the treatment field where the tumor was removed or where the surgical clips were placed at the time of surgery. (Campbell & Illingworth, 1992)

### **Breast shell**

Device used for immobilization of large breasts. (Heggie et al., 2002)

### **Clinical target volume (CTV)**

CTV is an anatomical concept defining the tissue volume that contains a gross tumor volume (GTV) and subclinical microscopic malignant disease that has to be eliminated. The CTV is an anatomical-clinical concept that is used to determine choice of treatment modality and technique. (Tyng et al., 2009)

**Dry desquamation**

Dry desquamation is an inflammatory reaction to radiation characterized by dry flaky skin and pruritus. (Heggie et al., 2002)

**Dermis**

The deep layer of the skin containing blood vessels, glands, nerves, and hair follicles. (Haas, 2005)

**Epidermis**

The superficial layer of the skin. (Haas, 2005)

**Erythema**

An inflammatory skin reaction characterized by reddened skin that may be edematous and feel hot. Redness that outlines the treatment field intensifies as the treatment continues. (Maher, 2000)

**Fraction**

The division of a total prescribed dose of radiation into smaller daily doses, generally 1.8–2.0 Gy. (Ma, 2005)

**Gross tumor volume (GTV)**

Three dimensional volume of tumor that is clinically evident and visible in imaging studies. This identifies the greatest area of tumor cells. (Tyng et al., 2009)

**Gray (Gy)**

Unit of measurement to determine the amount of energy absorbed per unit of mass. Radiation was previously described in RADS. (radiation absorbed dose). 100 RADS = 1 Gy (Ma, 2005)

**Hyperfractionation**

Multiple daily fractions, usually twice a day separated by at least six hours between doses. (Liguori et al., 1997; Ma, 2005)

**Hyperpigmentation**

Darkening of the skin within the treatment field that begins approximately two to three weeks after treatment is initiated. (Sparks, 2005; Wickline, 2004)

**Induration**

Dermal thickening causing the cutaneous surface to feel thicker and firmer. A hardened bump on the skin. (<http://medical-dictionary.thefreedictionary.com/induration>)

**Intensity modulated radiation therapy (IMRT)**

An advanced form of 3-dimensional conformal radiotherapy in which varying intensities of small subdivisions of beams are used to custom-design optimal radiation dose distribution. This technique limits the amount of radiation to healthy tissues and allows for custom-designed optimal radiation dose distribution. (Light, 2005)

**Ionizing radiation**

Radiation with sufficient energy to penetrate cells and cause permanent alterations in DNA. It causes skin reactions by damaging the ability of stem cells to divide in the rapidly growing, radiosensitive basal layer of the epidermis. (Ma, 2005)

### **LPG technique**

An antifibrosis therapy technique of mechanical massage that allows skin mobilization by folding/unfolding. This technique is delivered by a mechanical device (Cellu-M50 by LPG Systems). The procedure consists of tissue mobilization between two rollers, creating a skin fold and stretching the underlying tissue. (Bourgeois et al., 2008)

### **Moist desquamation**

Moist desquamation is an inflammatory reaction to radiation characterized by serous drainage. Moist desquamation is a major source of distress for patients causing pain or discomfort, and increases the risk of infection. Most commonly occurs in regions of friction such as the inframammary fold or axilla. (Gollins et al., 2008)

### **Necrosis**

The premature death of cells and living tissue. (<http://medicaldictionary.thefreedictionary.com/necrosis>)

### **Opposed lateral fields**

A radiation beam is directed to the lateral fields on both the right and left sides, used primarily with radiation to the head and neck or lung. (Lievens et al., 1998)

### **Oral mucositis**

The inflammation and ulceration of the oral mucosa that is a result of the epithelial cell production as a consequence of radiation-induced cell death. (Evensen et al., 2001; Gujral et al., 2001)

