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Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

Proceedings from a Clinical Investigator Think Tank

FACULTY

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Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

A Continuing Medical Education Audio Program

OVERVIEW OF ACTIVITY

Many controversies and clinical questions currently surround the management of localized breast and colorectal cancers. Central among these is the use and effectiveness of available biomarkers in guiding decision-making regarding adjuvant treatment. This CME program brings together leading clinical investigators in the fields of breast and colon cancer to provide perspectives on the development, assessment and clinical utility of select genomic assays and biomarkers that are available to assist clinicians managing these highly prevalent diseases. By reviewing available clinical trial data and relevant case scenarios, this initiative will help learners to ascertain the effectiveness of diagnostic, prognostic and predictive biomarkers as they relate to the adjuvant treatment of breast and/or colorectal cancer.

LEARNING OBJECTIVES

- Recognize the evolving application of biomarkers and multigene assays in the management of breast and colon cancer, and effectively use these tools to refine or individualize treatment plans for selected patients.
- Determine the utility of the Onco*type* DX® Recurrence Score® assay in counseling patients with ER-positive early breast cancer about their risk of recurrence and the potential benefits of adjuvant chemotherapy.
- Counsel patients with Stage II and Stage III colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options based on an evaluation of this information.
- Assess the utility of the Onco*type* DX DCIS Score® assay in counseling patients with DCIS about their risk of recurrence and the potential benefits of radiation therapy.
- Evaluate the evidence-based benefits of adjuvant chemotherapy for patients with Stage II colon cancer and the risks and benefits of oxaliplatin-containing chemotherapy in lower-risk Stage III disease.
- Counsel appropriately selected patients about participation in ongoing clinical trials.

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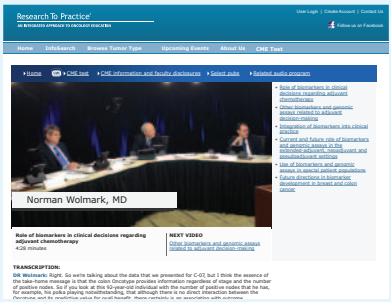
Video Highlights of the Clinical Investigator Think Tank



Visit www.ResearchToPractice.com/BiomarkersTT115/Video to access a number of short video segments and corresponding transcripts from the Think Tank featuring the faculty discussing and debating some of the key clinical management and research issues in the field.

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BONUS AUDIO AVAILABLE EXCLUSIVELY ONLINE

Please visit www.ResearchToPractice.com/BiomarkersTT115 for additional discussion.

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Track 3 The gene expression-based signature BC index (BCI) identifies patients with ER-positive BC at risk for early and late distant recurrences

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Track 27 Interpreting the results of CALGB/SWOG-80405 and FIRE-3 (FOLFIRI with cetuximab versus FOLFIRI with bevacizumab as first-line therapy for metastatic colorectal cancer)

Track 28 Evaluation of the RAS wild-type patient population from the CALGB/SWOG-80405 and FIRE-3 trials

Track 29 Ongoing correlative retrospective analyses of the CALGB/SWOG-80405 study

Track 30 Importance of correlative studies in furthering cancer research

SELECT PUBLICATIONS

Ahn SG et al. **Prognostic discrimination using a 70-gene signature among patients with estrogen receptor-positive breast cancer and an intermediate 21-gene Recurrence Score.** *Int J Mol Sci* 2013;14(12):23685-99.

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Shivers SC et al. **Direct comparison of risk classification between MammaPrint®, Onco*type* DX® and MammoStrat® assays in patients with early stage breast cancer.** San Antonio Breast Cancer Symposium 2013;Abstract P6-06-02.

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Yothers G et al. **Validation of the 12-gene colon cancer Recurrence Score in NSABP C-07 as a predictor of recurrence in patients with stage II and III colon cancer treated with fluorouracil and leucovorin (FU/LV) and FU/ LV plus oxaliplatin.** *J Clin Oncol* 2013;31(36):4512-9.

