Rounds with the Investigators

Clinical Research Leaders Consult on Challenging Cases of Early Breast Cancer

Proceedings from a Satellite Symposium Held in Conjunction with the 11th Annual Meeting of The American Society of Breast Surgeons

Faculty

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Thomas B Julian, MD
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Moderator

Neil Love, MD

Featuring faculty discussion of five cases submitted and presented by American Society of Breast Surgeons members

From the publishers of:
Breast Cancer® UPDATE

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Rounds with the Investigators: Clinical Research Leaders Consult on Challenging Cases of Early Breast Cancer

A Continuing Medical Education Program

OVERVIEW OF ACTIVITY

Historically, surgery has been the primary method for treating early breast cancer. More recently, the diagnostic, surgical and medical management of breast cancer has escalated in complexity because of advancements in technology and clinical experience in addition to the availability of novel pharmaceutical agents. Thus, the care of breast cancer has evolved toward a multifaceted approach necessitating input from a variety of interdisciplinary experts. This paradigm shift has created the opportunity for extensive knowledge exchange among oncologic subspecialties and the challenge of ensuring that major clinical advances influencing local and systemic treatment algorithms are effectively disseminated among the cross-functional team members. To bridge the gap between research and patient care, this CME activity features a panel discussion with leading breast cancer investigators. By providing access to the latest research developments and expert perspectives, this program assists breast surgeons in the formulation of up-to-date clinical management strategies.

LEARNING OBJECTIVES

- Apply the results of emerging research in breast cancer clinical management to treatment and referral strategies for patients with early-stage disease.
- Recognize the variability in routine ER, PR and HER2 testing, and implement appropriate guidelines to maximize accurate pathologic assessment.
- Develop a treatment plan for patients with HER2-positive breast cancer, considering tumor size and nodal status.
- Effectively utilize biomarkers and genomic risk classifiers to estimate patient prognosis and select or recommend adjuvant therapy.
- Counsel patients about the value of sentinel lymph node biopsy and its influence on further local and systemic treatment.
- Recall the design and eligibility criteria for ongoing breast cancer clinical trials, and enroll or refer appropriate patients for study participation.

ACCREDITATION STATEMENT

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HOW TO USE THIS CME ACTIVITY

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CME INFORMATION

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CONTENT VALIDATION AND DISCLOSURES

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FACULTY — **Drs Alfonse**, **Gralow**, **Han**, **Jablon**, **Lago-Toro** and **McDonald** 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: **Prof Dixon** — Advisory Committee: Novartis Pharmaceuticals Corporation, Pfizer Inc. **Dr Hudis** — Advisory Committee: Amgen Inc, Boehringer Ingelheim Pharmaceuticals Inc, Genentech BioOncology, Roche Laboratories Inc; Paid Research: AstraZeneca Pharmaceuticals LP, Bayer HealthCare Pharmaceuticals. **Dr Julian** — Protocol Advisor: SenoRx Inc. **Dr Swain** — Paid Research: Bristol-Myers Squibb Company, Genentech BioOncology; Paid Travel: Sanofi-Aventis.

MODERATOR — Dr Love is president and CEO of Research To Practice, which receives funds in the form of educational grants to develop CME activities from the following commercial interests: Abraxis BioScience, Allos Therapeutics, Amgen Inc, AstraZeneca Pharmaceuticals LP, Aureon Laboratories Inc, Bayer HealthCare Pharmaceuticals/Onyx Pharmaceuticals Inc, Biogen Idec, Boehringer Ingelheim Pharmaceuticals Inc, Bristol-Myers Squibb Company, Celgene Corporation, Cephalon Inc, Eisai Inc, EMD Serono Inc, Genentech BioOncology, Genomic Health Inc, Genzyme Corporation, Lilly USA LLC, Millennium Pharmaceuticals Inc, Monogram BioSciences Inc, Novartis Pharmaceuticals Corporation, OSI Oncology, Sanofi-Aventis and Spectrum Pharmaceuticals Inc.

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POST-TEST

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QUESTIONS (PLEASE CIRCLE ANSWER):

1. **Although the Onco*type* DX® assay has been integrated into the clinical management of node-negative breast cancer, recent data have emerged suggesting its potential utility in the management of node-positive tumors.**
   a. True
   b. False

2. **The Onco*type* DX assay may be ordered for _____ patients with ER- and/or PR-positive breast cancer.**
   a. Premenopausal
   b. Postmenopausal
   c. Either pre- or postmenopausal

3. **T-DM1 is a novel agent that combines a maytansine derivative with _____.**
   a. Docetaxel
   b. Paclitaxel
   c. Trastuzumab
   d. None of the above

