Challenging Cases in Breast Cancer

Oncologist and Nurse Investigators Consult on Actual Patients from the Practices of the Invited Faculty

Audio Highlights



Proceedings from a Satellite Symposium Held in Conjunction with the 2012 Oncology Nursing Society Annual Congress

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Moderator

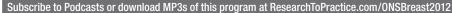
Neil Love, MD



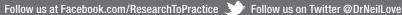
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OVERVIEW OF ACTIVITY

Breast cancer is one of the most rapidly evolving fields in oncology nursing. Published results from 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, oncology nurses must be well informed of these advances and their associated efficacy benefits and related toxicities. This program provides nurses with access to the latest research developments in the systemic treatment of breast cancer and the perspectives of expert oncology nurses and clinical investigators regarding the application of this emerging research information to patient care. Upon completion of this CNE activity, oncology nurses, nurse practitioners and clinical nurse specialists should be able to formulate a more up-to-date and evidence-based approach to the care of patients with breast cancer.

LEARNING OBJECTIVES

- Use case-based learning to formulate individualized disease-management strategies for patients with breast cancer.
- Discuss the benefits and risks associated with evidence-based systemic therapies used in the treatment of breast cancer, including endocrine agents, chemotherapy regimens and biologic treatments.
- Identify opportunities to enhance the collaborative role of oncology nurses in the comprehensive biopsychosocial care
 of patients with breast cancer.
- Recall ongoing trials of investigational approaches in breast cancer, and refer patients and obtain consent for study participation.

ACCREDITATION STATEMENT

Research To Practice is accredited as a provider of continuing nursing education by the American Nurses Credentialing Center's Commission on Accreditation.

CREDIT DESIGNATION STATEMENT

This educational activity for 1.5 contact hours is provided by Research To Practice during the period of August 2012 through August 2013.

HOW TO USE THIS CNE ACTIVITY

This is an audio CNE program. This book contains CNE information, including learning objectives, faculty disclosures, a Post-test and an Educational Assessment and Credit Form. The corresponding website **ResearchToPractice.com/ONSBreast2012** also includes links to relevant abstracts and full-text articles.

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SELECT PUBLICATIONS

Aapro M et al. Anthracycline cardiotoxicity in the elderly cancer patient: A SIOG expert position paper. *Ann Oncol* 2011;22(2):257-67.

Baselga J et al. Everolimus in postmenopausal hormone–receptor–positive advanced breast cancer. $N Engl\ J\ Med\ 2012;366(6):520-9.$

Baselga J et al. Pertuzumab plus trastuzumab plus docetaxel for metastatic breast cancer. $N \ Engl\ J \ Med\ 2012;366(2):109-19.$

Baselga J et al. A Phase III, randomized, double-blind, placebo-controlled registration trial to evaluate the efficacy and safety of pertuzumab + trastuzumab + docetaxel vs placebo + trastuzumab + docetaxel in patients with previously untreated HER2-positive metastatic breast cancer (CLEOPATRA). San Antonio Breast Cancer Symposium 2011:Abstract S5-5.

Blackwell K et al. Primary results from EMILIA, a phase III study of trastuzumab emtansine (T-DM1) versus capecitabine (X) and lapatinib (L) in HER2-positive locally advanced or metastatic breast cancer (MBC) previously treated with trastuzumab (T) and a taxane. *Proc ASCO* 2012; Abstract LBA1.

Cortés J et al. 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.

Fabi A et al. HER2 protein and gene variation between primary and metastatic breast cancer: Significance and impact on patient care. Clin Cancer Res 2011;17(7):2055-64.

Gradishar WJ et al. A randomized Phase II trial of first-line metastatic breast cancer (MBC) patients: Sub-set analysis of albumin-bound paclitaxel (ab-pac) given weekly at 150 mg/m². San Antonio Breast Cancer Symposium 2011; Abstract P5-19-13.

Gradishar WJ et al. Significantly longer progression-free survival with nab-paclitaxel compared with docetaxel as first-line therapy for metastatic breast cancer. J Clin Oncol 2009;27(22):3611-9.

Perez EA et al. Efficacy and safety of ixabepilone (BMS-247550) in a phase II study of patients with advanced breast cancer resistant to an anthracycline, a taxane, and capecitabine. *J Clin Oncol* 2007;25(23):3407-14.

Punam R, Srikala S. Efficacy and tolerability of lapatinib in the management of breast cancer. Breast Cancer (Auckl) 2012;6:67–77.

Rugo H et al. CALGB 40502/NCCTG N063H: Randomized phase III trial of weekly paclitaxel (P) compared to weekly nanoparticle albumin bound nab-paclitaxel (NP) or ixabepilone (Ix) with or without bevacizumab (B) as first-line therapy for locally recurrent or metastatic breast cancer (MBC). Proc ASCO 2012; Abstract CRA1002.

