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Breast Cancer® UPDATE

An Audio Review Journal for Surgeons

Bridging the Gap between Research and Patient Care

FACULTY INTERVIEWS

Harry D Bear, MD, PhD
Harold J Burstein, MD, PhD
Susan K Boolbol, MD
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EDITOR

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2 Audio CDs

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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, has 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 that 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

- Appreciate the similarities and differences among existing genomic assays, and use this information to select appropriate platform(s) to assess risk and individualize therapy for patients with early breast cancer.
- Develop an evidence-based approach to the management of the axilla in patients with localized breast cancer and a positive sentinel lymph node biopsy.
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for 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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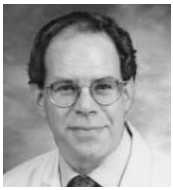

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FACULTY — **Dr Burstein** has no real or apparent conflicts of interest to disclose. The following faculty (and their spouses/partners) reported real or apparent conflicts of interest, which have been resolved through a conflict of interest resolution process: **Dr Bear** — Advisory Committee, Contracted Research and Speakers Bureau: Genomic Health Inc. **Dr Boolbol** — Speakers Bureau: Genentech BioOncology, Genomic Health Inc. **Dr Smith** — Advisory Committee: Pfizer Inc; Speakers Bureau: Eisai Inc.

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Interview with Harry D Bear, MD, PhD

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Track 6 Rationale for using pertuzumab in the adjuvant setting

Track 7 Five-year analysis of NeoSphere: Addition of neoadjuvant pertuzumab to trastuzumab and/or docetaxel in locally advanced or inflammatory HER2-positive BC

SELECT PUBLICATIONS

A phase II randomized study evaluating the biological and clinical effects of the combination of palbociclib with letrozole as neoadjuvant therapy in post-menopausal women with estrogen-receptor positive primary breast cancer. NCT02296801

A phase III, randomized clinical trial of standard adjuvant endocrine therapy +/- chemotherapy in patients with 1-3 positive nodes, hormone receptor-positive and HER2-negative breast cancer with Recurrence Score (RS) of 25 or less. RxPONDER: A clinical trial Rx for positive node, endocrine responsive breast cancer. NCT01272037

A randomized, multicenter, open-label phase III study to evaluate the efficacy and safety of trastuzumab emtansine versus trastuzumab as adjuvant therapy for patients with HER2-positive primary breast cancer who have residual tumor present pathologically in the breast or axillary lymph nodes following preoperative therapy. NCT01772472

A randomized phase III study of conventional whole breast irradiation (WBI) versus partial breast irradiation (PBI) for women with stage 0, I, or II breast cancer. NCT00103181

Adams BJ et al. **The role of margin status and reexcision in local recurrence following breast conservation surgery.** *Ann Surg Oncol* 2013;20(7):2250-5.

Albain KS et al. **Prognostic and predictive value of the 21-gene Recurrence Score assay in postmenopausal women with node-positive, oestrogen-receptor-positive breast cancer on chemotherapy: A retrospective analysis of a randomised trial.** *Lancet Oncol* 2010;11(1):55-65.

Choosing neoadjuvant chemotherapy versus hormonal therapy for breast cancer based on gene expression profile. NCT01293032

Finn RS et al. **The cyclin-dependent kinase 4/6 inhibitor palbociclib in combination with letrozole versus letrozole alone as first-line treatment of oestrogen receptor-positive, HER2-negative, advanced breast cancer (PALOMA-1/TRIO-18): A randomised phase 2 study.** *Lancet Oncol* 2015;16(1):25-35.

Francis PA et al. **Adjuvant ovarian suppression in premenopausal breast cancer.** *N Engl J Med* 2015;372(5):436-46.

Gianni L et al. **Five-year analysis of the phase II NeoSphere trial evaluating four cycles of neoadjuvant docetaxel (D) and/or trastuzumab (T) and/or pertuzumab (P).** *Proc ASCO* 2015;**Abstract 505**.

Giuliano AE et al. **Locoregional recurrence after sentinel lymph node dissection with or without axillary dissection in patients with sentinel lymph node metastases: The American College of Surgeons Oncology Group Z0011 randomized trial.** *Ann Surg* 2015;252(3):426-33.

Giuliano AE et al. **Axillary dissection vs no axillary dissection in women with invasive breast cancer and sentinel node metastasis: A randomized clinical trial.** *JAMA* 2011;305(6):569-75.

Golshan M et al. **Impact of neoadjuvant therapy on breast conservation rates in triple-negative and HER2-positive breast cancer: Combined results of CALGB 40603 and 40601 (Alliance).** *Proc ASCO* 2015;**Abstract 1007**.

Margolese RG et al. **Primary results, NRG Oncology/NSABP B-35: A clinical trial of anastrozole (A) versus tamoxifen (tam) in postmenopausal patients with DCIS undergoing lumpectomy plus radiotherapy.** *Proc ASCO* 2015;**Abstract LBA500**.

Moran MS et al; American Society for Radiation Oncology. **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.

Rakovitch E et al. **A large prospectively-designed study of the DCIS score: Predicting recurrence risk after local excision for ductal carcinoma in situ patients with and without irradiation.** San Antonio Breast Cancer Symposium 2014;**Abstract S5-04**.

