

THE BREAST CANCER SYMPOSIUM

SEPTEMBER 5-7, 2008

COSPONSORED BY



American Society
of Breast Disease

THE AMERICAN SOCIETY OF
Breast Surgeons



American Society of Clinical Oncology



AMERICAN SOCIETY FOR THERAPEUTIC
RADIOLOGY AND ONCOLOGY



National Consortium
of Breast Centers, Inc.



The Society
of Surgical
Oncology

EMBARGOED FOR RELEASE:
September 3, 2008, 6:00 PM (EDT)

CONTACT: Dan Sweet
571-483-1355
dan.sweet@asco.org

BREAST CANCER SYMPOSIUM HIGHLIGHTS NEW STUDIES ON BREAST CANCER SCREENING, TREATMENT AND ACCESS TO CARE

**– Black Women are Less Likely than White Women to Receive Radiation
Therapy after Lumpectomy;**

**Access to Radiation Can't Explain Higher Rates of Mastectomy Among Rural
Women;**

**Molecular Breast Imaging More Effective Than Mammography in Women with
Dense Breasts, Increased Cancer Risk;**

**Change in HER2 Status Suggests Why Some Women Do Not Respond Fully to
Trastuzumab –**

Washington, DC— New research on breast cancer treatment, detection and disparities in care were released today in advance of the 2008 Breast Cancer Symposium, being held September 5-7, 2008, at the Washington Hilton.

Studies highlighted today in a media webcast include:

- A study finding that black women are less likely than white women to receive radiation therapy following surgery for breast cancer, and these disparities vary greatly by region of the United States.
- A study finding that women in rural and urban areas have equivalent rates of radiation therapy following breast cancer surgery, suggesting that factors other than access to radiation are responsible for significant differences in mastectomy rates.
- A study concluding that molecular breast imaging detects three times as many breast tumors as mammography in women with dense breasts and an increased risk of breast cancer
- A study finding that there may be changes in the HER2 status of a tumor in about one-third of women who do not have a complete response to treatment with chemotherapy and the HER2-targeted therapy trastuzumab (Herceptin) before surgery.

It is estimated that more than 184,000 new cases of breast cancer will be diagnosed in the United States in 2008, and nearly 41,000 people will die from the disease.

2318 MILL ROAD, SUITE 800
ALEXANDRIA, VA 22314

571-303-2500
FAX: 571-366-9530

- More -

“We’ve seen major improvements in breast cancer treatment over the past several years, but it’s unacceptable that these advances are not reaching everyone in need. One of the highlighted studies demonstrates that disparities in care between black and white women persist. We need to work harder to close the gap in access to care,” said Eric Winer, MD, professor of medicine at Harvard Medical School, director of the Breast Oncology Center at Dana-Farber Cancer Institute and moderator of the press briefing. “Another study offers new insight into a promising and future alternative to mammography, while a third will help us personalize care based on a better understanding of the molecular characteristics of a patient’s tumor.”

The 2008 Breast Cancer Symposium is co-sponsored by the American Society of Breast Disease, The American Society of Breast Surgeons, the American Society of Clinical Oncology, the American Society for Therapeutic Radiology and Oncology, the National Consortium of Breast Centers, Inc. and the Society of Surgical Oncology.

Information for Media: www.asco.org/BCSpresskit08

Relevant Links on ASCO’s Cancer.Net:

- [Cancer.Net Guide to Breast Cancer](#)
- [Cancer.Net Feature: Breast Cancer: Questions to Ask Your Doctor](#)
- [Cancer.Net Feature: Frequently Asked Questions About Radiation Therapy](#)
- [ASCO Expert Corner: Race and Breast Cancer](#)
- [ASCO Expert Corner: Health Disparities in Cancer](#)
- [ASCO Patient Guide: HER2 Testing for Breast Cancer](#)
- [Cancer.Net Feature: Mammography – What to Expect](#)
- [Cancer.Net Feature: Breast MRI for Early Detection of Breast Cancer](#)

General Poster Session A
Friday, September 5
12:00 – 1:15 PM ET

Lead Author: Grace L. Smith, MD, PhD, MPH
M. D. Anderson Cancer Center
Houston, TX

Black Women Less Likely than White Women to Receive Radiation Therapy after Lumpectomy for Early-Stage Breast Cancer

(This summary contains updated data not in the abstract.)

