

Breast Cancer[®]

U P D A T E

An Audio Review Journal for Surgeons
Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Kathy D Miller, MD

Eleftherios P Mamounas, MD, MPH

Sara A Hurvitz, MD

Stephen B Edge, MD

EDITOR

Neil Love, MD

CONTENTS

2 Audio CDs

This activity provides Category 1 CME that may be used as self-assessment credit toward Part 2 of the American Board of Surgery MOC Program.



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Breast Cancer Update for Surgeons

A Continuing Medical Education Audio Series

OVERVIEW OF ACTIVITY

Historically, surgery has been the primary mode of treatment for early breast cancer. The diagnostic, surgical and medical management of breast cancer, however, have escalated in complexity because of numerous advances in novel technologies and available adjunctive therapies. Hence, the multifaceted treatment of breast cancer now requires the input of an interdisciplinary group of expert care providers. This paradigm shift has created the challenge of ensuring that knowledge of major clinical advances in local and systemic breast cancer therapy is effectively disseminated among all members of the cross-functional team. To bridge the gap between research and patient care, *Breast Cancer Update for Surgeons* uses one-on-one interviews with leading breast cancer investigators to efficiently distill the latest research developments so they may be incorporated into clinical practice as appropriate. By providing access to cutting-edge data and expert perspectives, this CME program assists breast surgeons in the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Recognize the evolving application of biomarkers and multigene assays in breast cancer management, and effectively use these tools to refine or individualize treatment plans for patients.
- Develop an evidence-based approach to the management of the axilla in patients with localized breast cancer and a positive sentinel lymph node biopsy.
- Recognize the recent FDA approval of neoadjuvant pertuzumab, and consider this therapeutic approach when evaluating appropriate patients with HER2-positive early breast cancer.
- Describe the importance of adequate surgical margins in mitigating local recurrence risk for women with early-stage invasive breast cancer treated with breast-conserving surgery.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials.

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FACULTY INTERVIEWS



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5 SELECT PUBLICATIONS

6 POST-TEST

7 EDUCATIONAL ASSESSMENT AND CREDIT FORM

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EDITOR



Neil Love, MD
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CONTENT VALIDATION AND DISCLOSURES

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FACULTY — **Dr Edge** had no real or apparent conflicts of interest to disclose. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Miller** — Contracted Research: Astellas, Genentech BioOncology, Roche Laboratories Inc. **Dr Mamounas** — Advisory Committee and Consulting Agreements: Celgene Corporation, Eisai Inc, Genomic Health Inc, GlaxoSmithKline, Pfizer Inc; Speakers Bureau: Genentech BioOncology, Genomic Health Inc. **Dr Hurvitz** — Contracted Research: Amgen Inc, Bayer HealthCare Pharmaceuticals, Boehringer Ingelheim Pharmaceuticals Inc, Eisai Inc, Genentech BioOncology, GlaxoSmithKline, Novartis Pharmaceuticals Corporation, Pfizer Inc, Roche Laboratories Inc, Sanofi; **Paid Travel:** Boehringer Ingelheim Pharmaceuticals Inc, Genentech BioOncology, Novartis Pharmaceuticals Corporation.

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Tracks 1-14

- Track 1** Results from the Phase III CALOR (IBCSG 27-02, NSABP-B-37, BIG 1-02) trial: Adjuvant chemotherapy prolongs survival for patients with isolated local or regional recurrence of breast cancer (BC)
- Track 2** Use of the *Oncotype DX*® assay for patients with locoregional recurrence of BC
- Track 3** Comparison of risk classification with *Oncotype DX* and other genomic assays
- Track 4** Major ongoing clinical trials evaluating the *Oncotype DX* and MammaPrint® assays
- Track 5** Use of *Oncotype DX* to guide adjuvant chemotherapy decision-making for patients with small tumors or limited nodal involvement
- Track 6** **Case discussion:** A 26-year-old woman who previously received anthracycline-based therapy for Ewing sarcoma presents with ER-positive, PR-negative, HER2-positive poorly differentiated invasive ductal carcinoma
- Track 7** Mechanism of action and tolerability of T-DM1
- Track 8** NSABP-B-50-I: A Phase III trial of T-DM1 versus trastuzumab for women with HER2-positive BC who have residual tumor present after neoadjuvant therapy
- Track 9** Pathologic complete response to trastuzumab/lapatinib with endocrine therapy on the Phase II TBCRC 023 trial
- Track 10** Mechanism of action of pertuzumab and overview of FDA indications for its use in the metastatic and neoadjuvant settings
- Track 11** Perspective on the NCCN guidelines for the use of (neo)adjuvant pertuzumab
- Track 12** Results of a Phase II study of adjuvant paclitaxel and trastuzumab for node-negative, HER2-positive BC
- Track 13** Perspective on the results of a meta-analysis of the effects of bisphosphonates on recurrence and cause-specific mortality in women with early BC
- Track 14** Breast Cancer Research Foundation project on the effects of BC therapy on physical fitness

