

Meet The Professors

A case-based discussion on the management
of breast cancer in the adjuvant and
metastatic settings



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from the publishers of

Breast Cancer[™]
UPDATE



Meet The Professors

STATEMENT OF NEED/TARGET AUDIENCE

Breast cancer is one of the most rapidly evolving fields in medical oncology. Published results from a plethora of ongoing clinical trials lead to the continuous emergence of new therapeutic agents and changes in the indications for existing treatments. In order to offer optimal patient care — including the option of clinical trial participation — the practicing medical oncologist must be well informed of these advances. In order to incorporate research advances into developing treatment strategies for patients, the CME program *Meet The Professors* utilizes case-based discussions between community oncologists and research leaders.

LEARNING OBJECTIVES

- Critically evaluate the clinical implications of emerging clinical trial data in breast cancer treatment and incorporate these data into a management strategy in the adjuvant, neoadjuvant and metastatic settings.
- Counsel appropriately selected patients about the availability of ongoing clinical trials.
- Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of adjuvant aromatase inhibitors and of sequencing aromatase inhibitors after tamoxifen, and counsel premenopausal women about the risks and benefits of adjuvant ovarian suppression alone or with other endocrine interventions.
- Describe and implement an algorithm for HER2 testing and treatment of patients with HER2-positive breast cancer in the adjuvant, neoadjuvant and metastatic settings.
- Evaluate the emerging data on various adjuvant chemotherapy approaches, including dose-dense treatment and the use of taxanes, and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients.
- Counsel appropriate patients with metastatic disease about selection and sequencing of endocrine therapy and about the risks and benefits of combination versus single-agent chemotherapy.
- Describe the computerized risk models and genetic markers to determine prognostic information on the quantitative risk of breast cancer relapse, and when applicable, utilize these to guide therapy decisions.

EDUCATIONAL METHOD

To receive CME credit, the participant should listen to the CDs or tapes and complete the evaluation form.

ACCREDITATION STATEMENT

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HOW TO USE THIS MONOGRAPH

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Meet The Professors:

Recorded in Los Angeles, California, May 20, 2005

Faculty for session 1



Stephen E Jones, MD



Charles L Vogel, MD

Faculty for session 2



William J Gradishar, MD



Peter M Ravdin, MD, PhD

Guide to Audio Programs

Audio Tapes

Tape 1, Side A:

- Introduction by Neil Love, MD
- Case from Mansoor Javeed, MD

Tape 1, Side B:

- Case from Edmund W Tai, MD
- Case from Joan F Kroener, MD
- Case from Michael A Harris, MD

Tape 2, Side A:

- Case from Robert A Moss, MD
- Case from Michael J Messer, MD

Tape 2, Side B:

- Case from Dr Messer (cont)
- Case from Helen Collins, MD
- Case from Behrooz Zidehsarai, MD
- Q&A session including case from Edmund W Tai, MD

Audio Compact Disks

CD 1 Tracks:

- 1: Introduction by Neil Love, MD
- 2-15: Case from Mansoor Javeed, MD
- 16-22: Case from Edmund W Tai, MD

CD 2 Tracks:

- 1-5: Case from Joan F Kroener, MD
- 6-9: Case from Michael A Harris, MD
- 10-23: Case from Robert A Moss, MD

CD 3 Tracks:

- 1-9: Case from Michael J Messer, MD
- 10-14: Case from Helen Collins, MD
- 15-16: Case from Behrooz Zidehsarai, MD
- 17-21: Q&A session including case from Edmund W Tai, MD

