Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Best evidence statement (BESt). Using oral cryotherapy to prevent oral mucositis in patients receiving chemotherapy.

Bibliographic Source(s)

Cincinnati Children's Hospital Medical Center. Best evidence statement (BESt). Using oral cryotherapy to prevent oral mucositis in patients receiving chemotherapy. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2013 Jun 20. 5 p. [5 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

The strength of the recommendation (strongly recommended, recommended, or no recommendation) and the quality of the evidence (1a-5b) are defined at the end of the "Major Recommendations" field.

It is strongly recommended that patients being treated with bolus 5-fluorouracil (5-FU), melphalan, or high dose carmustine, etoposide, cytarabine, and cyclophosphamide (BEAC) chemotherapy regimens receive oral cryotherapy during the infusion to prevent, or reduce the severity of, oral mucositis (Worthington et al., 2011 [1a]; Nikoletti et al., 2005 [2a]; Svanberg, Ohrn, & Birgegard, 2010 [2a]; Katranci et al., 2012 [2b]).

> Notes: There is not enough evidence to make a recommendation for or against the use of oral cryotherapy in patients being treated with methotrexate (Worthington et al., 2011 [1a]). There was no evidence found related to the use of oral cryotherapy with other chemotherapy drugs.

Definitions:

Table of Evidence Levels

Quality Level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain

Quality Level	Definition
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Table of Language and Definitions for Recommendation Strength

Language for Strength	Definition
It is strongly recommended that… It is strongly recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
It is recommended that… It is recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.
There is insufficient evidence and a lack of consensus to make a recommendation…	

Note: See the original guideline document for the dimensions used for judging the strength of the recommendation.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Oral mucositis

Guideline Category

Prevention

Clinical Specialty

Nursing

Oncology

Intended Users

Advanced Practice Nurses

Nurses

Physicians

Guideline Objective(s)

To evaluate, among patients of all ages receiving chemotherapy, if oral cryotherapy compared to no intervention reduces the severity of, or prevents, chemotherapy-induced oral mucositis

Target Population

Oncology or bone marrow transplant patients being treated with bolus 5-fluorouracil (5-FU), melphalan, or high dose carmustine, etoposide, cytarabine, and cyclophosphamide (BEAC) chemotherapy regimens

Note: The guideline does not include patients with malignancies of the head or neck; patients who are unable to eat or drink; and patients who are developmentally or physically unable to perform the intervention.

Interventions and Practices Considered

Oral cryotherapy

Major Outcomes Considered

Reduced severity or prevention of chemotherapy-induced oral mucositis

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Search Strategy

- Databases: MEDLINE, CINAHL, Scopus, the Cochrane Library
- Search Terms: mucositis, stomatitis, cryotherapy, chemotherapy
- Limits, Filters, Search Dates: English language, humans, 1990-present
- Date Last Search Done: March 12, 2013

Number of Source Documents

Not stated

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Table of Evidence Levels

Quality Level	Definition
1a† or 1b†	Systematic review, meta-analysis, or meta-synthesis of multiple studies
2a or 2b	Best study design for domain
3a or 3b	Fair study design for domain
4a or 4b	Weak study design for domain
5a or 5b	General review, expert opinion, case report, consensus report, or guideline
5	Local Consensus

†a = good quality study; b = lesser quality study

Methods Used to Analyze the Evidence

Systematic Review

Description of the Methods Used to Analyze the Evidence

Not stated

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Not stated

Rating Scheme for the Strength of the Recommendations

Table of Language and Definitions for Recommendation Strength

Language for Strength	Definition
It is strongly recommended that… It is strongly recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is high support that benefits clearly outweigh risks and burdens (or visa-versa for negative recommendations).
It is recommended that… It is recommended that… not…	When the dimensions for judging the strength of the evidence are applied, there is moderate support that benefits are closely balanced with risks and burdens.

Language for Strength	Definition
	There is insufficient evidence and a lack of consensus to make a recommendation…

Note: See the original guideline document for the dimensions used for judging the strength of the recommendation.