An analysis of more than 37,000 Medicare records by researchers at MD Anderson Cancer Center found that among women who underwent lumpectomy for early-stage invasive breast cancer, black women were less likely than white women to receive standard post-operative radiation therapy, and that disparities varied greatly by geographic region.

Earlier studies have examined racial disparities in care provided to breast cancer patients, but this is the first to look at radiation therapy rates on a national scale and compare differences among geographic regions of the United States.

“The results of this study indicate that we need to identify and correct the obstacles that are causing these disparities, and work to increase awareness about the benefits of radiation therapy following lumpectomy among breast cancer patients,” said Grace Smith, MD, PhD, MPH, a postdoctoral fellow in the Department of Radiation Oncology at the University of Texas M. D. Anderson Cancer Center and the study’s lead author. “We don’t know if fewer black women are receiving radiation therapy because it is not offered to them, because they decline the treatment, or perhaps because they are unable to complete a whole course of treatment.”

The investigators used a national Medicare database to review treatment of all beneficiaries aged 66 and older who were treated in 2003 for early-stage, newly diagnosed breast cancer. They found that of 37,305 women treated with lumpectomy, 34,024 were white and 2,305 were black. Overall, 74 percent of white women received radiation therapy following lumpectomy, compared with 65 percent of black women. Researchers also examined rates of radiation in patients under age 70 in whom radiation therapy would be expected to be most common. They found that the disparity persisted (81 percent of white women received radiation therapy, versus 71 percent of black women).

Geographically, the largest racial disparities were seen in the East South Central region (72 percent of whites received radiation therapy versus 57 percent of blacks), the Pacific West (72 percent of whites versus 55 percent of blacks), and New England (70 percent of whites versus 58 percent of blacks). The smallest differences were seen in the Mountain West (76 percent for whites versus 74 percent for blacks), and the West North Central Midwest (74 percent for whites, 72 percent blacks). The researchers stated the reason for the differences in geographic regions is unclear and will be the subject of future studies.

Abstract # 91

Racial disparities in treatment for early invasive breast cancer: A national Medicare study of radiotherapy after conservative surgery

G. L. Smith, Y. T. Shih, Y. Xu, S. H. Giordano, B. D. Smith, G. H. Perkins, W. Tereffe, W. A. Woodward, T. A. Buchholz
Background: In breast cancer patients, evidence suggests that receipt of standard treatments varies by race. However, prior studies of racial disparities were conducted in limited samples, failing to include the majority of patients across the US. In a national sample of Medicare patients, we quantified racial disparities in radiotherapy (RT) use after conservative surgery (CS) for treatment of early invasive breast cancer. **Methods:** A national Medicare database identified all beneficiaries (age \geq 65) with newly diagnosed invasive breast cancer treated with CS in 2003. ICD-9 and CPT codes indicated receipt of RT. Medicare demographic data indicated race. Percent RT use in white vs. black patients was compared using Pearson χ^2 . Logistic regression modeled racial disparities in RT use adjusted for age and geographic region. **Results:** In 34,759 breast cancer patients treated with CS, 32,562 were white and 2,197 were black. Mean age was 75 \pm 7. 76% of whites received RT vs. 69% of blacks (P<0.001). After covariate adjustment, blacks were still less likely to receive RT (OR=0.62, 95% CI 0.56-0.69, P<0.001). Racial disparities varied significantly by region. Across regions, RT use ranged from 73% to 80% in whites, vs. 61% to 83% in blacks. Disparities existed in all regions except the Mountain West and portions of the Midwest. Blacks in the Pacific West, New England, and in

the East South Central region fared particularly poorly, with only 61% RT use. In the subset of patients age<70, in whom RT use would be expected to be most common, racial disparities persisted. Specifically, 84% of whites vs. 78% of blacks in this younger group received RT (P<0.001). **Conclusion:** In this unique, comprehensive national sample of older breast cancer patients, substantial racial disparities and regional variation existed for RT after CS. Future efforts to improve breast cancer care will require overcoming these considerable disparities.