### **Planning target volume (PTV)**

PTV is a geometric concept that is defined to select appropriate beam sizes and beam arrangements. The PTV takes into account anatomical boundaries, variations and inaccuracies in order to ensure that the prescribed dose is absorbed in the CTV. The size and shape of the PTV are dependent upon the CTV as well as technique, organ movement, patient movement, and beam and patient setup during therapy. (Tyng et al., 2009)

### **Radiation-induced skin fibrosis**

Radiation-induced skin fibrosis is defined clinically as a change in the skin texture (dry, scaly, firmness on palpation with difficulty pinching the skin to form a fold) and skin retractions which can cause functional discomfort (Bourgeois et al., 2008). Fibrosis is a late skin effect that occurs months to years after treatment. (Heggie et al., 2002)

### **Radiation recall**

An inflammatory skin reaction at a previously irradiated field subsequent to the administration of a variety of chemotherapeutic agents, most commonly doxorubicin and other anthracyclines. (Sparks, 2005)

### **Radiation Therapy Oncology Group (RTOG) Scale**

The RTOG Scale is a toxicity grading scale that assesses the complications of radiation treatment involving the skin and other tissues and organs (Fisher et al., 2000; Haas, 2005). Toxicity is graded on a 0–4 scale. Toxicities manifest as erythema, pruritus, hyperpigmentation, dry desquamation, moist desquamation, ulceration, and necrosis. (Haas, 2005)



**Radiosensitivity**

The response of tumor cells to radiation in terms of degree and speed. Poorly differentiated immature cells, rapidly proliferating cells, or cells with a high mitotic potential are more radiosensitive. (Maher, 2000)

**Simulation**

The planning session for radiation treatment where the patient's position, treatment fields, and optimal beam directions are selected. (Bostrom et al., 2001; Light, 2005)

**Skin toxicity**

Dermatologic side effect encountered in radiation therapy that range from mild erythema to moist desquamation and ulceration. (Fisher et al., 2000; Elliott et al., 2006)

**Spectrophotometry**

A method of chemical analysis based on the absorption or attenuation by matter of electromagnetic radiation of a specific wavelength or frequency. It can be used to evaluate the intensity of the erythema and pigmentation. (Bostrom et al., 2001; Vuong et al., 2004)

**Tangential fields**

Radiation is directed to the tumor site at an angle. (Meegan & Haycocks, 1997)

**Target volume**

All gross disease or visible enhancing tumor. (Ma, 2005)

**Tattoos**

Small permanent marks made to indicate the center and edges of the treatment field. Used for daily set-up and helpful for duplicating a treatment field if a patient returns for treatment in the future. (Light, 2005)

**Telangiectasia**

An area of reddish discoloration displaying multiple, prominent, thin-walled, and dilated vessels. (Heggie et al., 2002)

**Three field technique**

Two opposed lateral fields and a cervical anterior field, used in radiation to the head and neck region. (Lievens et al., 1998)

**Tissue tolerance dose**

The radiation dose to which normal tissue can be irradiated and continue to function. (Ma, 2005)

**Transepidermal water loss**

The measurement of the quantity of water that passes from inside a body through the epidermal layer to the surrounding atmosphere via diffusion and evaporation processes. (Primavera et al., 2006)

**Wedge**

A beam modifier that is inserted into the path of the radiation beam to improve the dose uniformity. (Bostrom et al., 2001; Light, 2005)

