

Breast Cancer[®]

U P D A T E

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

FACULTY INTERVIEWS

William J Gradishar, MD

Tari King, MD

Joseph A Sparano, MD

Seema A Khan, MD, MPH

EDITOR

Neil Love, MD

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 (BC). The diagnostic, surgical and medical management of BC, however, have escalated in complexity because of numerous advances in novel technologies and available adjunctive therapies. Hence, the multifaceted treatment of BC 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 BC 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 BC 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

- Develop an understanding of the histopathologic characteristics and responsiveness to chemotherapy of invasive lobular carcinomas.
- Appreciate the information provided by genomic platforms to assess risk and individualize therapy for patients with ductal carcinoma in situ and early BC.
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-positive and triple-negative early BC.
- Describe the importance of adequate surgical margins in mitigating local recurrence risk for women with ductal carcinoma in situ treated with breast-conserving surgery and whole-breast irradiation.
- Develop an evidence-based approach to the management of the axilla in patients with localized BC and a positive sentinel lymph node biopsy.
- Counsel appropriately selected patients with BC 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



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FACULTY — **Drs Gradishar, King** and **Khan** had no relevant conflicts of interest to disclose. The following faculty (and his spouse/partner) reported relevant conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Sparano** — **Advisory Committee:** AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals, Celgene Corporation, Genentech BioOncology, Merck, Novartis Pharmaceuticals Corporation, Pfizer Inc; **Consulting Agreements:** Celldex Therapeutics, Genentech BioOncology, Lilly; **Contracted Research:** Deciphera Pharmaceuticals LLC, Eisai Inc, Genentech BioOncology, MedImmune Inc, Merck, Novartis Pharmaceuticals Corporation, Prescient Therapeutics; **Ownership Interest:** MetaStat Inc.

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Interview with William J Gradishar, MD

Tracks 1-6

- Track 1 Case discussion:** A 37-year-old woman with a 3.5-cm, ER/PR-low, HER2-positive, clinically node-negative breast cancer (BC)
- Track 2 Case discussion:** A 58-year-old woman with T1cN1, ER-positive, HER2-negative BC and a 21-gene Recurrence Score® (RS) of 12
- Track 3** MINDACT trial: Utility of the 70-gene signature in selecting patients with BC and 0 to 3 positive nodes for adjuvant chemotherapy
- Track 4** Fertility issues in early BC
- Track 5** Targeting the androgen receptor in patients with triple-negative BC (TNBC)
- Track 6** Adjuvant bisphosphonates for early BC

Interview with Tari King, MD

Tracks 1-10

- Track 1 Case discussion:** A 42-year-old woman with strongly ER/PR-positive, HER2-negative, node-negative multifocal invasive ductal carcinoma (IDC) and a 21-gene RS of 19
- Track 2** Pathologic features and risks of developing BC for patients with lobular carcinoma in situ
- Track 3** Comprehensive molecular portrait of invasive lobular BC
- Track 4 Case discussion:** A 36-year-old woman with a 4-cm, triple-negative IDC who wishes to have breast-conserving surgery (BCS) receives neoadjuvant cisplatin on a clinical trial
- Track 5** Effect of ER and HER2 status on the use of neoadjuvant chemotherapy
- Track 6** Use of the 21-gene RS to guide neoadjuvant therapy decision-making
- Track 7 Case discussion:** A 50-year-old perimenopausal woman who presents with a small group of microcalcifications in the right breast undergoes stereotactic biopsy and is diagnosed with intermediate-grade ER-positive ductal carcinoma in situ (DCIS)
- Track 8** Benefits and limitations of the DCIS Score™
- Track 9** Consensus guidelines on margins for BCS with whole-breast irradiation in patients with DCIS
- Track 10** Complexities, challenges and advances in the treatment of DCIS

Interview with Joseph A Sparano, MD

Tracks 1-12

- Track 1** POSITIVE: An intergroup study evaluating pregnancy outcomes and safety of interrupting endocrine therapy for young women with endocrine-responsive BC who desire pregnancy
- Track 2** The DCIS Score as a tool for identifying risk of BC recurrence
- Track 3** Use of the DCIS Score to facilitate decision-making regarding radiation therapy
- Track 4 Case discussion:** A 56-year-old woman with Stage IIIB (T3N1M0) ER/PR-positive, HER2-positive IDC initially treated with neoadjuvant docetaxel/carboplatin/trastuzumab/pertuzumab