Cost Analysis

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

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

This Best Evidence Statement (BESt) has been reviewed against quality criteria by two independent reviewers from the Cincinnati Children's Hospital Medical Center (CCHMC) Evidence Collaboration.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Katranci N, Ovayolu N, Ovayolu O, Sevinc A. Evaluation of the effect of cryotherapy in preventing oral mucositis associated with chemotherapy - a randomized controlled trial. Eur J Oncol Nurs. 2012 Sep;16(4):339-44. PubMed

Nikoletti S, Hyde S, Shaw T, Myers H, Kristjanson LJ. Comparison of plain ice and flavoured ice for preventing oral mucositis associated with the use of 5 fluorouracil. J Clin Nurs. 2005 Jul;14(6):750-3. PubMed

Svanberg A, Ohrn K, Birgegard G. Oral cryotherapy reduces mucositis and improves nutrition - a randomised controlled trial. J Clin Nurs. 2010 Aug;19(15-16):2146-51. PubMed

Worthington HV, Clarkson JE, Bryan G, Furness S, Glenny AM, Littlewood A, McCabe MG, Meyer S, Khalid T. Interventions for preventing oral mucositis for patients with cancer receiving treatment. Cochrane Database Syst Rev. 2011;(4):CD000978. PubMed

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for each recommendation (see the "Major Recommendations" field).

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Prevention of oral mucositis in patients receiving chemotherapy

Potential Harms

Nausea, mouth sensitivity, and headache were the most common adverse effects of cryotherapy, although it should be noted that nausea may be the result of the chemotherapy rather than the cryotherapy.

Qualifying Statements

Qualifying Statements

This Best Evidence Statement addresses only key points of care for the target population; it is not intended to be a comprehensive practice guideline. These recommendations result from review of literature and practices current at the time of their formulation. This Best Evidence Statement does not preclude using care modalities proven efficacious in studies published subsequent to the current revision of this document. This document is not intended to impose standards of care preventing selective variances from the recommendations to meet the specific and unique requirements of individual patients. Adherence to this Statement is voluntary. The clinician in light of the individual circumstances presented by the patient must make the ultimate judgment regarding the priority of any specific procedure.

Implementation of the Guideline

Description of Implementation Strategy

Applicability Issues

Patients should be given small ice cubes that can be easily moved around in the mouth without causing irritation. Ice should be replenished as it melts, and patients should be instructed to move the ice in an attempt to keep the entire oral cavity cold. The use of flavored ice may be useful in promoting compliance in pediatric patients.

For bolus 5-fluorouracil (5-FU), oral cryotherapy should be initiated five minutes prior to the start of the infusion and maintained for a total of thirty minutes. For melphalan and high dose carmustine, etoposide, cytarabine, and cyclophosphamide (BEAC) chemotherapy regimens, oral cryotherapy should begin at the start of the infusion and be maintained for the duration of the infusion.

Implementation Tools

Audit Criteria/Indicators

For information about availability, see the *Availability of Companion Documents* and *Patient Resources* fields below.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Living with Illness

Staying Healthy

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

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Adaptation

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

Date Released

2013 Jun 20

Guideline Developer(s)

Cincinnati Children's Hospital Medical Center - Hospital/Medical Center

Source(s) of Funding

Cincinnati Children's Hospital Medical Center

No external funding was received for development of this Best Evidence Statement (BESt).

Guideline Committee

Not stated

Composition of Group That Authored the Guideline

Team Leader/Author: Stephanie L. Feist, RN, BSN, Cancer and Blood Diseases Institute

Support/Consultant: Barbara K. Giambra, PhD(c), MS, RN, CPNP, Evidence-Based Practice Mentor-Research, Center for Professional Excellence, Research and Evidence-Based Practice

Financial Disclosures/Conflicts of Interest

Conflict of interest declaration forms are filed with the Cincinnati Children's Hospital Medical Center (CCHMC) Evidence-Based Decision Making (EBDM) group. No financial or intellectual conflicts of interest were found.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the Cincinnati Children's Hospital Medical Center Web site .

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

Availability of Companion Documents

The following are available:

- Judging the strength of a recommendation. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the Cincinnati Children's Hospital Medical Center (CCHMC) Web site .
- Grading a body of evidence to answer a clinical question. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the CCHMC Web site .
- Table of evidence levels. Cincinnati (OH): Cincinnati Children's Hospital Medical Center; 2009 May 7. 1 p. Available from the CCHMC Web site .

Print copies: For information regarding the full-text guideline, print copies, or evidence-based practice support services contact the Cincinnati Children's Hospital Medical Center Health James M. Anderson Center for Health Systems Excellence at EBDMInfo@cchmc.org.

In addition, suggested process or outcome measures are available in the original guideline document .

Patient Resources

None available

NGC Status

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