Percent Use of Radiotherapy (RT) after Conservative Surgery (CS) by Race and Region				
Region	States	% RT in Whites	% RT in Blacks	P
Pacific West	CA, OR, WA	75	61	0.003
Mountain West	AZ, CO, ID, MT, NV, NM, UT, WY	79	83	0.57
Midwest, West North Central	IA, KS, MN, MO, NE, ND, SD	76	76	0.99
Midwest, East North Central	IL, IN, MI, OH, WI	79	74	0.03
Northeast, New England	CT, ME, MA, NH, NJ, NY, VT	73	62	<0.001
Northeast, Mid-Atlantic	DE, DC, MD, PA, RI	75	66	0.002
Southwest, West South Central	AR, LA, OK, TX	77	70	0.03
Southeast, East South Central	AL, KY, MS, TN	74	61	<0.001
Southeast, South Atlantic	FL, GA, NC, SC, VA, WV	80	74	<0.001

*Non-white, non-black race excluded. Separate data for each state available for the presentation.

Disclosures: Nothing to disclose.

General Poster Session E
Sunday, September 7
7:00 AM – 12:00 PM ET

Lead Author: Lisa K. Jacobs, MD
Johns Hopkins University
Baltimore, MD

Access to Radiation Therapy Not Driving Higher Mastectomy Rate In Rural Women

(This summary contains updated data not in the abstract.)

In an effort to identify the reasons for higher mastectomy rates in rural areas, researchers at Johns Hopkins University have found that rates of radiation therapy following breast cancer surgery do not differ between women who live in urban versus rural areas. The findings contradict the long-held belief that mastectomies are more common among women who live in rural areas because they do not have the same access to radiation therapy as urban women and thus cannot undergo less-invasive lumpectomy surgery, which must be followed by radiation therapy.

“This was a surprising finding. We thought that access to radiation was driving rural women to choose mastectomy over more conservative surgery with follow-up radiation, but our findings show this is not the case,” said Lisa K. Jacobs, MD, an assistant professor of surgery at Johns Hopkins University and the study’s lead author. “Since these findings show access to radiation therapy is not influencing women’s decisions about which type of surgery to have for breast cancer, we will need to start looking at other factors such as the quality of patient education about treatment options.”

The study also confirmed significant differences in mastectomy rates between rural and urban women. Nearly 60 percent (59.9) of rural women opted for mastectomy, compared with 44.9 percent of urban women.

Researchers examined nearly 80,000 patient records using data from the 2006 Surveillance, Epidemiology, and End Results database, combined with data from the 2004 Area Resource File (a government database that provides health-related information by county). Researchers looked at radiation therapy rates in two groups of urban and rural women: women who had lumpectomy and were indicated for follow-up radiation, and women who had mastectomy and were indicated for post-surgery radiation. Because patients who require radiation therapy after mastectomy usually do not know they will need radiation therapy until after their surgery has been completed, access to radiation therapy likely did not play a role in these women’s decisions about which type of surgery to have. These patients were thus a better measure of access to radiation facilities.

The researchers found that among women who had lumpectomy, 81 percent of urban women and 80 percent of rural women had follow-up radiation therapy. Among women who underwent mastectomy, 39 percent of urban women and 38 percent of rural women received radiation therapy.

A number of studies have documented that increasing distance to a radiation therapy site results in an increased rate of mastectomy, but this study suggests otherwise. Instead, this study finds that some other factor is playing a role in the decision for mastectomy because the rates of radiation in the two populations are the same.