Rugo H et al. **Clinical performance of the DigniCap system, a scalp hypothermia system, in preventing chemotherapy-induced alopecia.** *Proc ASCO* 2015;**Abstract 9518**.

Rutter CE et al. **Influence of a 21-gene Recurrence Score assay on chemotherapy delivery in breast cancer.** *Clin Breast Cancer* 2015;[Epub ahead of print].

Solin L et al. **A multigene expression assay to predict local recurrence risk for ductal carcinoma in situ of the breast.** *J Natl Cancer Inst* 2013;105(10):701-10.

Turner NC et al. **Palbociclib in hormone-receptor–positive advanced breast cancer.** *N Engl J Med* 2015;373(3):209-19.

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The SOFT trial evaluating ovarian suppression in premenopausal women with hormone receptor-positive BC demonstrated the following results with the addition of ovarian suppression to tamoxifen or exemestane versus tamoxifen alone:**
   a. A significant reduction in the risk of recurrence in the cohort who remained premenopausal after chemotherapy
   b. A significant benefit with ovarian suppression in the cohort of women who did not receive chemotherapy
   c. Both a and b

2. **Palbociclib was recently approved by the FDA for use in combination with _____ as treatment for postmenopausal women with ER-positive, HER2-negative advanced BC in the first-line setting.**
   a. Letrozole
   b. Fulvestrant
   c. Tamoxifen

3. **The results of a prospective trial of the scalp hypothermia system reported the technique to be highly effective with a success rate of approximately 70% in reducing chemotherapy-induced alopecia in women with Stage I/II BC receiving nonanthracycline-based neoadjuvant or adjuvant chemotherapy regimens.**
   a. True
   b. False

4. **The Onco*type* DX assay for patients with DCIS who have undergone local excision predicts _____.**
   a. The risk of DCIS recurrence
   b. The risk of invasive BC
   c. Both a and b

5. **The results of the ACOSOG Z0011 study evaluating ALND for women with T1-2 BC who have 1 to 2 positive sentinel nodes demonstrated a significantly lower locoregional recurrence rate with ALND.**
   a. True
   b. False

6. **Pertuzumab has been approved by the FDA for use in BC in the _____ setting.**
   a. Neoadjuvant
   b. Adjuvant
   c. Both a and b

7. **Five-year analysis of the Phase II NeoSphere trial evaluating the addition of neoadjuvant pertuzumab to trastuzumab and/or docetaxel in locally advanced or inflammatory HER2-positive BC demonstrated that pertuzumab did not add any benefit in disease-free survival.**
   a. True
   b. False

8. **The Phase III RxPONDER study randomly assigns patients with hormone receptor-positive, HER2-negative BC with _____ and an Onco*type* DX RS of 25 or lower to adjuvant endocrine therapy with or without chemotherapy.**
   a. Negative lymph nodes
   b. One to 3 positive lymph nodes
   c. Microscopically positive sentinel lymph node(s)

9. **Results of the NSABP-B-35 trial of anastrozole versus tamoxifen in postmenopausal patients with DCIS undergoing lumpectomy and radiation therapy demonstrated _____.**
   a. A significant improvement in BC-free interval with anastrozole
   b. No difference in overall survival
   c. No difference in the risk of contralateral invasive BC
   d. All of the above
   e. Both a and b

10. **The Onco*type* DX 21-gene RS _____ for patients with early-stage, node-negative, ER-positive invasive BC.**
    a. Predicts chemotherapy benefit
    b. Predicts likelihood of distant BC recurrence
    c. Both a and b
    d. Neither a nor b

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Breast Cancer Update for Surgeons — Issue 1, 2015

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
Utility of the Onco*type* DX assay for predicting local recurrence risk in DCIS	4 3 2 1	4 3 2 1
NSABP-B-50-I (KATHERINE): A Phase III trial of T-DM1 versus trastuzumab for women with HER2-positive BC who have residual tumor in the breast or axillary nodes	4 3 2 1	4 3 2 1
Results of the NSABP-B-35 trial of anastrozole versus tamoxifen in patients with DCIS	4 3 2 1	4 3 2 1
RxPONDER: A Phase III trial of adjuvant endocrine therapy with or without chemotherapy for patients with node-positive BC and an RS of ≤25	4 3 2 1	4 3 2 1
Five-year analysis of the Phase II NeoSphere trial evaluating neoadjuvant docetaxel and/or trastuzumab and/or pertuzumab	4 3 2 1	4 3 2 1
Role of margin status and re-excision in local recurrence after breast conservation surgery	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:

- Appreciate the similarities and differences among existing genomic assays, and use this information to select appropriate platform(s) to assess risk and individualize therapy for patients with early breast cancer.. . . . . 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
- Individualize the selection of evidence-based neoadjuvant and adjuvant chemobiologic regimens for 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: .....

.....

.....

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
Harry D Bear, MD, PhD	4 3 2 1	4 3 2 1
Harold J Burstein, MD, PhD	4 3 2 1	4 3 2 1
Susan K Boolbol, MD	4 3 2 1	4 3 2 1
Ian E Smith, 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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