## References

- Bernier, J., Bonner, J., Vermorken, J.B., Bensadoun, R.-J., Dummer, R., Giralt, J., Ang, K.K. (2008). Consensus guidelines for the management of radiation dermatitis and coexisting acne-like rash in patients receiving radiotherapy plus EGFR inhibitors for the treatment of squamous cell carcinoma of the head and neck. *Annals of Oncology*, 19, 142–149. doi:10.1093/annonc/mdm400.
- Bieck, T., & Phillips, S. (2010). Appraising the evidence for avoiding lotions or topical agents prior to radiation therapy. *Clinical Journal of Oncology Nursing*, 14, 103–105. doi:10.1188/10.CJON.103-105.
- Biersdorf, Inc. (n.d.). Product info. Retrieved from <http://www.aquaphorhealing.com/#/main/skincare/products>.
- Bolderston, A., Lloyd, N.S., Wong, R.K.S., Holden, L., Robb-Blenderman, L., & Supportive Care Guidelines Group. (2006). The prevention and management of acute skin reactions related to radiation therapy: A clinical practice guideline (Practice Guidelines Report #13-7). Toronto, Canada: Cancer Care Ontario. Retrieved from <http://www.cancercare.on.ca/search/default.aspx?q=radiodermatitis&type=0,6-76,6-40484|-1,1377-78>.
- Boström, A., Lindman, H., Swartling, C., Berne, B., & Bergh, J. (2001). Potent corticosteroid cream (mometasone furoate) significantly reduces acute radiation dermatitis: Results from a double-blind, randomized study. *Radiotherapy and Oncology*, 59, 257–265. doi:10.1016/S0167-8140(01)00327-9.
- Bourgeois, J.F., Gourjou, S., Kramar, A., Lagarde, J.M., & Guillot, B. (2008). A randomized, prospective study using the LPG technique in treating radiation-induced skin fibrosis: Clinical and profilometric analysis. *Skin Research and Technology*, 14, 71–76. doi:10.1111/j.1600-0846.2007.00263.x.
- Burch, S.E., Parker, S.A., Vann, A.M., and Arazie, J.C. (1997). Measurement of 6-MV x-ray surface dose when topical agents are applied prior to external beam irradiation. *International Journal of Radiation Oncology, Biology, Physics*, 38, 447–451. doi:10.1016/S0360-3016(97)00095-3.
- Campbell, I.R., & Illingworth, M.H. (1992). Can patients wash during radiotherapy to the breast or chest wall? A randomized controlled trial. *Clinical Oncology*, 4, 78–82.
- Elliott, E.A., Wright, J.R., Swann, R.S., Nguyen-Tân, F., Takita, C., Bucci, M.K., Berk, L. (2006). Phase III trial of an emulsion containing trolamine for the prevention of radiation dermatitis in patients with advanced squamous cell carcinoma of the head and neck: Results of Radiation Therapy Oncology Group Trial 99-13. *Journal of Clinical Oncology*, 24, 2092–2096. doi:10.1200/JCO.2005.04.9148.
- Enomoto, T.M., Johnson, T., Peterson, N., Homer, L., Walts, D., & Johnson, N. (2005). Combination glutathione and anthocyanins as an alternative for skin care during external beam radiation. *American Journal of Surgery*, 189, 627–631. doi:10.1016/j.amjsurg.2005.02.001.
- Evensen, J.F., Bjordal, K., Jacobsen, A.-B., Løkkevik E. & Tausjø, J.E. (2001). Effects of Nasucroseoctasulfate on skin and mucosa reactions during radiotherapy of head and neck cancers. *ACTA Oncologica*, 40, 751–755.
- Falkowski, S., Trouillas, P., Duroux, J.-L., Bonnetblanc, J.-M., & Clavère, P. (2009). Radiodermatitis prevention with sucralfate in breast cancer: Fundamental and clinical studies [E-publication before print]. *Supportive Cancer Care*. doi:10.1007/s00520-009-0788-y.
- Fenig, E., Brenner, B., Katz, A., Sulkes, J., Lapidot, M., Schachter, J., Gutman, H. (2001). Topical Biafine and Lipiderm for the prevention of radiation dermatitis: A randomized prospective trial. *Oncology Reports*, 8, 305–309.
- 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.
- Freedman, G.M., Anderson, P.R., Li, J., Jinsheng, L., Eisenberg, D.F., Hanlon, A.L., Nicolaou, N. (2006). Intensity modulated radiation therapy (IMRT) decreases acute skin toxicity for women receiving radiation for breast cancer. *American Journal of Clinical Oncology*, 29, 66–70. doi:10.1097/01.coc.0000197661.09628.03.
- Freedman, G.M., Li, T., Nicolaou, N., Chen, Y., Ma, C.C.-M., & Anderson, P.R. (2009). Breast intensity-modulated radiation therapy reduces time spent with acute dermatitis for women of all breast sizes during radiation. *International Journal of Radiation Oncology, Biology, Physics*, 74, 689–694. doi:10.1016/j.ijrobp.2008.08.071.
- Gollins, S., Gaffney, C., Slade, S., & Swindell, R. (2008). RCT on gentian violet versus a hydrogel dressing for radiotherapy-induced moist skin desquamation. *Journal of Wound Care*, 17, 268–275.
- Gosselin et al A. prospective randomized, placebo-controlled skin care study in women diagnosed with breast cancer undergoing radiation therapy (2010). *Oncol Nurs Forum*. 37(5); 619-626.