Abstract # 238

Radiation therapy in urban and rural breast cancer patients

L. K. Jacobs, K. Kelley, D. Chang

Background: The higher rate of mastectomy in rural patients is attributed to poor access to radiation therapy (RT). To evaluate the use of RT in urban and rural patients, we analyzed patient and community factors to assess their impact on use of RT. We hypothesized that use of RT is lower in rural patients and that access to RT is the strongest predictor of use. **Methods:** This is a retrospective study of a combined dataset of the 2006 Surveillance, Epidemiology, and End Results (SEER) and 2004 Area Resource File (ARF), linked by the FIPS state county variable. Patients chosen from SEER had lumpectomy or mastectomy with an indication for RT. Patient variables chosen from SEER were age, stage, race, and marital status. Community factors used from ARF were income, employment, and education level, and radiation facility staff density of the patient’s county of residence. Bivariate and multivariate analysis was completed to assess the effect of each variable on use of RT. **Results:** The SEER database includes 59,663 women who had lumpectomy (7.37 % rural) and 19,488 women that had mastectomy with RT indicated

(10.28 % rural) as treatment for breast cancer. RT followed lumpectomy in 80.70 % and mastectomy in 38.53 %. Use of RT is equivalent in the rural and urban populations receiving either lumpectomy or mastectomy (Table). Age, race, stage and marital status affect the use of RT, but density of radiation facility staff does not. **Conclusions:** While the literature documents that poor availability of RT increases the mastectomy rate, this study found no significant differences in the use of RT between urban and rural populations. The availability of RT was examined and no affect on urban versus rural treatment was identified. Patients treated with mastectomy that had an indication for RT received that treatment at the same rate regardless of urban or rural residence. In contrast to other studies, this would suggest that the previously identified disparity in urban/rural mastectomy rate may not be a result of access to RT.

Use of RT in Urban and Rural Populations				
	Lumpectomy	Mastectomy	RT after Lumpectomy	RT after Mastectomy
Total	59,663 women	19488 women	81%	38%
Urban	93%	90%	81%	39%
Rural	7%	10%	80%	38%

Disclosures: Nothing to disclose.

General Poster Session E
Sunday, September 7
7:00 AM – 12:00 PM ET

Lead Author: Carrie B. Hruska, PhD
Mayo Clinic
Rochester, MN

Molecular Breast Imaging More Effective than Mammography at Detecting Cancer in High-Risk Women with Dense Breasts

In the largest study to date to compare a screening technique called molecular breast imaging (MBI) to mammography, researchers have shown that MBI can detect three times as many cancers in women who have dense breast patterns on their mammogram and are at increased risk of breast cancer. Mammography is the current standard of care for breast cancer screening. However, it can be difficult to distinguish normal breast tissue from tumor tissue in women with dense breasts using mammography. As a consequence, women who have dense breasts as well as other breast cancer risk factors often need additional screening.

MBI is a relatively new screening method in which patients are injected with a short-living radioactive agent that is absorbed by breast tissue. This agent is tracked with a specialized camera that can distinguish healthy tissue from breast cancer tumors, as cancer cells absorb more of the radioactive agent than healthy cells. MBI is currently available at a limited number of cancer centers, but its availability is growing. While more expensive than mammography, MBI is about one-fifth of the cost of breast MRI (magnetic resonance imaging).

“These results suggest that MBI could become an important screening tool for women who have dense breast tissue and increased breast cancer risk,” said Carrie B. Hruska, PhD, lead author of the study and a research fellow in the Department of Radiology at the Mayo Clinic in Rochester, Minnesota. “Larger trials are needed to further validate our research, but it is encouraging to find that MBI can detect cancers that are not easily visible on screening mammography. Our next step will be to compare MBI prospectively to other screening methods, such as MRI.”

In the study, 940 women were screened with both MBI and mammography. Participants had to meet two criteria: first, their breasts were determined to be dense by a previous mammogram; second, they had an increased risk of breast cancer due to personal or family history, a genetic mutation related to breast cancer, a previous precancerous condition, or a history of radiation therapy to the chest.

