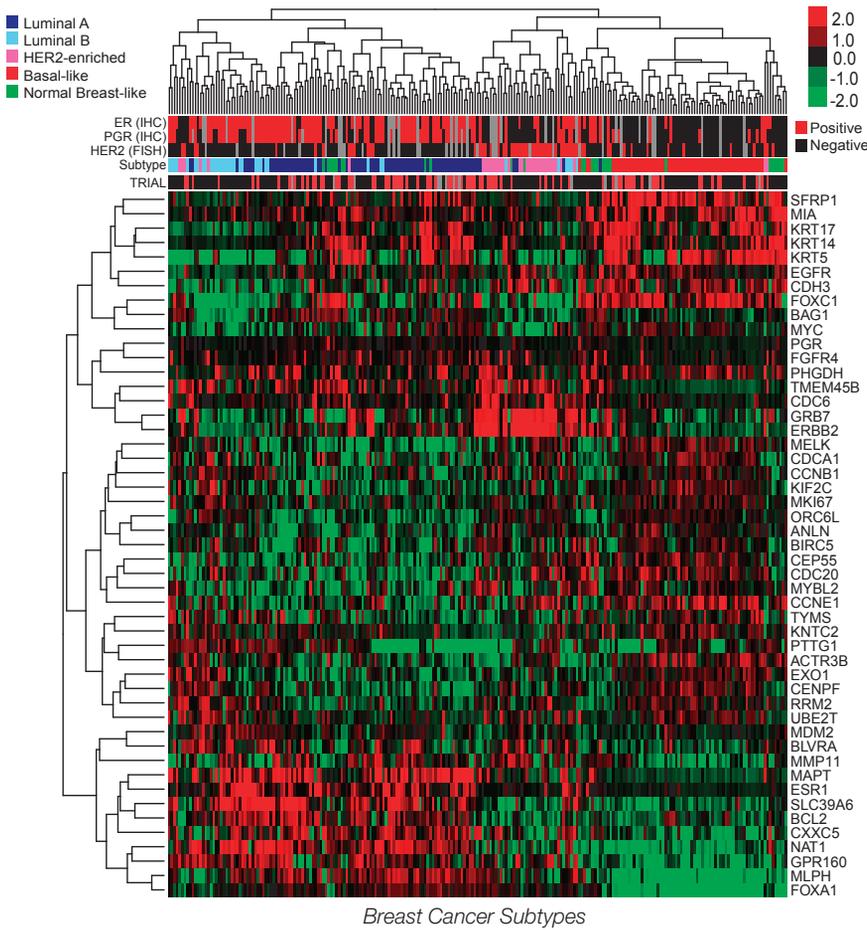


INNOVATIONS

in Cancer



Getting Personal: Genetics and Genomics Lead to Targeted Breast Cancer Treatments

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- Tomosynthesis helps pinpoint location, size and shape of breast tumors pg 3
- Risk reduction and early detection for high-risk breast cancer patients pg 6
- New radiation techniques may shield the heart during cancer treatment pg 7



University Hospitals Case Medical Center and Case Western Reserve University School of Medicine are consistently recognized as two of the premier institutions in the nation, according to U.S. News & World Report's annual rankings.

Toward a More Hopeful Future in Breast Cancer Treatment



In this issue of Innovations in Cancer, we focus on breast cancer because of the recent public discussion about the value and scope of mammography and tumor technologies for early detection of the disease. As well, there is increasing interest in the genetics of breast cancer and the importance of an accurate diagnosis for both treatment and prognosis.

For these reasons, the University Hospitals Seidman Cancer Center at UH Case Medical Center has organized its entire Breast Cancer Program in a manner that links accurate, early detection with genetics and treatment decisions through a highly coordinated team. Examples of this integrated team are found in the pages of this issue.

Lyndsay N. Harris, MD, who recently joined our institution as Director of the Breast Cancer Program, updates us on the latest developments, including a leading-edge emphasis on genomics. **Donna Plecha, MD**, discusses tomosynthesis, an innovative imaging approach that can improve diagnosis. **Robert R. Shenk, MD, FACS**, describes our new High-Risk Breast Cancer Program. **Janice Lyons, MD**, examines the role of cardioprotective radiation in the treatment of breast cancer.

In addition, two oncology leaders of our center have recently been recognized nationally, **Afshin Dowlati, MD**, and **Neal J. Meropol, MD**. The Cancer Therapy Evaluation Program bestowed on Dr. Dowlati the prestigious Michael C. Christian Oncology Development Lectureship and Award. Dr. Meropol has been elected to the Board of Directors of the American Society of Clinical Oncology, a leading and highly respected organization.

