VOLUME 35 · NUMBER 5 · FEBRUARY 10, 2017

JOURNAL OF CLINICAL ONCOLOGY

ASCO SPECIAL ARTICLE

Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update

Gary H. Lyman, Mark R. Somerfield, Linda D. Bosserman, Cheryl L. Perkins, Donald L. Weaver, and Armando E. Giuliano

Author affiliations and support information (if applicable) appear at the end of this article.

Published at ascopubs.org/journal/jco on December 12, 2016.

Clinical Practice Guideline Committee approved: October 13, 2016.

Editor's note: This American Society of Clinical Oncology (ASCO) Clinical Practice Guideline Update 2016 reaffirms and summarizes the recommendations that were previously published in 2014; the 2014 recommendations remain current as of September 2016. Additional information, including a Data Supplement, a Methodology Supplement, slide sets, clinical tools and resources, and links to patient information at www.cancer.net, is available at www.asco.org/breast-sentinel-node-biopsy-guideline and www.asco.org/guidelineswiki.

Reprint requests: 2318 Mill Rd, Suite 800, Alexandria, VA 22314; e-mail: guidelines@asco.org

Corresponding author: Mark R. Somerfield, PhD, American Society of Clinical Oncology, 2318 Mill Rd, Suite 800, Alexandria, VA 22314; e-mail: guidelines@asco.org.

0732-183X/17/3505w-561w/$20.00

ABSTRACT

Purpose
To provide current recommendations on the use of sentinel node biopsy (SNB) for patients with early-stage breast cancer.

Methods
PubMed and the Cochrane Library were searched for randomized controlled trials, systematic reviews, meta-analyses, and clinical practice guidelines from 2012 through July 2016. An Update Panel reviewed the identified abstracts.

Results
Of the eight publications identified and reviewed, none prompted a change in the 2014 recommendations, which are reaffirmed by the updated literature review.

Conclusion
Women without sentinel lymph node (SLN) metastases should not receive axillary lymph node dissection (ALND). Women with one to two metastatic SLNs who are planning to undergo breast-conserving surgery with whole-breast radiotherapy should not undergo ALND (in most cases). Women with SLN metastases who will undergo mastectomy should be offered ALND. These three recommendations are based on randomized controlled trials. Women with operable breast cancer and multicentric tumors, with ductal carcinoma in situ, who will undergo mastectomy, who previously underwent breast and/or axillary surgery, or who received preoperative/neoadjuvant systemic therapy may be offered SNB. Women who have large or locally advanced invasive breast cancer (tumor size T3/T4), inflammatory breast cancer, or ductal carcinoma in situ (when breast-conserving surgery is planned) or are pregnant should not undergo SNB.

J Clin Oncol 35:561-564. © 2016 by American Society of Clinical Oncology

INTRODUCTION

The goal of this 2016 guideline update is to provide oncologists and other clinicians with current recommendations regarding the use of sentinel node biopsy (SNB) for patients with early-stage breast cancer. ASCO first published an evidence-based clinical practice guideline in 2005, with an updated guideline published in 2014.[1] The current update assesses whether the 2014 recommendations remain valid. For a complete list of previous recommendations, visit www.asco.org/breast-sentinel-node-biopsy-guideline or see Data Supplement 1.

METHODS

Guideline Update Process

PubMed and the Cochrane Library were searched for randomized controlled trials, systematic reviews, meta-analyses, and clinical practice guidelines for the period from 2012 through July 2016. The disease and intervention search terms were those used for the 2014 guideline update. An Expert Panel (Appendix Table A1, online only), formed in accordance with ASCO's Conflict of Interest Management Procedures for Clinical Practice

ASSOCIATED CONTENT

Appendix
DOI: 10.1200/JCO.2016.71.0947

Data Supplement
DOI: 10.1200/JCO.2016.71.0947

DOI: 10.1200/JCO.2016.71.0947

THE BOTTOM LINE

Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update

Guideline Questions

How should the results of sentinel node biopsy (SNB) be used in clinical practice? What is the role of SNB in special circumstances in clinical practice? What are the potential benefits and harms associated with SNB?

Target Population

Medical oncologists, radiation oncologists, pathologists, surgeons, oncology nurses, patients/caregivers, and guideline implementers.

Target Audience

Medical oncologists, surgical oncologists, hospitalists, oncology nurses, patients, and other relevant oncologic professionals.

Methods

An Expert Panel was convened to determine whether previous recommendations remain valid, based on an updated review of evidence from the medical literature.

Recommendations

Recommendation 1. Clinicians should not recommend axillary lymph node dissection (ALND) for women with early-stage breast cancer who do not have nodal metastases (Type: evidence based; benefits outweigh harms. Evidence quality: high. Strength of recommendation: strong).