4. **Patients with HER2-positive metastatic disease previously treated with HER2-directed therapies had a response rate of approximately _____ with T-DM1.**
   a. Five percent
   b. 10 percent
   c. 30 percent
   d. 60 percent

5. **In the Phase III NSABP-B-32 trial, patients with clinically node-negative breast cancer were randomly assigned to undergo sentinel node resection alone or sentinel node resection followed by axillary resection.**
   a. True
   b. False

6. **Phase II and III trials have been completed evaluating PARP inhibitors in the treatment of _____.**
   a. Triple-negative breast cancer
   b. BRCA mutation carriers
   c. HER2-positive breast cancer
   d. Both a and b

7. **PARP inhibitors target which of the following?**
   a. Human epidermal growth factor receptor
   b. DNA repair mechanisms
   c. Vascular endothelial growth factor
   d. Epidermal growth factor receptor

8. **The Southwest Oncology Group is planning a clinical trial of endocrine therapy in combination with trastuzumab with or without _____ for patients with small, HER2-positive tumors.**
   a. Bevacizumab
   b. Lapatinib
   c. Olaparib
   d. Pertuzumab

9. **In patients with small T1a or T1b tumors, HER2 status _____ significantly affect prognosis.**
   a. Does
   b. Does not

10. **The College of American Pathologists and the American Society of Clinical Oncology joint guidelines on testing for ER/PR status in breast cancer recommend that ER assays be considered positive if _____ or more of tumor cell nuclei are immunoreactive.**
    a. One percent
    b. Five percent
    c. 10 percent
    d. 15 percent

11. **The NSABP is planning to conduct a clinical trial evaluating _____ in patients with HER2 FISH-negative, IHC 1+ or 2+ positive breast cancer.**
    a. Trastuzumab
    b. Lapatinib
    c. Both of the above
    d. None of the above

Post-test answer key: 1a, 2b, 3c, 4c, 5a, 6d, 7b, 8b, 9a, 10a, 11a

EDUCATIONAL ASSESSMENT AND CREDIT FORM

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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 ONE — 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
Axillary dissection after negative sentinel lymph node biopsy results	4 3 2 1	4 3 2 1
Trastuzumab for subcentimeter, node-negative, HER2-positive tumors	4 3 2 1	4 3 2 1
Onco*type* DX assay in node-positive breast cancer	4 3 2 1	4 3 2 1
Neoadjuvant endocrine therapy for ER-positive disease	4 3 2 1	4 3 2 1
Maintaining fertility during chemotherapy	4 3 2 1	4 3 2 1

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

☐ Yes ☐ No

If no, please explain: .....

.....

.....

Will this activity help you improve patient care?

☐ Yes ☐ No ☐ Not applicable

If no, please explain: .....

.....

.....

Did the activity meet your educational needs and expectations?

☐ 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:

- Apply the results of emerging research in breast cancer clinical management to treatment and referral strategies for patients with early-stage disease. .....4 3 2 1 N/M N/A
- Recognize the variability in routine ER, PR and HER2 testing, and implement appropriate guidelines to maximize accurate pathologic assessment. .....4 3 2 1 N/M N/A
- Develop a treatment plan for patients with HER2-positive breast cancer, considering tumor size and nodal status. .....4 3 2 1 N/M N/A
- Effectively utilize biomarkers and genomic risk classifiers to estimate patient prognosis and select or recommend adjuvant therapy. .....4 3 2 1 N/M N/A
- Counsel patients about the value of sentinel lymph node biopsy and its influence on further local and systemic treatment. .....4 3 2 1 N/M N/A
- Recall the design and eligibility criteria for ongoing breast cancer clinical trials, and enroll or refer appropriate patients for study participation. .....4 3 2 1 N/M N/A

EDUCATIONAL ASSESSMENT AND CREDIT FORM (continued)

What other practice changes will you make or consider making as a result of this activity?

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What additional information or training do you need on the activity topics or other oncology-related topics?

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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 TWO — Please tell us about the faculty and moderator for this educational activity

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

Faculty	Knowledge of subject matter	Effectiveness as an educator
Professor Mike Dixon	4 3 2 1	4 3 2 1
Julie R Gralow, MD	4 3 2 1	4 3 2 1
Clifford Hudis, MD	4 3 2 1	4 3 2 1
Thomas B Julian, MD	4 3 2 1	4 3 2 1
Sandra M Swain, MD	4 3 2 1	4 3 2 1
Moderator	**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 moderator for this activity:

.....

REQUEST FOR CREDIT — Please print clearly

Name:..... Specialty:.....

Professional Designation:

☐ MD ☐ DO ☐ PharmD ☐ NP ☐ RN ☐ PA ☐ Other .....

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I certify my actual time spent to complete this educational activity to be _____ hour(s).

Signature:..... Date:.....

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