Finally, I want to point out how proud we are that UH Case Medical Center has received the 2012 American Hospital Association-McKesson Quest for

Quality Prize. The prestigious award named UH Case Medical Center the top hospital in the nation for its leadership and innovation in quality improvement and safety. The criteria for the 2012 award include the demonstration of an organizational commitment to and progress in achieving the Institute of Medicine's six quality aims – safety, patient-centeredness, effectiveness, efficiency, timeliness and equity. UH Case Medical Center is the first large, urban academic medical center to earn this coveted prize.

Stanton L. Gerson, MD
Director, University Hospitals Seidman Cancer Center and Case Comprehensive Cancer Center
Asa and Patricia Shiverick - Jane Shiverick (Tripp)
Professor of Hematologic Oncology, Case Western Reserve University School of Medicine
Director, National Center for Regenerative Medicine

Contact Us

We have many trials, including early stage trials, linked to our innovative approach to care. We would be glad to discuss interest or questions about these trials. You can contact any of the physicians listed in this issue. A more complete listing of our current trials can be found at UHSeidman.org.

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Contributors: Stanton L. Gerson, MD; Lyndsay N. Harris, MD; Janice Lyons, MD; Donna Plecha, MD; Robert R. Shenk, MD, FACS
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The commitment to exceptional patient care begins with revolutionary discovery. University Hospitals Case Medical Center is the primary affiliate of Case Western Reserve University School of Medicine, a national leader in medical research and education and consistently ranked among the top research medical schools in the country by U.S. News & World Report. Through their faculty appointments at Case Western Reserve University School of Medicine, physicians at UH Case Medical Center are advancing medical care through innovative research and discovery that bring the latest treatment options to patients.

Tomosynthesis: An Advance in Imaging Breast Cancers

Three-dimensional mammography provides better detection

■ By Donna Plecha, MD



Donna Plecha, MD, Director, Breast Imaging, Department of Radiology, UH Case Medical Center; Co-Director, UH MacDonald Women's Hospital Breast Centers; and Assistant Professor of Radiology, Case Western Reserve University School of Medicine

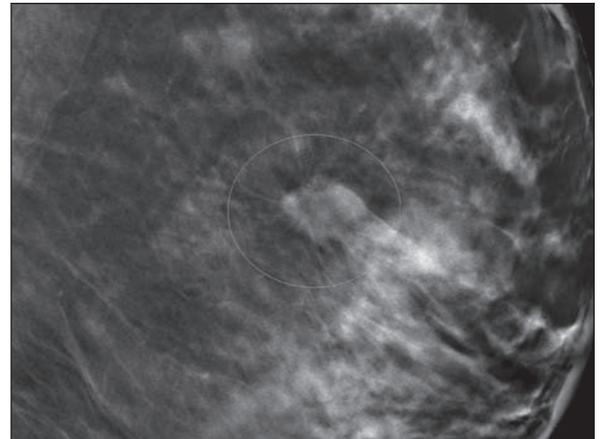
Early detection is key in the treatment of breast cancer. In fact, when breast cancer is detected early and confined to the breast, the five-year survival rate is now 98 to 100 percent. A major advancement for detection, tomosynthesis, is now available at the Breen Breast Health Pavilion, which is connected to UH Seidman Cancer Center. Tomosynthesis is an innovative technology that provides detailed, three-dimensional, exceptionally sharp images of the breast. It is an important new tool in our arsenal to detect breast cancer early. Tomosynthesis is also currently available at our UH Chagrin Highlands Breast Center. It will be available in 2013 at our UH Westlake Health Center.

During the test, the new system takes both standard digital mammograms and tomosynthesis images – nearly 200 1-millimeter-thick images for an average-sized breast, compared with four images in a regular 2-D digital mammogram – during the same imaging sweep of the breast. The machine's X-ray tube makes an arc over the patient, taking a series of low-dose images from different angles, similar to a CT scan. The additional images are then synthesized by a computer into a more detailed, highly focused, 3-D reconstruction of the breast. This can be viewed in 1-millimeter slices.

UH uses the Selenia® Dimensions® 3-D digital mammography system, manufactured by Hologic and approved by the FDA in early 2011.