Recommendation 2.1. Clinicians should not recommend ALND for women with early-stage breast cancer who have one or two sentinel lymph node metastases and will receive breast-conserving surgery with conventionally fractionated whole-breast radiotherapy (Type: evidence based; benefits outweigh harms. Evidence quality: high. Strength of recommendation: strong).

Recommendation 2.2. Clinicians may offer ALND for women with early-stage breast cancer with nodal metastases found in SNB specimens who will receive mastectomy (Type: evidence based; benefits outweigh harms. Evidence quality: low. Strength of recommendation: weak).

Recommendation 3. Clinicians may offer SNB for women who have operable breast cancer who have the following circumstances:

3.1. Multicentric tumors (Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: moderate).
3.2. Ductal carcinoma in situ when mastectomy is performed. (Type: informal consensus; benefits outweigh harms. Evidence quality: insufficient. Strength of recommendation: weak).
3.3. Prior breast and/or axillary surgery (Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: strong).
3.4. Preoperative/neoadjuvant systemic therapy (Type: evidence based; benefits outweigh harms. Evidence quality: intermediate. Strength of recommendation: moderate).

Recommendation 4. There are insufficient data to change the 2005 recommendation that clinicians should not perform SNB for women who have early-stage breast cancer and are in the following circumstances:

4.1. Large or locally advanced invasive breast cancers (tumor size T3/T4) (Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak).
4.2. Inflammatory breast cancer (Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak).
4.3. Ductal carcinoma in situ when breast-conserving surgery is planned (Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: strong).
4.4. Pregnancy (Type: informal consensus. Evidence quality: insufficient. Strength of recommendation: weak).

(continued on following page)

THE BOTTOM LINE (CONTINUED)

Additional Resources

More information, including a Data Supplement with additional evidence tables, a Methodology Supplement with information about evidence quality and strength of recommendations, slide sets, and clinical tools and resources, is available at www.asco.org/breast-sentinel-node-biopsy-guideline and www.asco.org/guidelineswiki. Patient information is available at www.cancer.net.

ASCO believes that cancer clinical trials are vital to inform medical decisions and improve cancer care, and that all patients should have the opportunity to participate.

Guidelines, reviewed the identified abstracts for predefined signals that would suggest the need to change a previous recommendation. Additional information about the results of the updated literature search (Data Supplement 2) and 2016 search strategy string and results (Data Supplement 3), as well as a discussion of ASCO's signals approach to guideline updating, are available at www.asco.org/breast-sentinel-node-biopsy-guideline in the 2016 Data Supplement and 2016 Methodology Supplement, respectively. A Quorum diagram of the updated search and the clinical questions are provided in Data Supplement 4 and Data Supplement 5, respectively.

Guideline Disclaimer

The clinical practice guidelines and other guidance published herein are provided by the American Society of Clinical Oncology (ASCO) to assist providers in clinical decision-making. The information herein should not be relied upon as being complete or accurate, nor should it be considered as inclusive of all proper treatments or methods of care or as a statement of the standard of care. With the rapid development of scientific knowledge, new evidence may emerge between the time information is developed and when it is published or read. The information is not continually updated and may not reflect the most recent evidence. The information addresses only the topics specifically identified therein and is not applicable to other interventions, diseases, or stages of diseases. This information does not mandate any particular course of medical care. Further, the information is not intended to substitute for the independent professional judgment of the treating provider, as the information does not account for individual variation among patients. Recommendations reflect high, moderate, or low confidence that the recommendation reflects the net effect of a given course of action. The use of words like "must," "must not," "should," and "should not" indicates that a course of action is recommended or not recommended for either most or many patients, but there is latitude for the treating physician to select other courses of action in individual cases. In all cases, the selected course of action should be considered by the treating provider in the context of treating the individual patient. Use of the information is voluntary. ASCO provides this information on an as is basis and makes no warranty, express or implied, regarding the information. ASCO specifically disclaims any warranties of merchantability or fitness for a particular use or purpose. ASCO assumes no responsibility for any injury or damage to persons or property arising out of or related to any use of this information, or for any errors or omissions.

This is the most recent information as of the publication date. For the most recent information, and to submit new evidence, please visit www.asco.org/breast-sentinel-biopsy-guideline and the ASCO Guidelines Wiki (www.asco.org/guidelineswiki).

Guideline and Conflicts of Interest

The Expert Panel was assembled in accordance with ASCO's Conflict of Interest Policy Implementation for Clinical Practice Guidelines ("Policy," found at http://www.asco.org/rwc). All members of the Expert Panel completed ASCO's disclosure form, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline. Categories for disclosure include employment; leadership; stock or other ownership; honoraria, consulting or advisory role; speaker's bureau; research funding; patents, royalties, other intellectual property; expert testimony; travel, accommodations, expenses; and other relationships. In accordance with the Policy, the majority of the members of the Expert Panel did not disclose any relationships constituting a conflict under the Policy.

