

Visiting Professors

A case-based discussion on the management of breast cancer

CLINICAL INVESTIGATORS

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CONSULTING ONCOLOGISTS

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Featuring clinical investigators' perspectives on a day spent visiting patients with breast cancer in the clinics of general oncologists

CONTENTS

2 Audio CDs

EDITOR

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From the publishers of:





Visiting Professors: A case-based discussion on the management of breast cancer

OVERVIEW OF ACTIVITY

Individualized treatment decisions for patients with early, locally advanced or metastatic breast cancer are driven by disease- and patient-specific characteristics. The numerous therapeutic agents and regimens with significant activity in the management of breast cancer provide ample opportunity to deliver tailored care. However, the multiplicity of alternatives may also yield clinical scenarios in which several acceptable treatment options are available, with the optimal strategy being highly debatable and dependent on a thorough understanding of each agent's unique benefits and risks.

To provide clinicians with therapeutic strategies to address the disparate needs of patients with breast cancer, the *Visiting Professors* audio series employs an innovative case-based approach that unites the perspectives of leading breast cancer investigators and general oncologists as they explore the intricacies of making treatment decisions. Upon completion of this CME activity, medical oncologists should be able to formulate an up-to-date and more complete approach to the care of patients with breast cancer.

LEARNING OBJECTIVES

- Apply case-based learning, innovative communication strategies and shared clinical insight to provide comprehensive and compassionate oncology care.
- Effectively integrate biologic, hormonal and cytotoxic therapy into the multifaceted management of metastatic breast cancer.
- Develop evidence-based treatment approaches for patients diagnosed with HER2-positive breast cancer in the neoadjuvant, adjuvant and metastatic settings.
- Formulate individualized approaches to later-line therapy for patients with metastatic HER2-negative or triple-negative breast cancer.
- Evaluate recently presented data supporting the use of extended adjuvant endocrine therapy in pre- and postmenopausal women with hormone-dependent breast cancer and, where appropriate, integrate these findings into clinical practice.
- Counsel appropriately selected patients with breast cancer about participation in ongoing clinical trials.

ACCREDITATION STATEMENT

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SELECT PUBLICATIONS

A randomized Phase II study of trastuzumab emtansine (T-DM1) vs paclitaxel in combination with trastuzumab for stage I HER2-positive breast cancer (ATEMPT trial). NCT01853748

APHINITY: A randomized multicenter, double-blind, placebo-controlled comparison of chemotherapy plus trastuzumab plus placebo versus chemotherapy plus trastuzumab plus pertuzumab as adjuvant therapy in patients with operable HER2-positive primary breast cancer. NCTO1358877

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Balko JM et al. JAK2 amplifications are enriched in triple negative breast cancers (TNBCs) after neoadjuvant chemotherapy and predict poor prognosis. San Antonio Breast Cancer Symposium 2013; Abstract S6-01.

Blackwell KL et al. Exome sequencing reveals clinically actionable mutations in the pathogenesis and metastasis of triple negative breast cancer. San Antonio Breast Cancer Symposium 2013; Abstract S4-03.

Cortes J et al; EMBRACE (Eisai Metastatic Breast Cancer Study Assessing Physician's Choice Versus E7389) Investigators. Eribulin monotherapy versus treatment of physician's choice in patients with metastatic breast cancer (EMBRACE): A phase 3 open-label randomised study. Lancet 2011;377(9769):914-23.

Davies C et al; Adjuvant Tamoxifen: Longer Against Shorter (ATLAS) Collaborative Group. Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years after diagnosis of oestrogen receptor-positive breast cancer: ATLAS, a randomised trial. Lancet 2013;381(9869):805-16.

Gianni L et al. Efficacy and safety of neoadjuvant pertuzumab and trastuzumab in women with locally advanced, inflammatory, or early HER2-positive breast cancer (NeoSphere): A randomised multicentre, open-label, phase 2 trial. Lancet Oncol 2012;13(1):25-32.

Gray RG et al. aTTom: Long-term effects of continuing adjuvant tamoxifen to 10 years versus stopping at 5 years in 6,953 women with early breast cancer. *Proc ASCO* 2013; Abstract 05.

Kaufman PA et al. A phase III, open-label, randomized, multicenter study of eribulin mesylate versus capecitabine in patients with locally advanced or metastatic breast cancer previously treated with anthracyclines and taxanes. San Antonio Breast Cancer Symposium 2012; Abstract S6-6.

Perez EA et al. A combination of pertuzumab, trastuzumab, and vinorelbine for first-line treatment of patients with HER2-positive metastatic breast cancer: An open-label, two-cohort, phase II study (VELVET). Proc ASCO 2012; Abstract TPS653.

Phase I/II dose escalation trial to assess safety of intrathecal trastuzumab for the treatment of leptomeningeal metastases in HER2 positive breast cancer. NCTO1325207

Schneeweiss A et al. Pertuzumab plus trastuzumab in combination with standard neoadjuvant anthracycline-containing and anthracycline-free chemotherapy regimens in patients with HER2-positive early breast cancer: A randomized phase II cardiac safety study (TRYPHAENA). Ann Oncol 2013;24(9):2278-84.