Tracks 1-11

- Track 1** **Case discussion:** A 52-year-old woman with a family history of BC presents with a 2.5-cm, ER/PR-positive, HER2-negative invasive lobular carcinoma with 2 of 3 positive sentinel lymph nodes and undergoes bilateral skin-sparing mastectomy
- Track 2** Status of the ongoing Phase III TAILORx and RxPONDER trials evaluating the use of adjuvant therapy based on *Oncotype DX* Recurrence Score®
- Track 3** Local versus systemic therapeutic approaches for invasive lobular carcinoma
- Track 4** Use of the *Oncotype DX* assay for patients with invasive lobular carcinoma
- Track 5** An ongoing pilot study of choosing neoadjuvant chemotherapy versus hormonal therapy based on the *Oncotype DX* assay Recurrence Score
- Track 6** Consensus guidelines on margins for breast-conserving surgery with whole-breast irradiation in Stages I and II invasive BC
- Track 7** **Case discussion:** A 13-year-old girl with significant enlargement of the right breast for which ultrasound-guided core needle biopsy indicates pseudoangiomatous stromal hyperplasia
- Track 8** **Case discussion:** A 23-year-old woman with a stable, well-defined nodule in her right breast that grows into an 18-cm phyllodes mass after she becomes pregnant
- Track 9** Recurrence Score and quantitative ER expression for assessing the risk of late distant recurrence in patients with ER-positive BC after 5 years of tamoxifen

Dr Mamounas (continued)

Tracks 1-11

Track 10 NSABP-B-43: An ongoing Phase III study evaluating concurrent trastuzumab and radiation therapy (RT) versus RT alone for patients with HER2-positive ductal

carcinoma in situ (DCIS) resected by lumpectomy

Track 11 Perspective on the clinical implications of the CALOR trial results

Sara A Hurvitz, MD

Tracks 1-8

Track 1 **Case discussion:** A 38-year-old woman with a 2.3-cm, strongly ER/PR-positive, node-negative BC for which HER2 status is difficult to assess

Track 5 Patient-reported endocrine symptoms, sexual functioning and quality of life analyses on the IBCSG TEXT and SOFT trials

Track 2 Results of the Intergroup SWOG-S0230/POEMS (Prevention Of Early Menopause Study) of LHRH analog during chemotherapy to reduce ovarian failure in early-stage, hormone receptor-negative BC

Track 6 Use of aromatase inhibitors versus tamoxifen for postmenopausal women with DCIS

Track 3 Duration of endocrine therapy for younger patients who wish to become pregnant after treatment

Track 7 Does primary tumor resection improve survival for patients with metastatic BC?

Track 4 Results of a joint analysis of the IBCSG TEXT and SOFT trials: Adjuvant exemestane with ovarian function suppression versus tamoxifen with ovarian function suppression for premenopausal women with ER-positive early BC

Track 8 **Case discussion:** A 34-year-old woman with ER/PR-negative, HER2-positive inflammatory BC achieves a pathologic complete response with neoadjuvant docetaxel/carboplatin/trastuzumab/pertuzumab

Stephen B Edge, MD

Tracks 1-11

Track 1 **Case discussion:** A 45-year-old woman who previously underwent RT for Hodgkin lymphoma (HL) presents with a 2-mm focus of low- to intermediate-grade DCIS

Track 6 Viewpoint on the quality of surgical care in BC

Track 2 Increased BC risk for female survivors of HL treated with RT

Track 7 Surgical margins and local recurrence in women with early-stage invasive BC treated with breast-conserving surgery