By providing added detail, the 3-D images allow radiologists to identify and characterize individual breast structures and clearly see features that might otherwise be obscured. Dense tissue and overlapping tissue structures can lead to false positive or false negative results with standard 2-D mammography. Tomosynthesis helps radiologists more readily pinpoint the location, size and shape of the tumors, hopefully while they are small, early stage cancers. Recent studies of 10,000 to 25,000 women screened with tomosynthesis have shown 47 to 61 percent increases in cancer detection rates compared with 2-D digital mammography.

Tomosynthesis may also decrease the number of women who need to return for additional testing when a potential abnormality is detected. These return visits, which affect about 10 percent of mammography



Single thin slice from the 3-D tomosynthesis mammogram through the left breast showing a cancer that was not seen on the 2-D mammogram.

patients nationally, can be very stressful and can lead to additional patient costs when insurance plans consider them as diagnostic rather than screening mammograms. Studies have shown a decrease in callback rates of 30 to 38 percent with tomosynthesis compared with 2-D mammography.

Tomosynthesis provides more detailed, clearer views than traditional 2-D mammography, and recent studies have shown it to be beneficial for all patients when screening for breast cancer. Our patients are now offered the option for tomosynthesis when they arrive for their screening mammography. The entire process takes approximately the same time as standard, 2-D digital mammography alone, and the amount of breast compression is identical to a conventional mammogram.

Our best defense against breast cancer is detecting it early and curing it at a more treatable stage, and tomosynthesis provides us with an important new tool to decrease cancer mortality and save lives.

Contact Our Expert

To discuss tomosynthesis with Donna Plecha, MD, call **216-844-5330** or email **Donna.Plecha@UHhospitals.org**.

Personalized Medicine: Advances in Breast Cancer Treatment

Will identifying the genomic fingerprint of a tumor improve outcomes?

■ By Lyndsay N. Harris, MD



Lyndsay N. Harris, MD, Director, Breast Cancer Program, UH Seidman Cancer Center; and Professor of Medicine, Hematology and Oncology, Case Western Reserve University School of Medicine

The Breast Cancer Program at UH Seidman Cancer Center located on the campus of UH Case Medical Center is enhancing and increasing opportunities for clinical research in new therapies and molecular technologies as we move toward a program in personalized medicine for our patients with breast cancer.

High-Risk Group Program

Personalized medicine begins even before diagnosis, as soon as we recognize the presence of a high-risk predisposition to breast cancer. Identifiable genetic abnormalities predict that certain women and men will develop breast cancer. The UH Seidman Cancer Center's genetics program screens and consults with individuals in the community who think they might be at high risk for breast cancer. We can help those individuals who want to know how quantifiable that risk is and what their options are to help reduce their risk of developing cancer.

This High-Risk Group Program, run by **Robert R. Shenk, MD, FACS**, Co-Director of the Breen Breast Health Pavilion at UH Seidman Cancer Center; and Associate Professor of Surgery, Case Western Reserve University School of Medicine, is available to any patient who thinks he or she might be at high risk of developing breast cancer because of a family history or any concerning factor. We help our patients become fully informed about their true risk through evaluation, counseling and genetic testing, if it is appropriate.

When screening confirms that someone is at high risk of developing breast cancer, for example, due to the presence of an inherited gene like BRCA1 or BRCA2, we offer additional specific testing to clarify the individual's actual genetic predisposition. Dr. Shenk's clinic follows these patients to make sure they have access both to the most advanced screening for breast cancer and to novel clinical trials designed to develop new means of preventing breast cancer.

Our Breast Cancer Program merges our broad clinical experience with breast cancer with a state-of-the-art understanding of molecular biology – moving toward whole genome sequencing in patients who are potentially at high risk of developing this disease. We want not only to identify known genes but also discover potential new genetic predictors.