Interview with Dr Sparano (continued)

- Track 5** **Case discussion:** A 47-year-old premenopausal woman with Stage IIB (T2N1M0) ER/PR-positive, HER2-negative IDC and a 21-gene RS of 13 elects to receive endocrine therapy alone
- Track 6** TAILORx: Results of the low-risk registry of a prospective trial of adjuvant systemic therapy for patients with ER-positive, HER2-negative BC based on the 21-gene RS
- Track 7** Results of the Phase III West German Study Group PlanB trial: Effect of the 21-gene RS and concordance of prognostic markers in ER-positive, HER2-negative high-risk node-negative and node-positive BC
- Track 8** Critical evaluation of the MINDACT trial results
- Track 9** Perspective on the utility of the 70-gene signature in clinical practice
- Track 10** Results of a prospective registry of patients with early BC for whom treatment decisions in clinical practice were made incorporating the 21-gene RS
- Track 11** BC-specific survival in patients with ER-positive, node-negative invasive BC and 21-gene signature results in the SEER database
- Track 12** **Case discussion:** A 50-year-old postmenopausal woman with Stage IIA, ER/PR-positive, HER2-negative IDC

Interview with Seema A Khan, MD, MPH

Tracks 1-12

- Track 1** **Case discussion:** A 52-year-old postmenopausal woman with ER/PR-positive, HER2-negative, node-negative IDC and an RS of 12 undergoes BCS
- Track 2** Role of the 21-gene signature in neoadjuvant decision-making
- Track 3** **Case discussion:** A 43-year-old woman with triple-negative, BRCA-negative IDC who deferred treatment for 1 year
- Track 4** Adjuvant capecitabine in patients with HER2-negative BC and pathologic residual invasive disease after neoadjuvant chemotherapy
- Track 5** Viewpoint on performing sentinel lymph node biopsy (SLNB) prior to the administration of neoadjuvant chemotherapy
- Track 6** SLNB after neoadjuvant chemotherapy in patients with node-negative versus node-positive BC
- Track 7** Approach to BRCA mutation testing in patients with TNBC
- Track 8** **Second opinion:** Surgical resection of an intact primary tumor in a 49-year-old woman with ER/PR-negative, HER2-positive metastatic BC after complete response of a solitary liver metastasis to paclitaxel/trastuzumab/pertuzumab
- Track 9** Status of ECOG-E2108: A Phase III trial evaluating early surgery versus standard palliative therapy in treating Stage IV BC
- Track 10** **Second opinion:** A 41-year-old woman with ER/PR-positive, HER2-negative, clinically node-negative BC: Distinction between locally advanced and inflammatory disease
- Track 11** **Second opinion:** Role of SLNB in the setting of recurrent BC
- Track 12** 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 BC

SELECT PUBLICATIONS

A randomized phase III trial of the value of early local therapy for the intact primary tumor in patients with metastatic breast cancer. NCT01242800

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

ALternate approaches for clinical stage II or III Estrogen Receptor positive breast cancer NeoAdjuvant TrEatment (ALTERNATE) in postmenopausal women: A Phase III study (A011106). NCT01953588

Badwe R et al. **Locoregional treatment versus no treatment of the primary tumour in metastatic breast cancer: An open-label randomised controlled trial.** *Lancet Oncol* 2015;16(13):1380-8.

Boughey JC et al. **Sentinel lymph node surgery after neoadjuvant chemotherapy in patients with node-positive breast cancer: The ACOSOG Z1071 (Alliance) clinical trial.** *JAMA* 2013;310(14):1455-61.

Cardoso F et al. **70-gene signature as an aid to treatment decisions in early-stage breast cancer.** *N Engl J Med* 2016;375(8):717-29.

Ciriello G et al. **Comprehensive molecular portraits of invasive lobular breast cancer.** *Cell* 2015;163(2):506-19.