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Case Studies

- Case 1: A 56-year-old woman with a 1.3-centimeter, high-grade, strongly ER/PR-positive, HER2-positive infiltrating ductal carcinoma with 6/15 positive nodes and extracapsular extension and an ejection fraction of 47 percent but an otherwise unremarkable cardiologic evaluation (*from the practice of Dr Mansoor Javeed*)
- Case 2: A 52-year-old woman with a one-centimeter, ER/PR-positive, HER2-negative, node-negative breast cancer who has received three years of adjuvant tamoxifen and became amenorrheic in the past year (*from the practice of Dr Edmund W Tai*)
- Case 3: A 70-year-old woman with painful bony metastases and red-cell transfusion dependence who has been treated with multiple sequential hormonal therapies and zoledronic acid but is reluctant to receive chemotherapy due to concerns about being the sole caretaker of her husband, who has Alzheimer's disease (*from the practice of Dr Joan F Kroener*)
- Case 4: A 66-year-old woman who was diagnosed with lobular carcinoma at age 59 and progressive metastatic disease to the cervical spine one year later, with anemia, bone marrow invasion and skin nodules. The patient experienced a complete clinical remission for approximately 3.5 years while on tamoxifen with subsequent recurrence of bony metastases, skin lesions and pancytopenia (*from the practice of Dr Michael A Harris*)
- Case 5: A 48-year-old woman with a high-grade, five-millimeter, node-negative, ER/PR-negative, HER2-positive ductal carcinoma with extensive DCIS (*from the practice of Dr Robert A Moss*)
- Case 6: A functional 81-year-old woman with hypertension and osteoporosis who lives alone and has a six-centimeter, Grade I, ER/PR-positive, HER2-negative breast cancer with 3/13 positive lymph nodes (*from the practice of Dr Michael J Messer*)
- Case 7: A 43-year-old woman with a 1.2-centimeter, ER/PR-negative, HER2-positive, node-negative breast cancer treated with adjuvant CMF chemotherapy who two years later developed a skin nodule, a 1.8-centimeter lung mass and rib metastases (*from the practice of Dr Helen Collins*)
- Case 8: A 61-year-old woman who presented with an ER/PR-positive, node-positive breast cancer who received AC chemotherapy and tamoxifen and developed bone and lung metastases five years post adjuvant therapy (*from the practice of Dr Behrooz Zidehsarai*)
- Case 9: A 25-year-old woman with a five-centimeter, ER/PR-positive, HER2-positive breast cancer with a positive sentinel lymph node (*from the practice of Dr Edmund W Tai*)



Editor's Note

Figuring it out

The recent ASCO meeting in Orlando was unlike any I have attended in the last 30 years. While there were many new clinically relevant data sets presented in a variety of cancers, the real revelation occurred at the May 16th "education session" on monoclonal antibody therapy for breast cancer chaired by George Sledge, in which groundbreaking data were presented on the use of bevacizumab in metastatic disease and trastuzumab as adjuvant therapy.

Three days later, I found myself at a previously planned Meet The Professors recording session in Los Angeles. This turned out to be a fascinating opportunity to observe how clinical research findings are made available to medical oncologists in practice. Most striking was that only a couple of these community physicians had actually attended ASCO, and as a result, at the beginning of this MTP recording session, the level of information in the room about these groundbreaking data sets was minimal.

The discussions that took place over the day were riveting. As we sifted through a series of actual cases from the practices of these clinicians, it was fascinating to observe how the new information on bevacizumab and trastuzumab was being processed. It was also interesting to see a number of other recent and obvious shifts in standard care.

Many of the cases presented to our faculty of Steve Jones, Chuck Vogel, Peter Ravdin and Bill Gradishar related to the use of aromatase inhibitors in the adjuvant setting, and it is clear that oncologic practice has made a dramatic shift from an emphasis on cytotoxic agents to targeted biologic therapy.

As I moderated the discussion that day, and observed the uncertainty surrounding the implications of the new bev/trastuzumab data, my thoughts went back to December 2001 and the confusion generated by Mike Baum's first presentation of the ATAC data demonstrating an advantage for anastrozole over tamoxifen as adjuvant therapy for postmenopausal women with early breast cancer.

For the next year, our CME group observed a rather slow uptake of this new treatment strategy, and it took perhaps another two or three years for aromatase inhibitors to be routinely incorporated into the management of early disease.

In retrospect, it is apparent that thousands of unnecessary relapses, endometrial cancers and deep vein thromboses occurred in postmenopausal patients continuing to receive tamoxifen as clinical investigators and oncologists in practice pondered the ATAC results.

Perhaps it was important to allow the data to mature, and additional data sets from similar trials to be presented to provide the necessary justification for this approach, but in 2001, there were also many researchers like Aman Buzdar who immediately concluded that the first ATAC data set warranted a change in clinical practice.

As I began the process of selecting cases from this most recent MTP recording session to include in our final edited audio program, a compelling dilemma quickly appeared: Namely, there was way too much good stuff to squeeze onto two audio CDs. We therefore

decided to cut back on the print monograph supporting the discussion and expand the program to three audio CDs.

The enclosed discussion represents one of the first attempts to distill the clinical relevance of the May 16th ASCO session, and it will be interesting to go back a few years from now and see how accurately these initial reactions predict the long-term response of academic and community-based oncologists to perhaps the most important new data set in breast cancer in 30 years.