POST-TEST

Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

QUESTIONS (PLEASE CIRCLE ANSWER):

1. **The Phase III RxPONDER study randomly assigns patients with ER-positive, HER2-negative BC, 1 to 3 positive nodes and an Onco*type* DX 21-gene RS of 25 or _____ to adjuvant endocrine therapy with or without chemotherapy.**
   a. Lower
   b. Higher

2. **The Onco*type* DX 12-gene RS predicts recurrence risk in which of the following?**
   a. Stage II colon cancer
   b. Stage III colon cancer
   c. Both a and b
   d. Neither a nor b

3. **Which of the following statements is true about the direct comparison of risk classification among the MammaPrint, Onco*type* DX and Mammostrat assays for patients with early-stage BC?**
   a. The 3 assays classify a large proportion of patients differently, resulting in significant discordance rates for all risk categories
   b. Considerable homogeneity and concordance are seen across risk categories for all 3 assays
   c. The 3 assays provide equivalent information and uniformly guide treatment decision-making
   d. Both b and c

4. **The Onco*type* DX assay for patients with DCIS who have undergone local excision, with or without tamoxifen, predicts the risk of local recurrence.**
   a. True
   b. False

5. **Patients with colon cancer and an Onco*type* DX 12-gene low-risk RS derive less absolute benefit from adjuvant oxaliplatin than do patients with a higher-risk RS.**
   a. True
   b. False

6. **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 breast cancer recurrence
   c. Both a and b
   d. Neither a nor b

7. **In comparison to currently available multigene BC assays, which of the following is a limitation of the Adjuvant! Online program for patients with BC?**
   a. Lack of reliability in prognostic predictions
   b. Prediction that all patients will benefit from adjuvant therapy to some extent
   c. No limitations; both are equally useful

8. **Which of the following statements is true about currently available multigene assays for early BC?**
   a. They are interchangeable for classifying patients into prognostic risk groups
   b. Each is largely driven by estrogen receptor expression and proliferation
   c. Each predicts benefit from adjuvant chemotherapy

EDUCATIONAL ASSESSMENT AND CREDIT FORM

Putting It in Perspective: Clinical Investigators Discuss the Use of Biomarkers to Guide Adjuvant Therapy for Breast and Colon Cancer

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
Validation of the Onco*type* DX 12-gene RS as a predictor of recurrence in patients with Stage II and Stage III colon cancer treated with 5-FU/leucovorin with or without oxaliplatin on the Phase III NSABP-C-07 trial	4 3 2 1	4 3 2 1
Utility of the 12-gene RS to guide decision-making regarding the addition of oxaliplatin to adjuvant 5-FU	4 3 2 1	4 3 2 1
Prospective validation study of the Onco*type* DX DCIS Score in predicting the risk of local recurrence after resection alone for DCIS	4 3 2 1	4 3 2 1
Prognostic and predictive utility of available breast cancer genomic assays	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 and colon cancer do you see per year? Breast ..... Colon.....

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 the management of breast and colon cancer, and effectively use these tools to refine or individualize treatment plans for selected patients .....4 3 2 1 N/M N/A
- Determine the utility of the Onco*type* DX Recurrence Score assay in counseling patients with ER-positive early breast cancer about their risk of recurrence and the potential benefits of adjuvant chemotherapy.....4 3 2 1 N/M N/A
- Counsel patients with Stage II and Stage III colon cancer about their individual risk of recurrence based on clinical, pathologic and genomic biomarkers, and consider adjuvant therapeutic options based on an evaluation of this information .....4 3 2 1 N/M N/A
- Assess the utility of the Onco*type* DX DCIS Score assay in counseling patients with DCIS about their risk of recurrence and the potential benefits of radiation therapy.....4 3 2 1 N/M N/A
- Evaluate the evidence-based benefits of adjuvant chemotherapy for patients with Stage II colon cancer and the risks and benefits of oxaliplatin-containing chemotherapy in lower-risk Stage III disease.....4 3 2 1 N/M N/A
- Counsel appropriately selected patients 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:

.....

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☐ 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 moderator for this educational activity

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

Faculty	Knowledge of subject matter	Effectiveness as an educator
Steven R Alberts, MD, MPH	4 3 2 1	4 3 2 1
Harold J Burstein, MD, PhD	4 3 2 1	4 3 2 1
Joseph A Sparano, MD	4 3 2 1	4 3 2 1
Alan P Venook, MD	4 3 2 1	4 3 2 1
Norman Wolmark, 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:

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QID 1425

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