Complete Summary

GUIDELINE TITLE

The prevention and management of acute skin reactions related to radiation therapy.

BIBLIOGRAPHIC SOURCE(S)

Supportive Care Guidelines Group. Bolderston A, Lloyd NS, Wong RK, Holden L, Robb-Blenderman L. The prevention and management of acute skin reactions related to radiation therapy [full report]. Toronto (ON): Cancer Care Ontario (CCO); 2005 Feb 21. 34 p. (Practice guideline report; no. 13-7). [46 references]

GUIDELINE STATUS

This is the current release of the guideline.

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SCOPE

DISEASE/CONDITION(S)

- Cancers requiring radiation therapy
- Acute skin reactions related to radiation therapy

GUIDELINE CATEGORY

Management
Prevention
Treatment

CLINICAL SPECIALTY

Oncology
Radiation Oncology

INTENDED USERS

Physicians

GUIDELINE OBJECTIVE(S)

- To evaluate the optimal methods to prevent acute skin reactions (occurring within the first six months of irradiation) related to radiation therapy
- To evaluate the optimal methods to manage acute skin reactions related to radiation therapy

TARGET POPULATION

Adult patients with cancer of any histology who are undergoing radiation therapy

INTERVENTIONS AND PRACTICES CONSIDERED

Prevention of Acute Skin Reaction

1. Washing practices
2. Calendula ointment
3. Plain, non-scented, lanolin-free hydrophilic cream

Notes:

- Guideline developers recommended against limiting personal hygiene practices.
- Guideline developers found insufficient evidence to support or refute other specific topical agents (i.e., corticosteroids, sucralfate cream, Biafine, ascorbic acid, aloe vera, chamomile cream, almond ointment, polymer adhesive skin sealant) for the prevention of acute skin reactions
- Guideline developers found insufficient evidence to support or refute specific oral agents (i.e., enzymes, sucralfate) or intravenous agents (i.e., amifostine) for the prevention of acute skin reaction

Management of Acute Skin Reaction

Low-dose (i.e., 1%) corticosteroid cream

Note: Guideline developers found insufficient evidence to support or refute topical agents, such as corticosteroids, sucralfate cream, or specific dressings for the management of acute skin reactions.

MAJOR OUTCOMES CONSIDERED

- Acute skin reaction
- Pain

- Itching
- Burning
- Quality of life
- Adverse events

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

A search of PreMEDLINE, MEDLINE, CANCERLIT, and the Cochrane Library (2004, Issue 1) was conducted to identify comparative studies published between 1980 and April 2004. Relevant articles were identified by combining terms and phrases related to skin and specific skin conditions with radiation therapy terms and combining these terms with terms specific to study design. The Medical Subject Heading (MeSH) terms "dermis," "epidermis," and "skin/re" (radiation effects) and text words and phrases "erythema," "radiation dermatitis," "radiodermatitis," "desquamation" (dry and moist), and "acute skin reaction" were combined with search terms for radiation therapy including "explode radiotherapy," "radiotherapy/ae" (adverse effects) and a text word search for "radiotherapy" or "radiation therapy." These terms were then combined with the search terms for the following publication types: practice guidelines, systematic reviews, meta-analyses, reviews, randomized controlled trials, controlled clinical trials, and comparative studies.

In addition, conference proceedings of the meetings of the American Society of Clinical Oncology (ASCO) were searched for abstract reports published between 1997 and 2003. The Canadian Medical Association Infobase (http://www.mdm.ca/cpgsnew/cpgs/index.asp) and the National Guidelines Clearinghouse (http://www.guideline.gov/) were also searched for existing evidence-based practice guidelines. Relevant articles and abstracts were selected and reviewed by two reviewers, and the reference lists from these sources were searched for additional trials, as were the reference lists from relevant review articles.

Inclusion Criteria

Articles were selected for inclusion if they met all of the following criteria:

1. They were systematic reviews, meta-analyses, evidence-based practice guidelines, or comparative studies comparing skin care practices administered by any route for the prevention or treatment of acute skin reactions due to radiation therapy.
2. Data were collected prospectively in at least one arm of the trial. Historical controls were permitted.

3. Clinically relevant outcomes to skin reaction were reported. The trial reported degree of skin reaction (using a validated skin reaction score) as an outcome. Other outcomes of interest included pain, itchiness, burning, quality of life, and toxicities.
4. The article was a fully published or abstract report.