—Neil Love, MD
NLove@ResearchToPractice.net

Select publications related to the case discussions

Case 1: From the practice of Dr Mansoor Javeed

Perez EA et al. **HER2 testing by local, central, and reference laboratories in the NCCTG N9831 Intergroup Adjuvant Trial.** *Proc ASCO* 2004;[Abstract 567](#).

Perez EA et al. **NCCTG N9831: May 2005 update.** Presentation. ASCO 2005; [Abstract 556](#).

Piccart-Gebhart MJ. **First results of the HERA trial.** Presentation. ASCO 2005. No abstract available

Romond EH et al. **Doxorubicin and cyclophosphamide followed by paclitaxel with or without trastuzumab as adjuvant therapy for patients with HER-2 positive operable breast cancer: Combined analysis of NSABP-B31/NCCTG-N9831.** Presentation. ASCO 2005. No abstract available

Case 2: From the practice of Dr Edmund W Tai

Miller KD et al. **E2100: A randomized phase III trial of paclitaxel versus paclitaxel plus bevacizumab as first-line therapy for locally recurrent or metastatic breast cancer.** Presentation. ASCO 2005. No abstract available

Miller KD et al. **Randomized phase III trial of capecitabine compared with bevacizumab plus capecitabine in patients with previously treated metastatic breast cancer.** *J Clin Oncol* 2005;23(4):792-9. [Abstract](#)

Case 3: From the practice of Dr Joan F Kroener

Bajetta E et al. **Safety and efficacy of two different doses of capecitabine in the treatment of advanced breast cancer in older women.** *J Clin Oncol* 2005;23(10):2155-61. [Abstract](#)

Hennessy BT et al. **Lower dose capecitabine has a more favorable therapeutic index in metastatic breast cancer: Retrospective analysis of patients treated at MD Anderson Cancer Center and a review of capecitabine toxicity in the literature.** *Ann Oncol* 2005;16(8):1289-96. [Abstract](#)

O'Shaughnessy J et al. **Superior survival with capecitabine plus docetaxel combination therapy in anthracycline-pretreated patients with advanced breast cancer: Phase III trial results.** *J Clin Oncol* 2002;20(12):2812-23. [Abstract](#)

Case 4: From the practice of Dr Michael A Harris

Cristofanilli M et al. **Invasive lobular carcinoma classic type: Response to primary chemotherapy and survival outcomes.** *J Clin Oncol* 2005;23(1):41-8. [Abstract](#)

Howell A et al. **Comparison of fulvestrant versus tamoxifen for the treatment of advanced breast cancer in postmenopausal women previously untreated with endocrine therapy: A multinational, double-blind, randomized trial.** *J Clin Oncol* 2004;22(9):1605-13. [Abstract](#)

Mauriac L et al. **Fulvestrant (Faslodex) versus anastrozole for the second-line treatment of advanced breast cancer in subgroups of postmenopausal women with visceral and non-visceral metastases: Combined results from two multicentre trials.** *Eur J Cancer* 2003;39(9):1228-33. [Abstract](#)

Case 5: From the practice of Dr Robert A Moss

Carey LA et al. **The triple negative paradox: Primary tumor chemosensitivity of the basal-like breast cancer (BBC) phenotype.** San Antonio Breast Cancer Symposium 2004; [Abstract 1023](#).

Paik S et al. **A multigene assay to predict recurrence of tamoxifen-treated, node-negative breast cancer.** *N Engl J Med* 2004;351(27):2817-26. [Abstract](#)

Case 6: From the practice of Dr Michael J Messer

Boccardo F et al. **Switching to anastrozole versus continued tamoxifen treatment of early breast cancer: Preliminary results of the Italian Tamoxifen Anastrozole trial.** *J Clin Oncol* 2005;23(22):5138-47. [Abstract](#)

Coombs RC et al; Intergroup Exemestane Study. **A randomized trial of exemestane after two to three years of tamoxifen therapy in postmenopausal women with primary breast cancer.** *N Engl J Med* 2004;350(11):1081-92. [Abstract](#)

Goss PE et al. **A randomized trial of letrozole in postmenopausal women after five years of tamoxifen therapy for early-stage breast cancer.** *N Engl J Med* 2003;349(19):1793-802. [Abstract](#)

Howell A et al; ATAC Trialists' Group. **Results of the ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial after completion of 5 years' adjuvant treatment for breast cancer.** *Lancet* 2005;365(9453):60-2. [Abstract](#)

Jakesz R, on behalf of the ABCSG. **Benefits of switching postmenopausal women with hormone-sensitive early breast cancer to anastrozole after 2 years adjuvant tamoxifen: Combined results from 3,123 women enrolled in the ABCSG Trial 8 and the ARNO 95 Trial.** Presentation. San Antonio Breast Cancer Symposium 2004; [Abstract 2](#).