Early Breast Cancer Trialists' Collaborative Group (EBCTCG). **Adjuvant bisphosphonate treatment in early breast cancer: Meta-analyses of individual patient data from randomised trials.** *Lancet* 2015;386(10001):1353-61.

Gluz O et al. **Prospective WSG Phase III PlanB trial: Clinical outcome at 5-year follow up and impact of 21 gene Recurrence Score result, central/local-pathological review of grade, ER, PR and Ki67 in HR+/HER2- high risk node-negative and -positive breast cancer.** *Proc EBCC* 2016;**Abstract 8LBA.**

Gluz O et al. **West German Study Group Phase III PlanB trial: First prospective outcome data for the 21-gene Recurrence Score assay and concordance of prognostic markers by central and local pathology assessment.** *J Clin Oncol* 2016;34(20):2341-9.

King TA et al. **A prospective analysis of surgery and survival in stage IV breast cancer (TBCRC 013).** *Proc ASCO* 2016;**Abstract 1006.**

King TA et al. **Lobular carcinoma in situ: A 29-year longitudinal experience evaluating clinico-pathologic features and breast cancer risk.** *J Clin Oncol* 2015;33(33):3945-52.

Love N et al. **HER2 and estrogen receptor status drive decisions regarding the use of neoadjuvant chemotherapy.** San Antonio Breast Cancer Symposium 2015;**Abstract P1-14-20.**

Miller K et al. **Improved clinical outcomes on enzalutamide observed in patients with PREDICT AR+ triple-negative breast cancer: Prognosis or prediction?** San Antonio Breast Cancer Symposium 2015;**Abstract P3-07-25.**

Morrow M et al. **Society of Surgical Oncology-American Society for Radiation Oncology-American Society of Clinical Oncology consensus guideline on margins for breast-conserving surgery with whole-breast irradiation in ductal carcinoma in situ.** *Pract Radiat Oncol* 2016;6(5):287-95.

Shak S et al. **Breast cancer specific survival in 38,568 patients with node negative hormone receptor positive invasive breast cancer and Oncotype DX Recurrence Score results in the SEER database.** San Antonio Breast Cancer Symposium 2015;**Abstract P5-15-01.**

Soran A et al. **A randomized controlled trial evaluating resection of the primary breast tumor in women presenting with de novo stage IV breast cancer: Turkish Study (Protocol MF07-01).** *Proc ASCO* 2016;**Abstract 1005.**

Sparano JA et al. **Prospective validation of a 21-gene expression assay in breast cancer.** *N Engl J Med* 2015;373(21):2005-14.

Stemmer SM et al. **Real-life analysis evaluating 1594 N0/Nmic breast cancer patients for whom treatment decisions incorporated the 21-gene Recurrence Score result: 5-year KM estimate for breast cancer specific survival with Recurrence Score results <30 is >98%.** San Antonio Breast Cancer Symposium 2015;**Abstract P5-08-02.**

Toi M et al. **A phase III trial of adjuvant capecitabine in breast cancer patients with HER2-negative pathologic residual invasive disease after neoadjuvant chemotherapy (CREATE-X, JBCRG-04).** San Antonio Breast Cancer Symposium 2015;**Abstract S1-07.**

QUESTIONS (PLEASE CIRCLE ANSWER):