Exclusion Criteria

The following articles were excluded from this systematic review of the evidence:

1. Letters, comments, and editorials
2. Articles published in a language other than English

NUMBER OF SOURCE DOCUMENTS

Twenty-eight trials were identified

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Expert Consensus (Committee)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not applicable

METHODS USED TO ANALYZE THE EVIDENCE

Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

The primary outcome of interest for this review was the degree of skin reaction. Secondary outcomes of interest included symptoms such as pain, itchiness, burning, quality of life, and toxicities. Meta-analysis was not performed because the included trials were too clinically heterogeneous, mainly since they evaluated different treatment regimens. For some interventions, only one trial was identified, thereby eliminating the possibility of pooling. In addition, most trials were too heterogeneous in terms of outcome assessment and reporting of results.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

During the initial discussion of this guideline topic, the Supportive Care Guidelines Group (SCGG) agreed that the evidence should be separated into trials aimed at the prevention of acute radiation skin reactions and those aimed at the

management of acute radiation skin reactions. The first draft of the practice guideline report was circulated to the SCGG in March 2004. Overall, the SCGG approved the draft guideline with some suggestions for clarification that were subsequently incorporated in the draft sent out for external review. A suggestion was made that more information on specific dressings for wound management be provided in the Interpretive Summary section; however, the authors felt this to be beyond the scope of this guideline report. A companion document on wound management will be considered as a future topic.

Feedback from the non-physician health care professional members of the SCGG suggested that a statement on the definition of "evidence-based" might provide some clarity. A nursing representative of the group commented that since the evidence does not lend itself to definitive recommendations for the majority of the interventions assessed, it might be worthwhile producing a document on "best practice." The authors considered this comment in the context of two types of documents produced by the Program in Evidence-based Care (PEBC), clinical practice guidelines and evidence summaries, and felt it was important to delineate the two and explain how these differ from the Registered Nurses Association of Ontario's (RNAO) "Best Practice Guidelines."

The PEBC's clinical practice guidelines and evidence summaries are based on a systematic review of the best available research evidence, with the practice guidelines consisting primarily of mature randomized trials that contribute to the development of recommendations. When insufficient evidence precludes the development of definitive recommendations, an evidence summary is produced, offering opinions of the SCGG until more mature research evidence on which to base recommendations becomes available. Of importance is the fact that the PEBC approach places great emphasis on the evidence base, and the SCGG, a multidisciplinary guideline panel, interprets this evidence to provide recommendations. The evidence source for our documents differs from that of the Registered Nurses Association of Ontario, which, in addition to using research evidence, also considers evidence from expert committee reports, expert opinions, clinical experience, or expert authorities.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

External Peer Review
Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Practitioner feedback was obtained through a mailed survey of 264 practitioners and health care professionals in Ontario (86 radiation oncologists, 146 oncology nurses, and 32, radiation therapists). The survey consisted of items evaluating the methods, results, and interpretive summary used to inform the draft recommendations and whether the draft recommendations above should be approved as a practice guideline. Written comments were invited. The practitioner feedback survey was mailed out on April 15, 2004. Follow-up reminders were sent at two weeks (post card) and four weeks (complete package mailed again). The Supportive Care Guidelines Group (SCGG) reviewed the results of the survey.

The practice guideline report was circulated to 15 members of the Practice Guidelines Coordinating Committee (PGCC) for review and approval. Ten of fifteen members of the PGCC returned ballots. Six PGCC members approved the practice guideline report as written, one member approved the guideline and provided suggestions for consideration by the SCGG, and three members of the PGCC were also members of the SCGG and were therefore not eligible to review the report.

Final approval of the guideline report is obtained from the Practice Guidelines Coordinating Committee.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

Prevention of Acute Skin Reaction

- Skin washing should not be restricted in patients receiving radiation therapy. Recommended washing practices include gentle washing[1] with water alone or gentle washing with mild[2] soap and water.
- Patients receiving radiation therapy to the head should be advised to follow gentle washing practices with mild shampoo.
- Limiting personal hygiene practices is not recommended as this may lead to psychosocial distress for the patient.
- Limited evidence suggests that calendula ointment may decrease the occurrence of $\geq$Grade 2 radiation dermatitis in breast cancer patients. Its application in other types of cancer is unknown at this time.
- There is insufficient evidence to support or refute other specific topical agents (i.e., corticosteroids, sucralfate cream, Biafine, ascorbic acid, aloe vera, chamomile cream, almond ointment, polymer adhesive skin sealant) for the prevention of acute skin reaction.
- There is insufficient evidence to support or refute specific oral agents (i.e., enzymes, sucralfate) or intravenous agents (i.e., amifostine) for the prevention of acute skin reaction. The side effects of these agents were more oppressive than those reported in the trials assessing topical agents, and therefore the benefits do not outweigh the risks.

Management of Acute Skin Reaction

- There is insufficient evidence to support or refute topical agents such as corticosteroids, sucralfate cream, or specific dressings for the management of acute skin reaction.