Thürlimann B et al. **BIG 1-98: Randomized double-blind phase III study to evaluate letrozole (L) vs tamoxifen (T) as adjuvant endocrine therapy for postmenopausal women with receptor-positive breast cancer.** *Proc ASCO* 2005; [Abstract 511](#).

Case 7: From the practice of Dr Helen Collins

O'Shaughnessy J et al. **ABI-007 (ABRAXANE), a nanoparticle albumin-bound (nab) paclitaxel demonstrates superior efficacy vs Taxol in MBC: A phase III trial.** Presentation. San Antonio Breast Cancer Symposium 2003; [Abstract 44](#).

O'Shaughnessy JA et al. **Weekly nanoparticle albumin paclitaxel (Abraxane) results in long-term disease control in patients with taxane-refractory metastatic breast cancer.** San Antonio Breast Cancer Symposium 2004; [Abstract 1070](#).

Case 8: From the practice of Dr Behrooz Zidehsarai

Jelovac D et al. **Additive antitumor effect of aromatase inhibitor letrozole and antiestrogen fulvestrant in a postmenopausal breast cancer model.** *Cancer Res* 2005;65(12):5439-44. [Abstract](#)

Case 9: From the practice of Dr Edmund W Tai

Buzdar AU et al. **Significantly higher pathologic complete remission rate after neoadjuvant therapy with trastuzumab, paclitaxel, and epirubicin chemotherapy: Results of a randomized trial in human epidermal growth factor receptor 2-positive operable breast cancer.** *J Clin Oncol* 2005;23(16):3676-85. [Abstract](#)

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To what extent does this issue of *MTP* address the following global learning objectives?

- Critically evaluate the clinical implications of emerging clinical trial data in breast cancer treatment and incorporate these data into a management strategy in the adjuvant, neoadjuvant and metastatic settings 5 4 3 2 1 N/A
- Counsel appropriately selected patients about the availability of ongoing clinical trials 5 4 3 2 1 N/A
- Counsel postmenopausal patients with ER-positive breast cancer about the risks and benefits of adjuvant aromatase inhibitors and of sequencing aromatase inhibitors after tamoxifen, and counsel premenopausal women about the risks and benefits of adjuvant ovarian suppression alone or with other endocrine interventions. 5 4 3 2 1 N/A
- Describe and implement an algorithm for HER2 testing and treatment of patients with HER2-positive breast cancer in the adjuvant, neoadjuvant and metastatic settings. 5 4 3 2 1 N/A
- Evaluate the emerging data on various adjuvant chemotherapy approaches, including dose-dense treatment and the use of taxanes, and explain the absolute risks and benefits of adjuvant chemotherapy regimens to patients. . . 5 4 3 2 1 N/A
- Counsel appropriate patients with metastatic disease about selection and sequencing of endocrine therapy and about the risks and benefits of combination versus single-agent chemotherapy. 5 4 3 2 1 N/A
- Describe the computerized risk models and genetic markers to determine prognostic information on the quantitative risk of breast cancer relapse, and when applicable, utilize these to guide therapy decisions. 5 4 3 2 1 N/A

EFFECTIVENESS OF THE INDIVIDUAL FACULTY MEMBERS

Faculty	Knowledge of subject matter					Effectiveness as an educator				
William J Gradishar, MD	5	4	3	2	1	5	4	3	2	1
Stephen E Jones, MD	5	4	3	2	1	5	4	3	2	1
Peter M Ravdin, MD, PhD	5	4	3	2	1	5	4	3	2	1
Charles L Vogel, MD	5	4	3	2	1	5	4	3	2	1

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Objectives were related to overall purpose/goal(s) of activity	5	4	3	2	1
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Will influence how I practice	5	4	3	2	1
Will help me improve patient care	5	4	3	2	1
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Overall quality of material	5	4	3	2	1
Overall, the activity met my expectations	5	4	3	2	1
Avoided commercial bias or influence	5	4	3	2	1

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Meet The Professors

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