RESULTS

The search yielded 184 publications. After careful review of the identified publications, eight full-text articles were selected for review by the Expert Panel. The Expert Panel concluded that there were no results that change the 2014 guideline recommendations. A bibliography of the results of the updated literature search is provided in Data Supplement 2.

RECOMMENDATIONS

The 2016 recommendations are listed in the Bottom Line Box. These recommendations are consistent with the previous (2014) recommendations. Similar to the 2014 recommendations, the Update Committee advises that axillary lymph node dissection can be avoided in patients with one or two positive sentinel nodes only when conventionally fractionated whole-breast radiation therapy is planned. Clinicians should also consider this recommendation with caution in patients with large primary tumors ($>$ 5 cm), those with large or bulky metastatic axillary sentinel lymph nodes, and/or those with gross extranodal extension of the tumor.

ADDITIONAL RESOURCES

More information, including Data and Methodology Supplements, slide sets, and clinical tools and resources, is available at www.asco.org/breast-sentinel-node-biopsy-guideline. Patient information is available at www.cancer.net. Visit www.asco.org/guidelineswiki to provide comments on the guideline or to submit new evidence.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Disclosures provided by the authors are available with this article at ascopubs.org/journal/jco.

AUTHOR CONTRIBUTIONS

Administrative support: Mark R. Somerfield
Manuscript writing: All authors
Final approval of manuscript: All authors

REFERENCES

1. Lyman GH, Temin S, Edge SB, et al: Sentinel lymph node biopsy for patients with early-stage breast cancer: American Society of Clinical Oncology clinical practice guideline update. J Clin Oncol 32:1365-1383, 2014

Affiliations

Gary H. Lyman, Fred Hutchinson Cancer Research Center and University of Washington, Seattle, WA; **Mark R. Somerfield**, American Society of Clinical Oncology, Alexandria, VA; **Linda D. Bosserman**, City of Hope, Duarte, CA; **Cheryl L. Perkins**, Dallas, TX; **Donald L. Weaver**, University of Vermont and Vermont Cancer Center, Burlington, VT; and **Armando E. Giuliano**, Cedars-Sinai Medical Center, Los Angeles, CA.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Sentinel Lymph Node Biopsy for Patients With Early-Stage Breast Cancer: American Society of Clinical Oncology Clinical Practice Guideline Update

The following represents disclosure information provided by authors of this manuscript. All relationships are considered compensated. Relationships are self-held unless noted. I = Immediate Family Member, Inst = My Institution. Relationships may not relate to the subject matter of this manuscript. For more information about ASCO's conflict of interest policy, please refer to www.asco.org/rwc or ascopubs.org/jco/site/ifc.

Gary H. Lyman
Consulting or Advisory Role: Halozyme, G1 Therapeutics
Research Funding: Amgen (Inst)

Mark R. Somerfield
No relationship to disclose

Linda D. Bosserman
Employment: City of Hope Medical Foundation, Front Line Medical Communications
Leadership: Anthem Blue Cross Wellpoint
Honoraria: Pfizer, Association of Managed Care Pharmacy, American Society of Breast Surgeons, Association of Nurse Navigators, Medscape, Physicians Education Resource, Merck & Co
Consulting or Advisory Role: Pfizer, Association of Community Cancer Centers, Novartis, Sandoz-Novartis, Merck & Co

Cheryl L. Perkins
No relationship to disclose

Donald L. Weaver
Patents, Royalties, Other Intellectual Property: I receive a royalty payment from UpToDate as an author for topic cards (electronic chapters) related to sentinel node biopsy in breast cancer

Armando E. Giuliano
No relationship to disclose

Acknowledgment

We thank the ASCO Clinical Practice Guidelines Committee leadership—Neelima Denduluri, Alok Khorana, Manish Shah, and Jaap Verweij—for their thoughtful reviews and insightful comments on this guideline document.

Appendix

Table A1. Clinical Practice Guideline Update 2016: Expert Panel Membership

Name	Location
Armando E. Giuliano, MD, co-chair	Cedars-Sinai Medical Center, Los Angeles, CA
Gary H. Lyman, MD, MPH, co-chair	Fred Hutchinson Cancer Research Center and University of Washington, Seattle, WA
Linda D. Bosserman, MD	City of Hope, Duarte, CA
Cheryl L. Perkins, MD (patient representative)	Dallas, TX
Donald L. Weaver, MD	University of Vermont College of Medicine and Cancer Center, Burlington, VT

ASCO staff: Mark R. Somerfield, PhD.