Agency for Healthcare Research and Quality
Advancing Excellence in Health Care

NATIONAL GUIDELINE CLEARINGHOUSE

General

Guideline Title

Staging investigations for asymptomatic and newly diagnosed breast cancer.

Bibliographic Source(s)

Alberta Provincial Breast Tumour Team. Staging investigations for asymptomatic and newly diagnosed breast cancer. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2012 Jul. 17 p. (Clinical practice guideline; no. BR-012). [30 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

All patients should have the appropriate medical history and physical examination performed by a qualified health care practitioner.

1. Baseline Investigations
    - Stage 0: bilateral mammography
    - Stage I: bilateral mammography and laboratory investigations*
    - Stage II: bilateral mammography, chest x-ray, laboratory investigations*, and optional abdominal imaging
    - Stage III: bilateral mammography, chest x-ray or chest computed tomography (CT)†, abdominal imaging (ultrasound [U/S] or CT†), bone scan, and laboratory investigations*
    - Stage IV: chest x-ray or chest CT†, abdominal imaging (U/S or CT†), bone scan, and laboratory investigations*
    - Unless metastatic disease is suspected from symptoms and/or physical exam, staging tests can be performed after surgery.
    - All baseline investigations (see Figure 1 in the original guideline document), as per this guideline, will be reviewed at the cancer centre.
2. Investigations Prior to Adjuvant Chemotherapy
    - For anthracycline-based chemotherapy (e.g., lymph node positive patients): multigated radionuclide angiography (MUGA) or echocardiogram (ECHO)
    - For trastuzumab (e.g., human epidermal growth factor receptor 2 [HER2+] patients): MUGA or ECHO
    - For adjuvant chemotherapy (e.g., lymph node positive patients, high risk, lymph node negative patients, stage III patients, or stage IV patients): laboratory investigations*
    - Baseline cardiac investigations (if required) for subsequent adjuvant therapy can be arranged at the time of the cancer centre triage review.
3. Tumour, Node, Metastasis (TNM) Classification

- The TNM staging system developed by the American Joint Committee on Cancer (Edge et al., 2010) is used to group patients with respect to prognosis. TNM staging definitions are included in Appendix A of the original guideline document.

*Laboratory investigations include complete blood count (CBC), creatinine, aspartate aminotransferase/alanine aminotransferase (AST/ALT), alkaline phosphatase (AP), total bilirubin, albumin, calcium, and lactate dehydrogenase (LDH).

†CT is preferred for inflammatory breast cancer.

Clinical Algorithm(s)

An algorithm for the staging of asymptomatic and newly diagnosed breast cancer is provided in the original guideline document.

Scope

Disease/Condition(s)

Asymptomatic and newly diagnosed breast cancer

Guideline Category

Evaluation

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Oncology

Pathology

Radiology

Intended Users

Advanced Practice Nurses

Allied Health Personnel

Nurses

Physician Assistants

Physicians

Guideline Objective(s)

To provide recommendations that outline which tests should be included in the staging investigation of patients with asymptomatic, biopsy confirmed breast cancer, in an effort to standardize clinical practice across the province and to expedite the subsequent assessment and treatment of patients in the cancer centres

Target Population

Patients with asymptomatic, biopsy-confirmed breast cancer, prior to referral to the cancer centre

Interventions and Practices Considered

1. Medical history and physical examination
2. Baseline investigations based on stage
    - Bilateral mammography
    - Laboratory investigations
    - Chest x-ray or chest computed tomography (CT)
    - Abdominal imaging (ultrasound or CT)
    - Bone scan
3. Investigations prior to adjuvant chemotherapy
    - Multigated radionuclide angiography (MUGA) or echocardiogram (ECHO)
    - Laboratory investigations
4. Tumour, Node, Metastasis (TNM) classification

Major Outcomes Considered

- Positive predictive value and negative predictive value of breast cancer staging tests
- Incremental cancer detection rate (ICDR)
- Reoperation rates
- Presence of metastases
- Detection of metastases

Methodology

Methods Used to Collect/Select the Evidence

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

Research Questions

Specific research questions to be addressed by the guideline document were formulated by the guideline lead(s) and Knowledge Management (KM) Specialist using the PICO question format (patient or population, intervention, comparisons, outcomes).

Guideline Questions

1. What are the appropriate staging investigations (e.g., imaging and blood work) for patients with asymptomatic, newly biopsy-confirmed breast cancer?
2. Do staging investigations vary according to stage of disease or other factors at diagnosis?

Search Strategy

A systematic search for clinical practice guidelines, systematic reviews, meta-analyses, and clinical studies was conducted of: MEDLINE, EMBASE, the Cochrane Library, Cancerview, and the National Guideline Clearinghouse. The search terms included "breast cancer" and "staging investigations." The search covered the period between 1965 and April 18, 2011. A total of seven clinical practice guidelines, one meta-analysis, and 10 clinical studies were deemed relevant.

In April 2012, the American Society of Clinical Oncology published five practices or interventions that are widely used, but not supported by high-

level clinical evidence. The recommendation against performing positron emission tomography (PET), computed tomography (CT), and radionuclide bone scans in the staging of early breast cancer at low risk for metastasis has been added to this guideline.

Number of Source Documents

18

Methods Used to Assess the Quality and Strength of the Evidence

Not stated

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

Evidence was selected and reviewed by a working group comprised of members from the Alberta Provincial Breast Tumour Team and a Knowledge Management (KM) Specialist from the Guideline Utilization Resource Unit (GURU). A detailed description of the methodology followed during the guideline development process can be found in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field).