- Graham, P., Browne, L., Capp, A., Fox, C., Graham, J., Hollis, J., & Nasser, E. (2004). Randomized, paired comparison of no-sting barrier film versus sorbolene cream (10% glycerine) skin care during post mastectomy irradiation. *International Journal of Radiation Oncology, Biology, Physics*, 58, 241–246. doi:10.1016/S0360-3016(03)01431-7.
- Gujral, M.S., Patnaik, P.M., Kaul, R., Parikh, H.K., Conradt, C., Tamhankar, C.P., & Daftary, G.V. (2001). Efficacy of hydrolytic enzymes in preventing radiation therapy-induced side effects in patients with head and neck cancers. *Cancer Chemotherapy and Pharmacology*, 47(Suppl.), S23–S28.
- Halperin, E.D., 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.
- Heggie, S., Bryant, G.P., 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. Induration (n.d). *Mosby's Medical Dictionary*. 8th edition (2009) retrieved from <http://medicaldictionary.com/induration>.
- Kedge, E.M. (2009). A systematic review to investigate the effectiveness and acceptability of interventions for moist desquamation in radiotherapy patients. *Radiography*, 15, 247–257. doi:10.1016/j.radi.2008.08.002.
- Kouvaris, J.R., Kouloulis, V.E., Plataniotis, G.A., Balafouta, E.J., & Vlahos, L.J. (2001). Dermatitis during radiation for vulvar carcinoma: Prevention and treatment with granulocyte-macrophage colony-stimulating factor impregnated gauze. *Wound Repair and Regeneration*, 9, 187–193.
- Leonardi, M.C., Gariboldi, S., Ivaldi, G.B., Ferrari, A., Serafini, F., Didier, F., Orecchia, R. (2008). A double-blind, randomised, vehicle-controlled clinical study to evaluate the efficacy of MAS065D in limiting the effects of radiation on the skin: Interim analysis. *European Journal of Dermatology*, 18, 317–321. doi:10.1684/ejd.2008.0396.
- Lievens, Y., Haustermans, K., Van den Weyngaert, D., Van den Bogaert, W., Scalliet, P., Hutsebaut, L., Lambin, P. (1998). Does sucralfate reduce the acute side-effects in head and neck cancer treated with radiotherapy? A double-blind randomized trial. *Radiotherapy and Oncology*, 47, 149–153.
- Light, K. (2007). Simulation and treatment planning. In M.L. Haas, W.P. Hogle, G.J. Moore-Higgs, & T.K. Gosselin-Acomb (Eds.), *Radiation therapy: A guide to patient care* (pp.59–70). St. Louis, MO: Mosby Elsevier.
- Liguori, V., Guillemin, C., Pesce, G.F., Mirimanoff, R.O., & Bernier, J. (1997). Double-blind, randomized clinical study comparing hyaluronic acid cream to placebo in patients treated with radiotherapy. *Radiotherapy and Oncology*, 42, 155–161. doi:10.1016/S0167-8140(96)01882-8.
- Liguori, V., Guillemin, C., Pesce, G.F., Mirimanoff, R.O., & Bernier, J. (1997). Double-blind, randomized clinical study comparing hyaluronic acid cream to placebo in patients treated with radiotherapy. *Radiotherapy and Oncology*, 42, 155–161. doi:10.1016/S0167-8140(96)01882-8.
- Løkkevik, E., Skovlund, E., Reitan, J.B., Hannisdal, E., & Tanum, G. (1996). Skin treatment with Bepanthen cream versus no cream during radiotherapy. *Acta Oncologica*, 35, 1021–1026.
- Ma, C.-M.C. (2005). The practice of radiation oncology. In D. Watkins Bruner, M.L. Haas, & T.K. Gosselin-Acomb (Eds.), *Manual for radiation oncology nursing practice and education* (3rd ed., pp. 12–21). Pittsburgh, PA: Oncology Nursing Society.
- Macmillan, M.S., Wells, M., MacBride, S., Raab, G.M., Munro, A., & MacDougall, H. (2007). Randomized comparison of dry dressings versus hydrogel in management of radiation induced moist desquamation. *International Journal of Radiation Oncology, Biology, Physics*, 68, 864–872. doi:10.1016/j.ijrobp.2006.12.049.
- Mak, S.S., Molassiotis, A., Wan, W.-M., Lee, I.Y.M., & Chan, E.S.J. (2000). The effects of hydrocolloid dressing and gentian violet on radiation-induced moist desquamation wound healing. *Cancer Nursing*, 23, 220–229.
- Mak, S.S., Zee, C.Y., Molassiotis, A., Chan, S.J., Leung, S.F., Mo, K.F., & Johnson, P.J. (2005). A comparison of wound treatments in nasopharyngeal cancer patients receiving radiation therapy. *Cancer Nursing*, 28, 436–445.
- Maher, K.E. (2000). Principles of radiation therapy. In B.M. Nevidjon & K.W. Sowers (Eds.), *A nurses guide to cancer care* (pp. 215–240). Philadelphia, PA: Lippincott Williams & Wilkins.
- Maiche, A.G. (1990). Effect of chamomile cream and almond ointment on acute radiation skin reaction.
- Maiche, A., Isokangas, O.-P., & Gröhn, P. (1994). Skin protection by sucralfate cream during electron beam therapy. *Acta Oncologica*, 33, 201–203.