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Shanafelt TD et al. Burnout and career satisfaction among US oncologists. J Clin Oncol 2014;32(7):678-86.

Sikov WM et al. Impact of the addition of carboplatin (Cb) and/or bevacizumab (B) to neoadjuvant weekly paclitaxel (P) followed by dose-dense AC on pathologic complete response (pCR) rates in triple-negative breast cancer (TNBC): CALGB 40603 (Alliance). San Antonio Breast Cancer Symposium 2013:Abstract S5-01.

Soran A et al. Early follow up of a randomized trial evaluating resection of the primary breast tumor in women presenting with de novo stage IV breast cancer; Turkish study (protocol MF07-01). San Antonio Breast Cancer Symposium 2013; Abstract S2-03.

Swain SM et al. Pertuzumab, trastuzumab, and docetaxel for HER2-positive metastatic breast cancer (CLEOPATRA study): Overall survival results from a randomised, double-blind, placebo-controlled, phase 3 study. Lancet Oncol 2013;14(6):461-71.

Tolaney SM et al. A phase II study of adjuvant paclitaxel (T) and trastuzumab (H) (APT trial) for nodenegative, HER2-positive breast cancer (BC). San Antonio Breast Cancer Symposium 2013; Abstract S1-04.

QUESTIONS (PLEASE CIRCLE ANSWER):

- Which of the following anti-HER2 directed monoclonal antibodies was recently approved by the FDA in combination with trastuzumab/ chemotherapy as a component of neoadjuvant therapy for patients with HER2-positive BC?
 - a. Pertuzumab
 - b. T-DM1
 - c. Neratinib
 - d. Lapatinib
- 2. The Phase III APHINITY trial is evaluating
 ________ in combination with chemotherapy/trastuzumab as adjuvant therapy for HER2-positive early-stage BC.
 - a. Bevacizumab
 - b. Enzalutamide
 - c. Pertuzumab
 - d. T-DM1
- Analysis of the Phase III HERA trial, which evaluated 1 versus 2 years of trastuzumab for patients with early-stage HER2-positive BC, demonstrated no difference in outcomes in patients receiving trastuzumab for 2 years versus 1 year.
 - a. True
 - b. False
- 4. Results of a Phase II study reported at the 2013 San Antonio Breast Cancer Symposium by Tolaney and colleagues demonstrated that the adjuvant regimen of weekly paclitaxel and trastuzumab was well tolerated with few recurrences in patients with node-negative, HER2-positive BC.
 - a. True
 - b. False
- 5. Which of the following side effects have been associated with pertuzumab?
 - a. Diarrhea
 - h. Rash
 - c. Both a and b
 - d. Neither a nor b

- 6. The Phase II ATEMPT trial is evaluating
 _______ versus paclitaxel/
 trastuzumab for patients with Stage I
 HER2-positive BC.
 - a. AC → TH
 - b. Single-agent trastuzumab
 - c. T-DM1
 - d. All of the above
- 7. Which of the following agents is being evaluated for patients with HER2-positive BC and brain metastases?
 - a. ARRY-380
 - b. Neratinib
 - c. Intrathecal trastuzumab
 - d. T-DM1
 - e. All of the above
- 8. The Phase III CALGB 40603 trial evaluated the addition of carboplatin and/or _____ to neoadjuvant dose-dense

AC for patients with TNBC.

- a. Bevacizumab
- b. Neratinib
- c. Enzalutamide
- 9. Side effects that may be associated with administration of everolimus include
 - a. Abdominal pain
 - b. Diarrhea
 - c. Rash
 - d. Stomatitis
 - e. All of the above
- 10. The Phase II VELVET trial is evaluating the combination of pertuzumab and trastuzumab with ______ as first-line treatment for HER2-positive mBC.
 - a. Paclitaxel
 - b. T-DM1
 - c. Vinorelbine
 - d. All of the above

Educational Assessment and Credit Form Visiting Professors Breast Cancer, Issue 1, 2014

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How would you characterize your level of knowledge on the following topics?

	4 = Excellent	3 = Good	2 = Adequate	1 = Suboptimal
			BEFORE	AFTER
Phase II trial results of adjuvant paclitaxel/tr node-negative, HER2-positive BC	rastuzumab for		4 3 2 1	4 3 2 1
Emerging clinical trial data evaluating primary patients with Stage IV BC	y tumor resection f	or	4 3 2 1	4 3 2 1
Intrathecal trastuzumab for leptomeningeal m	netastases in HER2-	positive BC	4 3 2 1	4 3 2 1
ATLAS and aTTom trials: Continuing adjuvant stopping at 5 years for ER-positive early BC	ars versus	4 3 2 1	4 3 2 1	
Activity of T-DM1 in patients with HER2-posit	tive brain metastas	es	4 3 2 1	4 3 2 1
Practice Setting:	☐ Community	Cancer Cente	r/Hospital	☐ Group Practice
☐ Solo Practice ☐ Government (eg, VA)		,		
Approximately how many new patients with	n breast cancer do	you see per	year?	patients
Nas the activity evidence based, fair, bala n ⊃ Yes No	nced and free from	n commercial	bias?	
If no, please explain:				
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