Track 3 **Case discussion:** A 58-year-old woman with a 3-cm, ER-positive, HER2-negative de novo metastatic BC undergoes bilateral mastectomy

Track 8 Viewpoint on SSO/ASTRO consensus guidelines on margins for breast-conserving surgery

Track 4 Perspective on the results of 2 randomized Phase III trials evaluating primary tumor resection for patients with metastatic BC

Track 9 Use of the *Oncotype* DX Recurrence Score to identify patients who will not benefit from chemotherapy

Track 5 **Case discussion:** A 50-year-old woman with a family history of BC and a T1cNOMO tumor undergoes mastectomy and sentinel lymph node biopsy

Track 10 Importance of communication among the members of a multidisciplinary team in providing quality care

Track 11 Implementation of tools and opportunities for quality improvement in the treatment of BC

SELECT PUBLICATIONS

A phase III clinical trial comparing trastuzumab given concurrently with radiation therapy and radiation therapy alone for women with HER2-positive ductal carcinoma in situ resected by lumpectomy. [NCT00769379](#)

Aebi S et al. **Chemotherapy for isolated locoregional recurrence of breast cancer (CALOR): A randomised trial.** *Lancet Oncol* 2014;15(2):156-63.

Aebi S et al. **Chemotherapy prolongs survival for isolated local or regional recurrence of breast cancer: The CALOR trial (Chemotherapy as Adjuvant for Locally Recurrent Breast Cancer; IBCSG 27-02, NSABP B-37, BIG 1-02).** San Antonio Breast Cancer Symposium 2012;**Abstract S3-2.**

Badwe R et al. **Surgical removal of primary tumor and axillary lymph nodes in women with metastatic breast cancer at first presentation: A randomized controlled trial.** San Antonio Breast Cancer Symposium 2013;**Abstract S2-02.**

Bernhard J et al. **Patient-reported endocrine symptoms, sexual functioning, and quality of life (QoL) in the IBCSG TEXT and SOFT trials: Adjuvant treatment with exemestane (E) plus ovarian function suppression (OFS) versus tamoxifen (T) plus OFS in premenopausal women with hormone receptor-positive (HR+) early breast cancer (BC).** *Proc ASCO* 2014;**Abstract 557.**

Choosing neoadjuvant chemotherapy versus hormonal therapy for breast cancer based on gene expression profile. [NCT01293032](#)

Cobleigh M et al. **NSABP B-43: A phase III clinical trial to compare trastuzumab (T) given concurrently with radiation therapy (RT) to RT alone for women with HER2+ DCIS resected by lumpectomy (Lx).** *Proc ASCO* 2013;**Abstract TPS666.**

DeBruin ML et al. **Breast cancer risk in female survivors of Hodgkin's lymphoma: Lower risk after smaller radiation volumes.** *J Clin Oncol* 2009;27(26):4239-46.

Dunne C et al. **Effect of margin status on local recurrence after breast conservation and radiation therapy for ductal carcinoma in situ.** *J Clin Oncol* 2009;27(10):1615-20.

Edge SB. **The NCCN Guidelines Program and opportunities for quality improvement.** *J Natl Compr Canc Netw* 2014;12(Suppl 1):1-4.

Edge SB. **Using the American College of Surgeons cancer registry to drive quality.** *J Oncol Pract* 2013;9(3):149-51.

Hormone therapy or chemotherapy before surgery based on gene expression analysis in treating patients with breast cancer. [NCT01293032](#)

Moore HCF et al. **Phase III trial (Prevention of Early Menopause Study [POEMS]-SWOG S0230) of LHRH analog during chemotherapy (CT) to reduce ovarian failure in early-stage, hormone receptor-negative breast cancer: An international Intergroup trial of SWOG, IBCSG, ECOG, and CALGB (Alliance).** *Proc ASCO* 2014;**Abstract LBA505.**

Moran MS et al. **Society of Surgical Oncology-American Society for Radiation Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in stages I and II invasive breast cancer.** *J Clin Oncol* 2014;32(14):1507-15.