- McQuestion, M. (2006). Evidence-based skin care management in radiation therapy. *Seminars in Oncology Nursing*, 27, 163–173. doi:10.1016/j.soncn.2006.04.004.
- McQuestion, M. (2010). Radiation-induced skin reactions. In M. Haas & G. Moore-Higgins (Eds.), *Principles of skin care and the oncology patient* (pp. 115–140). Pittsburgh, PA: Oncology Nursing Society.
- Meegan, M.A., & Haycocks, T.R. (1997). An investigation into the management of acute skin reactions from tangential breast irradiation. *Canadian Journal of Medical Radiation*, 28, 169–173.
- Merchant, T.E., Bosley, C., Smith, J., Baratti, P., Pritchard, D., Davis, T., ... Xiong, X. (2007). A phase III trial comparing an anionic phospholipid-based cream and aloe vera-based gel in the prevention of radiation dermatitis in pediatric patients. *Radiation Oncology*, 2, 45. doi:10.1186/1748-717X-2-45.
- Momm, F., Weibenberger, C., Bartelt, S., & Henke M. (2003). Moist skin care can diminish acute radiation-induced skin toxicity. *Strahlentherapie und Onkologie*, 179, 708–712. doi:10.1007/s00066-003-1142-9.
- Moore-Higgs, G. (2007). Basic principles of radiation therapy. In M.L. Haas, W.P. Hogle, G.J. Moore-Higgs, & T.K. Gosselin-Acomb (Eds.), *Radiation therapy: A guide to patient care* (pp. 8–24). St. Louis, MO: Mosby Elsevier.
- Morganti, A.G., Digesù, C., Panunzi, S., de Gaetano, A., Macchia, G., Deodato, F., de Gaetano, G. (2009). Radioprotective effect of moderate wine consumption in patients with breast carcinoma. *International Journal of Radiation Oncology, Biology, Physics*, 74, 1501–1505. doi:10.1016/j.ijrobp.2008.10.089.
- Necrosis (n.d) *Mosby's Medical Dictionary*, 8th edition (2009), retrieved from <http://medicaldictionary.thefreedictionary.com/necrosis>.
- Olsen, D.L., Raub, W., Jr., Bradley, C., Johnson, M., Macias, J.L., Love, V., & Markoe, A. (2001). The effect of aloe vera gel/mild soap versus mild soap alone in preventing skin reactions in patients undergoing radiation therapy. *Oncology Nursing Forum*, 28, 543–547.
- Omidvari, S., Saboori, H., Mohammadianpanah, M., Mosalaei, A., Ahmadloo, N., Mosleh-Shirazi, M.A., Namaz, S. (2007). Topical betamethasone for prevention of radiation dermatitis. *Indian Journal of Dermatology, Venereology and Leprology*, 73, 209–214.