Sharon H et al. Leuprolide acetate plus aromatase inhibition for male breast cancer. J Clin Oncol 2006;24(21):e42-e43.

Wong AL, Lee SC. Mechanisms of resistance to trastuzumab and novel therapeutic strategies in HER2-positive breast cancer. *Int J Breast Cancer* 2012;2012:415170.

POST-TEST

Challenging Cases in Breast Cancer: Oncologist and Nurse Investigators Consult on Actual Patients from the Practices of the Invited Faculty

QUESTIONS (PLEASE CIRCLE ANSWER):

1.	The mechanism of action of pertuzumab	A commonly reported side effect during treatment with T-DM1 is
	 a. Is the same as that of trastuzumab b. Is distinct from that of trastuzumab because pertuzumab binds to the dimerization domain of HER2 c. Allows for its use in combination with trastuzumab d. Both b and c 	 a. Alopecia b. Nausea c. Transient thrombocytopenia d. Transient neuropathy 6. The results of a Phase II trial of T-DM1 versus trastuzumab and docetaxel for patients with untreated HER2-positive
2.	The Phase III randomized CLEOPATRA study demonstrated a statistically significant advantage in with the addition of pertuzumab to trastuzumab and docetaxel in patients with metastatic breast cancer. a. Overall survival b. Progression-free survival c. Both a and b d. None of the above	metastatic breast cancer demonstrated a significant difference in in favor of T-DM1. a. Objective response rate b. Median progression-free survival c. Overall survival d. Both b and c 7. Benefits of nanoparticle albumin-bound (nab) paclitaxel include which of the
3.	T-DM1 is a novel agent that combines a maytansine derivative with a. Docetaxel b. Trastuzumab c. Bevacizumab d. None of the above	following? a. Avoidance of corticosteroid premedications b. Shorter infusion time than standard paclitaxel c. Oral administration d. Both a and b
4.	Neutropenia is one of the most commonly occurring side effects associated with the chemotherapy drug eribulin. a. True b. False	8. Which of the following toxicities can be associated with everolimus? a. Stomatitis b. Mucositis c. Interstitial pneumonitis d. All of the above

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 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 $3 = Good$ $2 = A$	Adequate 1	= Suboptimal							
	BEFORE	AFTER							
Novel agents pertuzumab and T-DM1 for the treatment of HER2-positive metastatic breast cancer	4 3 2 1	4 3 2 1							
Incorporation of the novel chemotherapy agents eribulin, <i>nab</i> paclitaxel and ixabepilone in the treatment of metastatic disease and the management of their side effects	4 3 2 1	4 3 2 1							
Emerging data with the mTOR inhibitor everolimus in combination with hormonal therapy for metastatic breast cancer: BOLERO-2 results	4 3 2 1	4 3 2 1							
Perspectives on hormone therapy in the treatment of male breast cancer	4 3 2 1	4 3 2 1							
Has the activity unfairly influenced you toward a particular product or Yes No	service?								
If yes, then describe what was presented:									
Will this activity help you improve patient care? Yes No No hot applicable									
If yes, how will it help you improve patient care?									
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									
4 = Yes $3 = Will consider$ $2 = No$ $1 = Already doing$ $N/M = LO not$									
As a result of this activity, I will be able to:									
Use case-based learning to formulate individualized disease-managements strategies for patients with breast cancer.	ent 4 3 :	2 1 N/M N/A							
Discuss the benefits and risks associated with evidence-based systemic therapies used in the treatment of breast cancer, including endocrine at chemotherapy regimens and biologic treatments	gents,	2 1 N/M N/A							
 Identify opportunities to enhance the collaborative role of oncology nurs in the comprehensive biopsychosocial care of patients with breast canc 		2 1 N/M N/A							
Recall ongoing trials of investigational approaches in breast cancer, and refer patients and obtain consent for study participation		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?													
What additional information or training do you need on the activity topics or other oncology-related topics?													
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 2 — Please tell us about t							-						
4 = Excellent 3 = Faculty	= Good			equate ct matter	1 = Sul			educat	hor				
Georgia Litsas, MSN, ANP-BC, AOCNP	4	3	2	1	4	3	2	1	.01				
Joyce O'Shaughnessy, MD	4	3	2	1	4	3	2	1					
Hope S Rugo, MD	4	3	2	1	4	3	2	1					
G Lita Smith, RN, ACNP	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					
Other comments about the faculty and moderator for this activity: Please recommend additional faculty for future activities: REQUEST FOR CREDIT — Please print clearly													
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