Opportunities for Patients

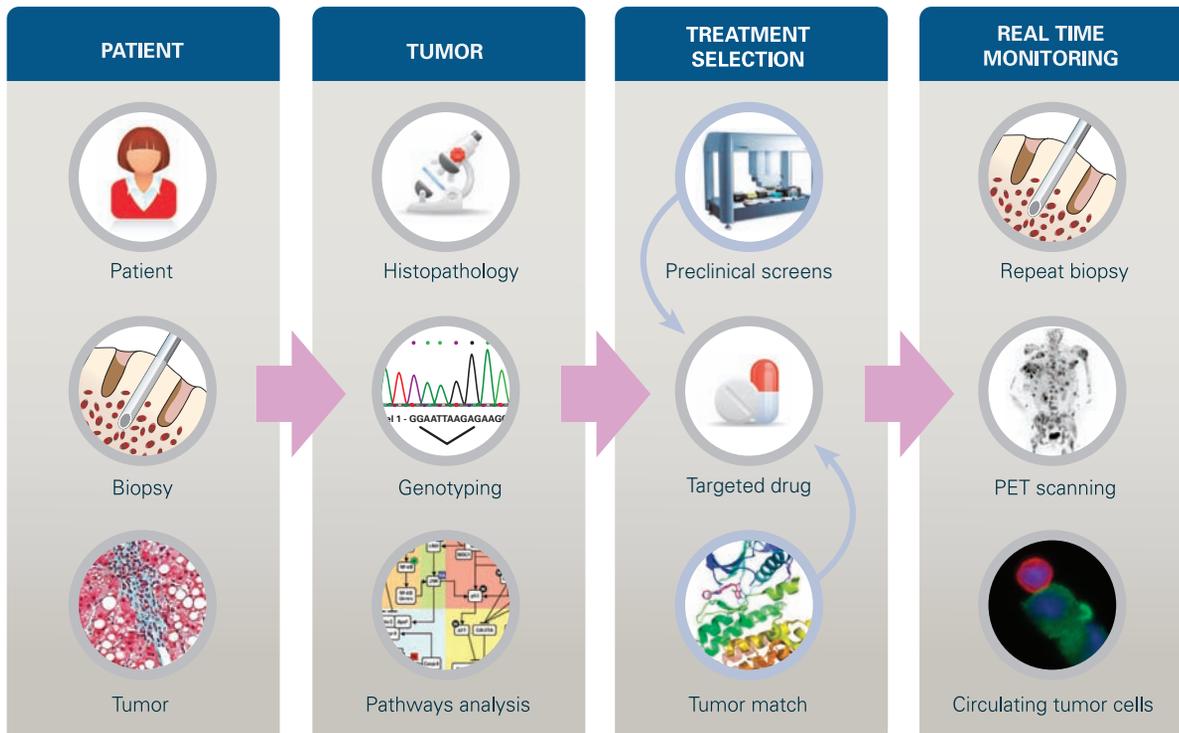
Our program also offers new opportunities to women with breast cancer. For example, **Donna Plecha, MD**, Co-Director of the Breen Breast Health Pavilion, and Assistant Professor of Radiology, Case Western Reserve University School of Medicine, leads the radiologic imaging group that, in addition to digital mammograms, provides tomosynthesis, a new, FDA-approved, three-dimensional digital mammography technique. Ours is the first group in Northeast Ohio to offer this approach, which reduces both false positive and false negative results found with digital mammography. And when indicated, our imaging group offers clinical trials in nuclear imaging and PET-MRI for the evaluation of response to treatment.

For breast cancer patients, we also focus on the genetics and genomics of their cancers to personalize their treatment. We hope that performing advanced genetic sequencing of the cancers will allow us to better determine the specific abnormalities in the tumors that may respond to specific targeted drug therapies. For instance, we know now that estrogen receptor-positive (ER+) and human epidermal growth factor receptor 2-positive (HER2+) breast cancers will benefit uniquely from specific targeted therapies. However, additional studies have shown that even within those groups of patients, specific genomic predictors may identify those most likely to benefit most from a given therapy. We are testing some of those predictors now in clinical trials.

Patients with Early Stage Disease

One study opening early in 2013 through the Case Comprehensive Cancer Center will enroll women with stage 2 or 3 breast cancer. They will be offered preoperative therapy in an attempt to shrink the tumor and improve surgical outcome. The study will enroll women with all types of receptor positive/negative breast cancers, but they will receive different preoperative targeted treatment regimens depending on the subtype of cancer that they have.

UH researchers also will look for specific genomic signatures in all participants at the time of their entry into the study to see if this will predict whether they are likely to benefit from a specific treatment protocol. For example, women who have early stage HER2-negative cancers have been shown to benefit from bevacizumab in the preoperative setting, but controversy still exists



Left: Matching each cancer with individually targeted therapy – steps toward implementing a new clinical strategy: In genotype-directed cancer therapy, the malignant tumor specimen is subjected to detailed biomarker analysis, including immunohistochemical as well as DNA-based markers. These biomarkers are interpreted within the relevant signaling pathway to identify a potential vulnerability for the cancer. Selection of an appropriate therapy (often oral agents of limited toxicity) is dependent upon prior preclinical validation of drug/genotype pairing and detailed analysis of drug/target interactions. Early drug response and development of acquired resistance are monitored by repeat biopsy of the tumor or, noninvasively, by functional imaging or circulating tumor cell analysis.