- Pignol, J.P., Olivotto, I., Rakovitch, E., Gardner, S., Sixel, K., Beckham, W., Paszat, L. (2008). A multicenter randomized trial of breast intensity-modulated radiation therapy to reduce acute radiation dermatitis. *Journal of Clinical Oncology*, 26, 2085–2092. doi:10.1200/JCO.2007.15.2488.
- 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.
- Primavera, G., Carrera, M., Berardesca, E., Pinnaró, P., Messina, M., & Arcangeli, G. (2006). A double-blind, vehicle-controlled clinical study to evaluate the efficacy of MAS065D(XClair), a hyaluronic acid-based formulation, in the management of radiation-induced dermatitis. *Cutaneous and Ocular Toxicology*, 25, 165–171. doi:10.1080/15569520600860009.
- Robson, V., & Cooper, R. (2009). Using leptospermum honey to manage wounds impaired by radiotherapy: A case series. *Ostomy Wound Management*, 55, 38–47.
- Röper, B., Kaisig, D., Auer, F., Mergen, E., & Molls, M. (2004). Theta-cream versus bepanthol lotion in breast cancer patients under radiotherapy. *Strahlentherapie und Onkologie*, 180, 315–322. doi:10.1007/s00066-004-1174-9.
- 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.
- Schmuth, M., Wimmer, M.A., Hofer, S., Sztankay, A., Weinlich, G., Linder, D.M., Fritsch, E. (2002). Topical corticosteroid therapy for acute radiation dermatitis: A prospective, randomized, double-blind study. *British Journal of Dermatology*, 146, 983–991. doi:10.1046/j.1365-2133.2002.04751.x.
- Schreck, U., Pausen, F., Bamberg, M., & Budach, W. (2002). Intraindividual comparison of two different skin care conceptions in patients undergoing radiotherapy of the head-and-neck region: Creme or powder? *Strahlentherapie und Onkologie*, 178, 321–329.
- Shukla, P.N., Gairola, M., Mohanti, B.K., & Rath, G.K. (2006). Prophylactic beclomethasone spray to the skin during postoperative radiotherapy of carcinoma breast: A prospective randomized study. *Indian Journal of Cancer*, 43, 180–184. doi:10.4103/0019-509X.29424.
- Sparks, S. (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.
- Szumacher, E., Wighton, A., Franssen, E., Chow, E., Tsao, M., Ackerman, I., ... Hayter, C. (2001). Phase II study assessing the effectiveness of Biafine cream as a prophylactic agent for radiation-induced acute skin toxicity to the breast in women undergoing radiotherapy with concomitant CMF chemotherapy. *International Journal of Radiation Oncology, Biology, Physics*, 51, 81–86. doi:10.1016/S0360-3016(01)01576-0.