1. Tumors classified as invasive lobular carcinoma are typically of which subtype?
 - a. ER-negative, HER2-negative
 - b. ER-negative, HER2-positive
 - c. ER-positive, HER2-negative
 - d. ER-positive, HER2-positive
2. The goal of the MINDACT trial, for which initial results were recently published, was to evaluate the benefit of genomic profiling with the _____ in addition to standard clinical-pathological criteria for patients with early BC and 0 to 3 positive lymph nodes who might safely forgo chemotherapy without compromising outcome.
 - a. PAM50 assay
 - b. 70-gene signature
 - c. 21-gene signature
3. A recent meta-analysis evaluating the use of adjuvant bisphosphonates for women with early BC pointed toward a reduction in the odds of disease recurrence in women who were _____ when they began treatment.
 - a. Premenopausal
 - b. Postmenopausal
4. The SSO-ASTRO-ASCO Consensus Guideline on Margins for Breast-Conserving Surgery with Whole-Breast Irradiation in Ductal Carcinoma in Situ states that clear margins wider than 2 millimeters result in significantly lower rates of recurrence.
 - a. True
 - b. False
5. The ongoing POSITIVE study is evaluating recurrence risk of interrupting endocrine therapy for young women with endocrine-responsive BC who desire pregnancy.
 - a. True
 - b. False
6. The DCIS Score for patients with DCIS who have undergone local excision is predictive of _____.
 - a. The risk of DCIS recurrence
 - b. The risk of invasive BC
 - c. Both a and b
7. Results of the low-risk registry of the TAILORx trial, which is evaluating adjuvant endocrine therapy with or without chemotherapy for patients with ER-positive, HER2-negative BC based on the 21-gene signature, reported an approximate _____ risk of distant recurrence at 5 years for patients with a low RS of less than 11 who received endocrine therapy alone without chemotherapy.
 - a. 0.1%
 - b. 1.0%
 - c. 10.0%
8. The Phase III _____ study randomly assigns patients with hormone receptor-positive, HER2-negative BC, 1 to 3 positive nodes and a 21-gene RS of 25 or lower to adjuvant endocrine therapy with or without chemotherapy.
 - a. ECOG-E2108
 - b. POSITIVE
 - c. RxPONDER
9. Results of the Phase III West German Study Group PlanB trial demonstrated a 5-year disease-free survival rate of 94% in patients with ER-positive, HER2-negative, _____ BC who did not receive adjuvant chemotherapy based on an RS of 11 or lower.
 - a. High-risk node-negative
 - b. Node-positive
 - c. Both a and b
10. The Phase III CALOR trial evaluating adjuvant chemotherapy for isolated local or regional recurrence of BC demonstrated a significant improvement in survival for patients who received chemotherapy.
 - a. True
 - b. False

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update for Surgeons — Issue 1, 2017

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
MINDACT trial: Utility of the 70-gene signature in selecting patients with BC and 0 to 3 positive nodes for adjuvant chemotherapy	4 3 2 1	4 3 2 1
Consensus guidelines on margins for BCS with whole-breast irradiation in patients with DCIS	4 3 2 1	4 3 2 1
Utility of the DCIS Score in assessing the benefit of radiation therapy after lumpectomy for patients with DCIS	4 3 2 1	4 3 2 1
TAILORx: Results of the low-risk registry of a prospective trial of adjuvant systemic therapy for patients with ER-positive, HER2-negative, node-negative BC based on the 21-gene signature	4 3 2 1	4 3 2 1
Results of the Phase III West German Study Group PlanB trial: Effect of the 21-gene RS and concordance of prognostic markers in ER-positive, HER2-negative, high-risk node-negative and node-positive BC	4 3 2 1	4 3 2 1
Targeting the androgen receptor in patients with TNBC	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:

- Develop an understanding of the histopathologic characteristics and responsiveness to chemotherapy of invasive lobular carcinomas.4 3 2 1 N/M N/A
- Appreciate the information provided by genomic platforms to assess risk and individualize therapy for patients with ductal carcinoma in situ and early BC.4 3 2 1 N/M N/A
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for patients with HER2-positive and triple-negative early BC.4 3 2 1 N/M N/A
- Describe the importance of adequate surgical margins in mitigating local recurrence risk for women with ductal carcinoma in situ treated with breast-conserving surgery and whole-breast irradiation.4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

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

- Develop an evidence-based approach to the management of the axilla in patients with localized BC and a positive sentinel lymph node biopsy.4 3 2 1 N/M N/A
- Counsel appropriately selected patients with BC about participation in ongoing clinical trials.4 3 2 1 N/M N/A

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:

.....

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
William J Gradishar, MD	4	3	2	1	4	3 2 1
Tari King, MD	4	3	2	1	4	3 2 1
Joseph A Sparano, MD	4	3	2	1	4	3 2 1
Seema A Khan, MD, MPH	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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QID 1720

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