Pagani O et al. **Randomized comparison of adjuvant aromatase inhibitor (AI) exemestane (E) plus ovarian function suppression (OFS) vs tamoxifen (T) plus OFS in premenopausal women with hormone receptor-positive (HR+) early breast cancer (BC): Joint analysis of IBCSG TEXT and SOFT trials.** *Proc ASCO* 2014;**Abstract LBA1.**

Pagani O et al; International Breast Cancer Study Group. **Adjuvant exemestane with ovarian suppression in premenopausal breast cancer.** *N Engl J Med* 2014;371(2):107-18.

Soran A et al. **Early follow up of a randomized trial evaluating resection of the primary breast tumor in women presenting with de novo stage IV breast cancer; Turkish study (protocol MF07-01).** San Antonio Breast Cancer Symposium 2013;**Abstract S2-03.**

TBCRC 023: A randomized multicenter phase II neoadjuvant trial of lapatinib, trastuzumab, with or without endocrine therapy for 12 weeks vs 24 weeks in patients with HER2 overexpressing breast cancer. [NCT00999804](#)

Vaz Duarte Luis IM et al. **Time trends in the use of adjuvant chemotherapy (CTX) and outcomes in women with T1N0 breast cancer (BC) in the National Comprehensive Cancer Network (NCCN).** *Proc ASCO* 2013;**Abstract 1006.**

Wolmark N et al. **Recurrence score and quantitative ER expression to predict in late distant recurrence risk in ER+ BC after 5 years of tamoxifen.** *Proc ASCO* 2014;**Abstract 11024.**

QUESTIONS (PLEASE CIRCLE ANSWER):

1. The Phase III CALOR trial comparing adjuvant chemotherapy to no adjuvant chemotherapy for isolated local or regional recurrence of BC demonstrated a significant improvement in 5-year disease-free and overall survival for patients who received chemotherapy.
 - a. True
 - b. False
2. The ongoing Phase III NSABP-B-50-1 trial is evaluating _____ versus trastuzumab as adjuvant therapy for patients with HER2-positive primary BC who have residual tumor pathologically present in the breast or axillary lymph nodes after preoperative therapy.
 - a. Lapatinib
 - b. Pertuzumab
 - c. T-DM1
 - d. All of the above
3. The Phase III RxPONDER study randomly assigns patients with node-negative, ER-positive, HER2-negative BC and Oncotype DX Recurrence Scores of 25 or higher to adjuvant endocrine therapy with or without chemotherapy.
 - a. True
 - b. False
4. The Phase II TBCRC 023 trial is evaluating the combination of _____ with or without endocrine therapy as neoadjuvant therapy for patients with HER2-positive BC.
 - a. Lapatinib and trastuzumab
 - b. Pertuzumab and trastuzumab
 - c. T-DM1 and trastuzumab
 - d. All of the above
5. The SSO-ASTRO Consensus Guideline on Margins for Breast-Conserving Surgery with Whole-Breast Irradiation in Stage I and II Invasive Breast Cancer states that wider margins result in significantly better local control.
 - a. True
 - b. False
6. Results of the Intergroup SWOG-S0230/POEMS (Prevention Of Early Menopause Study) of LHRH analog during chemotherapy for early-stage, hormone receptor-negative BC demonstrated _____ with the addition of goserelin to chemotherapy.
 - a. Improvement in preservation of ovarian function
 - b. Improvement in fertility
 - c. Improvement in disease-free survival
 - d. All of the above
7. Two randomized Phase III trials evaluating primary tumor resection for patients with metastatic BC reported a significant benefit in overall survival with locoregional therapy.
 - a. True
 - b. False
8. The ongoing Phase III TAILORx trial randomly assigned women who had undergone surgery for node-negative BC to hormonal therapy with or without chemotherapy based on the Oncotype DX Recurrence Score.
 - a. True
 - b. False
9. The ongoing Phase III NSABP-B-43 study is evaluating concurrent _____ and RT versus RT alone for patients with HER2-positive DCIS resected by lumpectomy.
 - a. Pertuzumab
 - b. Trastuzumab
 - c. T-DM1
10. Results of a joint analysis of the IBCSG TEXT and SOFT trials presented at ASCO 2014 evaluating adjuvant therapy with exemestane and ovarian function suppression versus tamoxifen and ovarian function suppression for premenopausal women with hormone receptor-positive early BC _____ a significantly reduced risk of recurrence with exemestane and ovarian function suppression.
 - a. Demonstrated
 - b. Did not demonstrate

Research To Practice is committed to providing valuable continuing education for oncology clinicians, and your input is critical to helping us achieve this important goal. Please take the time to assess the activity you just completed, with the assurance that your answers and suggestions are strictly confidential.