A total of 13 tumors in 12 patients were detected: eight by MBI alone, one by mammography alone, two by both techniques, and two by neither. The recall rates (the number of women who needed follow-up testing) were 7.7 percent for MBI versus 9.4 percent for mammography. Of the 36 biopsies prompted by MBI, 27.8 percent were positive for cancer; of the 17 biopsies prompted by mammography, 17.6 percent were positive for cancer.

Researchers are continuing to follow all of the patients in the study; to date, 375 have been followed for 15 months or longer after the initial screening. Based on follow-up screening in these women, researchers determined that the sensitivity (percent who were accurately diagnosed as positive for the disease) and specificity (percent of women who were accurately diagnosed as negative for the disease) of the two techniques. The sensitivity and specificity for MBI were 75 percent and 93.2 percent, respectively. The sensitivity and specificity for mammography were 25 percent and 91.3 percent, respectively.

Abstract # 68

Molecular breast imaging to screen for breast cancer in women with mammographically dense breasts and increased risk
C. B. Hruska, D. J. Rhodes, S. W. Phillips, D. H. Whaley, T. T. Alabin, M. K. O'Connor

Background: Molecular breast imaging (MBI) uses two opposing small semiconductor-based gamma cameras to image the breast in a comparable manner to mammography. The aim of this study was to evaluate MBI as a breast cancer screening method. **Methods:** MBI and screening mammography was performed in 940 women with mammographically dense breasts and increased risk of developing breast cancer. Following injection of 740 MBq Tc-99m sestamibi, craniocaudal and mediolateral oblique views of each breast (10 minutes/view) were obtained with a dual-head cadmium zinc telluride gamma camera. Two

radiologists read the MBIs while blinded to the mammographic interpretation and all ancillary patient information. A combination of pathology findings and clinical and/or imaging findings within a 15-month follow-up period was used to establish breast cancer status. **Results:** A total of 13 cancers in 12 patients were diagnosed. Eight cancers were detected by MBI alone, one by mammography alone, two by both modalities, and two by neither. Overall, MBI detected 10/13 cancers, mammography detected 3/13, and MBI plus mammography detected 11/13. Of eight patients with cancers detected only by MBI, three had film mammography and five had digital. The recall rates for mammography and MBI were 9.4% and 7.7% respectively. In the subset of 375 patients in whom >15 months have passed since the MBI, the sensitivity of MBI and mammography was 75% (6/8) and 25% (2/8), respectively, and the specificity of MBI and mammography was 93.2% and 91.3%, respectively. Of 17 biopsies prompted by mammography in 1.8% of patients, 17.6% were positive for cancer. Of 36 biopsies prompted by MBI in 3.5% of patients, 27.8% were positive for cancer. **Conclusions:** Mammography has reduced sensitivity in both women at increased risk and women with dense breasts. Interim results indicate that MBI is a promising adjunct to screening mammography for women in these categories. MBI detected 3 times as many cancers as mammography, with equivalent specificity and a higher positive predictive value.

Disclosures: Nothing to disclose.

Oral Abstract Presentation Session B
Saturday, September 6
2:00 – 3:30 PM ET

Lead Author: Elizabeth A. Mittendorf, MD
M. D. Anderson Cancer Center
Houston, TX

Change in HER2 Status May Explain Why Some Women Stop Responding to Trastuzumab

(This summary contains updated data not in the abstract.)

In a study of women with early-stage or locally-advanced HER2-positive breast cancer who did not have a pathologic complete response to the HER2-targeted therapy trastuzumab (Herceptin) and chemotherapy prior to surgery, nearly one-third had tumors that converted from HER2-positive to HER2-negative status during the treatment process.