Evidence Tables

Evidence tables containing the first author, year of publication, patient group/stage of disease, methodology, and main outcomes of interest are assembled using the studies identified in the literature search. Existing guidelines on the topic are assessed by the KM Specialist using portions of the AGREE II (http://www.agreetrust.org/) instrument and those meeting the minimum requirements are included in the evidence document. Due to limited resources, GURU does not regularly employ the use of multiple reviewers to rank the level of evidence; rather, the methodology portion of the evidence table contains the pertinent information required for the reader to judge for himself the quality of the studies.

Evidence tables, summarizing the information from the 18 sources, are included in Appendix B of the original guideline document.

Methods Used to Formulate the Recommendations

Expert Consensus

Description of Methods Used to Formulate the Recommendations

Formulating Recommendations

The working group members formulate the guideline recommendations based on the evidence synthesized by the Knowledge Management (KM) Specialist during the planning process, blended with expert clinical interpretation of the evidence. As detailed in the Guideline Utilization Resource Unit Handbook (see the "Availability of Companion Documents" field), the working group members may decide to adopt the recommendations of another institution without any revisions, adapt the recommendations of another institution or institutions to better reflect local practices, or develop their own set of recommendations by adapting some, but not all, recommendations from different guidelines.

The degree to which a recommendation is based on expert opinion of the working group and/or the Provincial Tumour Team members is explicitly

stated in the guideline recommendations. Similar to the American Society of Clinical Oncology (ASCO) methodology for formulating guideline recommendations, the Guideline Utilization Resource Unit (GURU) does not use formal rating schemes for describing the strength of the recommendations, but rather describes, in conventional and explicit language, the type and quality of the research and existing guidelines that were taken into consideration when formulating the recommendations.

The guideline development panel, including medical oncologists, radiation oncologists, and breast surgeons, initially reviewed the evidence in between May 2010 and October 2010. A draft document was subsequently developed, distributed for review, and discussed with the Breast Tumour Team at the annual meeting in January 2011. After a review of existing guidelines and clinical consensus, recommendations were agreed upon.

Rating Scheme for the Strength of the Recommendations

Not applicable

Cost Analysis

The guideline developers reviewed published cost analyses.

Method of Guideline Validation

Internal Peer Review

Description of Method of Guideline Validation

This guideline was reviewed and endorsed by the Alberta Provincial Breast Tumour Team.

When the draft guideline document is completed, revised, and reviewed by the Knowledge Management Specialist and the working group members, it is sent to all members of the Provincial Tumour Team for review and comment. The working group members then make final revisions to the document based on the received feedback, as appropriate. Once the guideline is finalized, it is officially endorsed by the Provincial Tumour Team Lead and the Executive Director of Provincial Tumour Programs.

Evidence Supporting the Recommendations

References Supporting the Recommendations

Edge SB, Byrd DR, Compton CC, Fritz AG, Greene FL, Trotti A, editor(s). AJCC cancer staging manual. 7th ed. New York (NY): Springer; 2010.

Type of Evidence Supporting the Recommendations

The type of evidence supporting the recommendations is not specifically stated.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Appropriate staging investigations in patients with newly diagnosed breast cancer can aid in expediting care at the tertiary and associate cancer

centres.

Potential Harms

False-positive results of staging investigations

Qualifying Statements

Qualifying Statements

The recommendations contained in this guideline are a consensus of the Alberta Provincial Breast Tumour Team and represent a synthesis of currently accepted approaches to management, derived from a review of relevant scientific literature. Clinicians applying these guidelines should, in consultation with the patient, use independent medical judgment in the context of individual clinical circumstances to direct care.

Implementation of the Guideline

Description of Implementation Strategy

- Present the guideline at the local and provincial tumour team meetings and weekly rounds.
- Post the guideline on the Alberta Health Services website.
- Send an electronic notification of the new guideline to all members of Alberta Health Services, Cancer Care.

Implementation Tools

Clinical Algorithm

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

Getting Better

Living with Illness

IOM Domain

Effectiveness

Identifying Information and Availability

Bibliographic Source(s)

Alberta Provincial Breast Tumour Team. Staging investigations for asymptomatic and newly diagnosed breast cancer. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2012 Jul. 17 p. (Clinical practice guideline; no. BR-012). [30 references]

Adaptation

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

Date Released

2012 Jul

Guideline Developer(s)

CancerControl Alberta - State/Local Government Agency [Non-U.S.]

Source(s) of Funding

Alberta Health Services, Cancer Care

Guideline Committee

Alberta Provincial Breast Tumour Team

Composition of Group That Authored the Guideline

Not stated

Financial Disclosures/Conflicts of Interest

Participation of members of the Alberta Provincial Breast Tumour Team in the development of this guideline has been voluntary and the authors have not been remunerated for their contributions. There was no direct industry involvement in the development or dissemination of this guideline. Alberta Health Services, Cancer Care recognizes that although industry support of research, education and other areas is necessary in order to advance patient care, such support may lead to potential conflicts of interest. Some members of the Alberta Provincial Breast Tumour Team are involved in research funded by industry or have other such potential conflicts of interest. However the developers of this guideline are satisfied it was developed in an unbiased manner.

Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Availability of Companion Documents

The following is available:

- Guideline utilization resource unit handbook. Edmonton (Alberta): Alberta Health Services, Cancer Care; 2011 Dec. 5 p. Electronic copies: Available in Portable Document Format (PDF) from the Alberta Health Services Web site .

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on December 6, 2012. The information was verified by the guideline developer on January 14, 2013.

Copyright Statement

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