Swedish Bitters Herb Company. (2009). About calendula. Retrieved from <http://www.calendulacream.com>.

Théberge, V., Harel, F., & Dagnault, A. (2009). Use of axillary deodorant and effect on acute skin toxicity during radiotherapy for breast cancer: a prospective randomized noninferiority trial. *International Journal of Radiation Oncology, Biology, Physics*, 75, 1048–1052. doi:10.1016/j.ijrobp.2008.12.046.

Tyng, D.R., Chojniak, R., Pinto, P., Borba, M.A., Bitencourt, A.G. Fogaroli, R.C. Novales, P.E. (2009). Conformal radiotherapy for lung cancer: Interobservers variability in the definition of gross tumor volume between radiologists and radiotherapists. *Radiation Oncology*.4. doi: 10.1186/1748-717x-4-28.

Vavassis, P., Gelinas, M., Chabot Tr, J., & Nguyen-Tân, P.F. (2008). Phase 2 study of silver leaf dressing for treatment of radiation-induced dermatitis in patients receiving radiotherapy to the head and neck. *Journal of Otolaryngology-Head and Neck Surgery*, 37, 124–129.

Vogler, B.K., & Ernst, E. (1999). Aloe vera: A systematic review of its clinical effectiveness. *British Journal of General Practice*, 49, 823–828. Retrieved from <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1313538/?tool=pubmed>.

Vuong, R., Franco, E., Lehnert, S., Lambert, C., Portelance, L., Nasr, E., Freeman, C. (2004). Silver leaf nylon dressing to prevent radiation dermatitis in patients undergoing chemotherapy and external beam radiotherapy to the perineum. *International Journal of Radiation Oncology, Biology, Physics*, 59, 809–814. doi:10.1016/j.ijrobp.2003.11.031.

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.ijrobp.2003.11.031.

Westbury, C., Hines, F., Hawkes, E., Ashley, S., & Brada, M. (2000). Advice on hair and scalp care during cranial radiotherapy: A prospective randomized trial. *Radiotherapy and Oncology*, 54, 109–116. doi:10.1016/S0167-8140(99)00146-2.

Wickline, 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.S., Burk, M., Loprinzi, C.L., Hill, M., Schomberg, P.J., 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, Physics*, 36, 345–349. doi:10.1016/S0360-3016(96)00320-3.

## Added references from the European expert group:

### Review Author & Reference

Gosselin et al (2010) *Oncol Nurs Forum*. 37(5); 619-626  
A prospective randomized, placebo-controlled skin care study in women diagnosed with breast cancer undergoing radiation therapy.

### Study Information

Design: Prospective randomised double-blinded, placebo-controlled study. Sample: 208 women with breast cancer. 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.

### Conclusions and Implications

Findings and Conclusion: 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. Findings however, do not demonstrate improved clinical outcomes with use of skin care products.  
Expert review comments: Only 3 skin care products compared so cannot use findings to generalize that the use of skin care

products does not improve clinical outcomes.  
Support for the development and use of clinical guidelines.

### Review Author & Reference

Hemati et al 2011, *Support Care Cancer*  
Topical silver sulfadiazine for the prevention of acute dermatitis during irradiation for breast cancer.

### Study Information

RCT, 102 patients. (breast)

Lower RTOG scores for patients using cream containing 1 % silver sulfadiazine compared with no topical skin care.

### Conclusions and Implications

Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline. More research is needed but this product could be effective.

## Review Author & Reference

Hollingworth H, Mann L (2010)  
Managing acute skin reactions to radiotherapy treatment.  
National survey of practice and recommendations.

## Conclusions and Implications

European Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline.

---

## Review Author & Reference

Kirova 2011, Radiother Oncol. 2011 Aug;100(2):205-9. Epub 2011 May 31. Can we decrease the skin reaction in breast cancer patients using hyaluronic acid during radiation therapy? Results of phase III randomised trial.

## Study Information

Blinded RCT, No significant differences in skin care using hyaluronic acid cream compared with placebo (200 patients with breast cancer).

## Conclusions and Implications

European Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline.

---

## Review Author & Reference

Kumar et al 2010, Liverpool Cancer Therapy Center  
J of Med Imaging and Rad Onc 54, 264-279.  
Management of skin toxicity during radiation therapy: a review of the evidence.

## Study Information

Literature review on 29 articles. Recent and well conducted systematic review.

## Conclusions and Implications

Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline. They conclude (among many other things) that washing skin with mild soap and water reduce the risk for moist desquamation ( $P < 0.05$ ) compared with no washing or washing with only water.