Opinions of the Supportive Care Guidelines Group

- In the opinion of the Supportive Care Guidelines Group, clinical experience suggests that initial use of a plain, non-scented, lanolin-free hydrophilic cream is helpful in preventing radiation skin reactions. This type of cream attracts and traps moisture at the skin surface to increase the skin's moisture and maintain skin pliability. The cream should be discontinued when skin breakdown occurs.
- In the opinion of the Supportive Care Guidelines Group, clinical experience suggests that low-dose (i.e., 1%) corticosteroid cream may be beneficial in the reduction of itching and irritation. There does appear to be an inflammatory process associated with radiation-induced erythema that may be alleviated somewhat by corticosteroid creams. More evidence is needed to support firm recommendations.

[1] "Gentle washing" involves using lukewarm water and taking care not to scrub the skin. Showers should also be lukewarm and low-pressure.
[2] "Mild soap" is defined as a pH-balanced, non-scented product that does not contain lanolin. There is no evidence to suggest that one type of mild soap is preferable to another. However, in one study that rated the irritant quality of 18 soaps, "Dove" was the only soap classified as mild and may therefore be considered.

CLINICAL ALGORITHM(S)

None provided

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are supported by practice guidelines, randomized, and non-randomized trials.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Reduction in incidence and severity of skin reactions related to radiation therapy

POTENTIAL HARMS

Adverse events were generally mild to moderate for those trials that assessed topical agents. The most common treatment-related toxicities were allergic reaction to the topical agent, itching, burning, and moist desquamation. Overall, there were no significant differences in adverse events between treatment groups for those trials evaluating topical agents, aside from one trial that reported significantly less pain in the aqueous cream group compared to patients in the aloe vera cream group. Allergic reaction was the most commonly reported adverse reaction in the aloe vera trials.

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

- Given the evidence for skin washing, it would seem likely that the same recommendations would follow for hair washing with shampoo for patients receiving radiation therapy to the head, but there is limited evidence to support this.
- Only one trial compared calendula ointment to Biafine cream. The promising results of this large trial (n=254) in breast cancer patients suggest that calendula ointment may be beneficial to cancer patients undergoing radiation therapy. However, administration difficulties may lead to treatment discontinuation for some patients. No trial compared calendula to no treatment or placebo. It is currently unclear if calendula is superior to placebo or no treatment or whether these results can be generalized to cancer patients undergoing radiation therapy for other types of malignancies.
- Caution must be used to avoid the overuse of corticosteroid cream; however, there is limited evidence to suggest that skin thinning would pose a problem for normal corticosteroid use during an average course of treatment (up to eight weeks). The practitioner must also be aware of potential patient allergies to topical corticosteroids and discontinue use if an allergic reaction occurs.
- Care has been taken in the preparation of the information contained in this document. Nonetheless, any person seeking to apply or consult these guidelines is expected to use independent medical judgment in the context of individual clinical circumstances or seek out the supervision of a qualified clinician. Cancer Care Ontario makes no representation or warranties of any kind whatsoever regarding their content or use or application and disclaims any responsibility for their application or use in any way.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better
Living with Illness
Staying Healthy

IOM DOMAIN

Effectiveness
Safety

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Supportive Care Guidelines Group. Bolderston A, Lloyd NS, Wong RK, Holden L, Robb-Blenderman L. The prevention and management of acute skin reactions related to radiation therapy [full report]. Toronto (ON): Cancer Care Ontario (CCO); 2005 Feb 21. 34 p. (Practice guideline report; no. 13-7). [46 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2005 Feb 21

GUIDELINE DEVELOPER(S)

Program in Evidence-based Care - State/Local Government Agency [Non-U.S.]

GUIDELINE DEVELOPER COMMENT

The Practice Guidelines Initiative (PGI) is the main project of the Program in Evidence-based Care (PEBC), a Province of Ontario initiative sponsored by Cancer Care Ontario and the Ontario Ministry of Health and Long-Term Care.

SOURCE(S) OF FUNDING

Cancer Care Ontario
Ontario Ministry of Health and Long-Term Care

GUIDELINE COMMITTEE

Provincial Supportive Care Guidelines Group

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

For a current list of past and present members, please see the Cancer Care Ontario Web site.

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Members of the Supportive Care Guidelines Group (SCGG) disclosed potential conflict of interest information and no conflicts were declared.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.

AVAILABILITY OF COMPANION DOCUMENTS

The following are available:

- The prevention and management of acute skin reactions related to radiation therapy. Summary. Toronto (ON): Cancer Care Ontario (CCO). Electronic copies: Available in Portable Document Format (PDF) from the Cancer Care Ontario Web site.
- Browman GP, Levine MN, Mohide EA, Hayward RSA, Pritchard KI, Gafni A, et al. The practice guidelines development cycle: a conceptual tool for practice guidelines development and implementation. J Clin Oncol 1995;13(2):502-12.

PATIENT RESOURCES

None available

NGC STATUS

This summary was completed by ECRI on May 2, 2005. The information was verified by the guideline developer on May 6, 2005.

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