PART 1 — Please tell us about your experience with this educational activity

How would you characterize your level of knowledge on the following topics?

4 = Excellent 3 = Good 2 = Adequate 1 = Suboptimal

	BEFORE	AFTER
Results from the CALOR (IBCSG 27-02, NSABP-B-37, BIG 1-02) trial: Adjuvant chemotherapy prolongs survival for patients with isolated local or regional recurrence of BC	4 3 2 1	4 3 2 1
Consensus guidelines on margins for breast-conserving surgery with whole-breast irradiation for Stages I and II invasive BC	4 3 2 1	4 3 2 1
Recent FDA approval of neoadjuvant pertuzumab for patients with HER2-positive BC	4 3 2 1	4 3 2 1
Recurrence Score and quantitative ER expression for assessing the risk of late distant recurrence in patients with ER-positive BC after 5 years of tamoxifen	4 3 2 1	4 3 2 1
NSABP-B-50-I: An ongoing Phase III trial of T-DM1 versus trastuzumab as adjuvant therapy for HER2-positive primary BC	4 3 2 1	4 3 2 1
Results of 2 recently presented trials evaluating primary tumor resection for patients with metastatic BC	4 3 2 1	4 3 2 1

Practice Setting:

- Academic center/medical school Community cancer center/hospital Group practice
 Solo practice Government (eg, VA) Other (please specify).....

Approximately how many new patients with breast cancer do you see per year? patients

Was the activity evidence based, fair, balanced and free from commercial bias?

- Yes No

If no, please explain:

Please identify how you will change your practice as a result of completing this activity (select all that apply).

- This activity validated my current practice
 Create/revise protocols, policies and/or procedures
 Change the management and/or treatment of my patients
 Other (please explain):

If you intend to implement any changes in your practice, please provide 1 or more examples:

The content of this activity matched my current (or potential) scope of practice.

- Yes No

If no, please explain:

Please respond to the following learning objectives (LOs) by circling the appropriate selection:

4 = Yes 3 = Will consider 2 = No 1 = Already doing N/M = LO not met N/A = Not applicable

As a result of this activity, I will be able to:

- Recognize the evolving application of biomarkers and multigene assays in breast cancer management, and effectively use these tools to refine or individualize treatment plans for patients 4 3 2 1 N/M N/A
- Develop an evidence-based approach to the management of the axilla in patients with localized breast cancer and a positive sentinel lymph node biopsy 4 3 2 1 N/M N/A
- Recognize the recent FDA approval of neoadjuvant pertuzumab, and consider this therapeutic approach when evaluating appropriate patients with HER2-positive early breast cancer. 4 3 2 1 N/M N/A
- Describe the importance of adequate surgical margins in mitigating local recurrence risk for women with early-stage invasive breast cancer treated with breast-conserving surgery. ... 4 3 2 1 N/M N/A
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials 4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

Please describe any clinical situations that you find difficult to manage or resolve that you would like to see addressed in future educational activities:

Would you recommend this activity to a colleague?

Yes No

If no, please explain:

Additional comments about this activity:

As part of our ongoing, continuous quality-improvement effort, we conduct postactivity follow-up surveys to assess the impact of our educational interventions on professional practice. Please indicate your willingness to participate in such a survey.

Yes, I am willing to participate in a follow-up survey.
 No, I am not willing to participate in a follow-up survey.

PART 2 — Please tell us about the faculty and editor for this educational activity

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal				
Faculty	Knowledge of subject matter				Effectiveness as an educator			
Kathy D Miller, MD	4	3	2	1	4	3	2	1
Eleftherios P Mamounas, MD, MPH	4	3	2	1	4	3	2	1
Sara A Hurvitz, MD	4	3	2	1	4	3	2	1
Stephen B Edge, MD	4	3	2	1	4	3	2	1
Editor	Knowledge of subject matter				Effectiveness as an educator			
Neil Love, MD	4	3	2	1	4	3	2	1

Please recommend additional faculty for future activities:

Other comments about the faculty and editor for this activity:

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Signature: Date:

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U P D A T E

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