---

## Review Author & Reference

McQuestion, M update 2011, Princess Margaret Hospital, Toronto  
Sem in Onc Nurs vol 27, no 2 (May). pp e1-e17.  
Evidence-based skin care management in radiation therapy: clinical update.

## Study Information

Update from an earlier review by the same author in 2006.

## Conclusions and Implications

Update by a Clinical Nurse Specialist, Advanced practice nurse. Conclusions in line with most on the content of the ONS guidelines. Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline.

---

## Review Author & Reference

Miller et al 2011, Mayo clinic, USA.  
Int J Radiat Oncol Biol Phys. 2011 Apr 1;79(5):1460-6.  
Epub 2010 Aug 26.

Mometasone furoate effect on acute skin toxicity in breast cancer patients receiving radiotherapy: a phase III double-blind, randomized trial from the North Central Cancer Treatment Group N06C4.

## Study Information

RTC, adjuvant breast cancer.  
(n = 169). Intervention: daily skin care with potent corticosteroid (group III) from onset of RT until healed. Controls: Placebo. Patients receiving daily MMF during radiotherapy might experience reduced acute skin toxicity compared with patients receiving placebo (shows improvement in patient reported outcomes). Well conducted study.

## Conclusions and Implications

No sign difference between the groups regarding pain but significantly less itching in the intervention group ( $p = 0.008$ ). No significant difference between the groups in CTCAE scores (clinician reported data). Significantly higher scores ( $p = 0.003$ ) among controls in Maximum Skindex Score (patient reported data) but no significant differences in proportion of dry or moist desquamation (with the same assessment tool and also reported by patients). This is the only large randomised, placebo controlled trial published on potent corticosteroids and is therefore an important reference for the guidelines. There is no follow-up data on the risks of using potent corticosteroids on irradiated skin. In this study the treatment period was up to 7-8 weeks.

---

## Review Author & Reference

Pinnix 2011  
Int J Radiat Oncol Biol Phys. 2011 Dec 14. [Epub ahead of print]  
Topical Hyaluronic Acid vs. Standard of Care for the Prevention of Radiation Dermatitis After Adjuvant Radiotherapy for Breast Cancer: Single-Blind Randomized Phase III Clinical Trial.

## Study Information

RCT, blinded, breast cancer  
The study was interrupted after the inclusion of 74 or 92 planned patients due to the results. All patients was randomly selected to used hyaluronic acid gel on one part of the irradiated skin and petrolatum-based gel on the other part.

---

### Conclusions and Implications

Significantly higher RTOG scores for skin treated with hyaluronic acid gel. (p=0.027)

---

### Review Author & Reference

Salvo et al 2010, Sunnybrook, Toronto Current Oncology vol 17 Nr 4, 94-112.

Prophylaxis and management of acute radiation-induced skin reactions: a systematic review of the literature.

### Study Information

Literature review on 39 articles. In conclusion, the evidence is insufficient to support the use of a particular agent for the prevention and management of acute radiation-induced skin reactions. Recent and well conducted systematic review.

### Conclusions and Implications

All the three reviews that are listed here are recent and draw similar conclusions and would be good to add to the reference list. Our concern is the current literature list has quite a few older studies.

Expert review comments: Findings should be considered to support the inclusion or exclusion of practice recommendations within PEP guideline.

---

### Review Author & Reference

Watson CL et al, International Journal of Radiation Oncology Biology- physics.

Volume 83, Number 1,2012 RCT: Antiperspirant use during EBRT.

### Study Information

A randomized control trial of 198 patients with stage 0, I, or II breast cancer receiving external beam radiotherapy after surgery compared the effects of using aluminum based antiperspirant versus standard-wash only skin care on skin toxicity and quality of life.

### Conclusions and Implications

The skin reaction data were analyzed using the generalized estimating equation. No statistically significant difference was seen in the skin reaction between the 2 groups over time.

The quality of life data also revealed no statistically significant difference between the 2 groups over time.