About one-quarter of breast cancers are HER2-positive, which means that tumor cells overexpress the HER2 (human epidermal growth factor receptor 2) protein; these patients generally respond well to trastuzumab, a monoclonal antibody that targets the HER2 receptor. A significant number of patients who have HER2-positive disease, however, eventually stop responding to treatment with trastuzumab. Researchers sought to determine if conversion to HER2-negative disease might be a reason why.

“This phenomenon is important for providers to keep in mind so we can provide patients with the most appropriate targeted therapy for their cancer’s biology,” said Elizabeth A. Mittendorf, MD, an assistant professor in the department of surgical oncology at the University of Texas M. D. Anderson Cancer Center and the study’s lead author. “We don’t yet know on a molecular level what causes tumors to change. This is an area that deserves more research.”

The study included 143 patients treated at MD Anderson Cancer Center who initially tested HER2-positive and were given a combination of chemotherapy and trastuzumab before undergoing surgery. Of those patients, 50 percent achieved a pathologic complete response, defined as no evidence of invasive disease in the breast or lymph nodes at the time of surgery. Pre- and post-treatment tissue was available from 23 patients who did not have a pathologic complete response. Of those, 30.4 percent were found to have converted to HER2-negative status by the time they had surgery.

At a median follow-up of 10.2 months, the researchers also confirmed that patients who did not have a pathologic complete response to treatment with trastuzumab were about three times more likely to have their cancer recur than those who did achieve a complete response: two patients (2.8 percent) who achieved a pathologic complete response experienced a relapse of their cancer, compared with eight patients (11.3 percent) who did not achieve a complete response.

Abstract # 150

Determination of HER2 status in patients achieving less than a pathologic complete response following neoadjuvant therapy with combination chemotherapy plus trastuzumab

E. A. Mittendorf, F. J. Esteva, Y. Wu, F. Meric-Bernstam, K. K. Hunt, A. Buzdar, S. Dawood, G. N. Hortobagyi, A. Gonzalez-Angulo

Background: Pathologic complete response (pCR) rates of 60% have been reported in women with HER2-overexpressing breast cancer treated with neoadjuvant chemotherapy plus concomitant trastuzumab. This study was undertaken to determine the HER2 status in residual tumor identified at the time of surgery in patients not achieving a pCR. **Methods:** Clinicopathologic data for 141 patients with HER2-overexpressing breast cancer receiving neoadjuvant therapy with a taxane, anthracycline and concomitant trastuzumab between 2004 and 2007 were reviewed. pCR was defined as no evidence of invasive disease in the breast and axilla at surgery. Surgical specimens for patients achieving less than a pCR were assessed to determine if there was enough residual tissue to re-evaluate HER2 status using fluorescence in situ hybridization (FISH). **Results:** Of 141 patients receiving neoadjuvant chemotherapy with concomitant trastuzumab, 72(51.1%) achieved a pCR. A partial response was achieved in 59(41.8%) while 6(4.3%) had stable disease and 4(2.8%) had progressive disease. Pre- and post-therapy tissue was available in 23 patients with less than a pCR. In all 23, repeat FISH on pre-treatment specimens confirmed the tumors were HER2-amplified prior to beginning therapy. In 7 (30.4%), FISH determined the residual tumor obtained at the time of surgery to be HER2-negative. At a median follow-up of 10.2 months (range 1-40), 2(2.8%) patients achieving a pCR experienced a recurrence versus 7(10.1%) patients achieving less than a pCR (p=0.07). Enough residual tumor was present at the time of surgery to reassess

HER2 status in 4 patients who did not achieve a pCR and recurred: 2 were HER2-negative. **Conclusions:** Patients with HER2-amplified breast cancer treated with a taxane and anthracycline-based chemotherapy with concomitant trastuzumab in the neoadjuvant setting can achieve high pCR rates. Approximately one-third of patients not achieving a pCR are found to have converted to HER2-negative disease, therefore residual tumor identified at the time of surgery should be reassessed for HER2 status and adjuvant therapy recommendations need to be studied in this population.

Disclosures: Nothing to disclose.