Image by: Haber, Gray, Baselga, "The Evolving War on Cancer," Cell 2011

over which of these women are most likely to gain the most. Using a genomic fingerprint of an individual's cancer, not just the determination of the presence or absence of receptors on the tumor cells, is the most up-to-date approach to this type of predictive testing.

We have a similar goal for women with advanced breast cancer. We plan to offer these women a resequencing or repeat analysis of the recurring tumor to help decide the best targeted therapy to treat the recurrence, also as part of a new clinical trial.

Personalized Care

We present the cases of all of our breast cancer patients to the entire multidisciplinary tumor board team to reach decisions about optimal therapy. For patients enrolled in our genomics clinical trials, we additionally will convene a multidisciplinary genomics tumor board, with representatives from surgical, medical and radiation oncology as well as pathology, cancer genetics and bioethics. The board will include a "genomics navigator," a person who is assigned to a patient to help her through the entire process. When a patient wishes to participate in a clinical trial, the navigator will explain details of the trial, genetic and genomic testing, the results of those tests, and the implications of those results for the patient and family members, as well as the details of the personalized treatment that is recommended.

Lyndsay N. Harris, MD

A nationally recognized expert in breast cancer treatment and research, Dr. Harris has focused her research into the genomic aspects of breast cancer and the development of novel strategies to evaluate and treat breast cancer. Her research includes the validation of a new 6-gene signature, discovered in her laboratory, that predicts complete response to trastuzumab, the molecular classification of response to therapy in HER2-positive, early stage breast cancer, and clinical trials investigating optimal therapy for various types of breast cancers. Dr. Harris came to UH Seidman Cancer Center from Yale, where she served as Head, Breast Medical Oncology, The Breast Center at Smilow Cancer Hospital at Yale-New Haven, and Co-Leader, Cancer Genetics and Genomics, Yale Cancer Center; and Associate Professor of Medicine, Medical Oncology, Yale Medical School. At UH Seidman Cancer Center, she is the Director of the Breast Cancer Program and holds the endowed Diana Hyland Chair for Breast Cancer, and at Case Western Reserve University School of Medicine, she is Professor of Medicine, Hematology and Oncology. She is the principal investigator for several Phase I, II and III clinical trials for the treatment of advanced breast cancer. Dr. Harris has served leadership roles on several prominent national committees, including as the Associate Chair for Breast Cancer, American Society of Clinical Oncology Tumor Marker Guidelines Subcommittee, and the Alliance for Clinical Trials in Oncology (formerly Cancer and Leukemia Group B) Breast Committee Correlative Science Co-Chair, and currently serves on the Eastern Cooperative Oncology Group Breast Committee.

Contact Our Expert

To contact Lyndsay N. Harris, MD, call **216-844-3951** or email **Lyndsay.Harris@UHhospitals.org**.

High-Risk Management

Assessment of breast cancer risk enables optimal care

■ By Robert R. Shenk, MD, FACS



Robert R. Shenk, MD, FACS, Co-Director, UH Breen Breast Health Pavilion, Head, Section of Breast Surgery, UH Case Medical Center; and Associate Professor of Surgery, Division of Surgical Oncology, Case Western Reserve University School of Medicine

When we talk about patients at high risk of developing breast cancer, we need to begin with a definition of average risk, greater-than-average risk, and truly high risk.

We know that the average American woman has a lifetime risk of developing breast cancer in the range of 10 to 12 percent.

We assess an individual patient's actual risk by using a statistical model such as the Gail or Claus breast cancer risk assessment tools to estimate five-year risk scores. These models take into account factors such as the patient's age, the age at which she first had children, family history (which is more detailed in the Claus model) and any history of biopsy and the biopsy results (for example, atypical ductal hyperplasia); and they define the short-term risk fairly accurately as shown prospectively in clinical studies. The models can help us identify women who are at higher-than-average risk.

If the patient's family history suggests the presence of one of the known breast cancer genes, BRCA1 or BRCA2, then we refer the patient for immediate genetic testing and counseling through the genetics department. The lifetime risk of developing breast cancer rises to as high as 80 to 85 percent for a woman with BRCA1 or BRCA2. Even in this very high-risk group, some families develop ovarian but not breast cancers.

Two Directions

For patients who are found to be at high risk of developing breast cancer, we can offer two strategies: reducing risk and finding breast cancers earlier.

For example, taking an estrogen receptor blocker, such as tamoxifen, will reduce risk by 50 percent. We also counsel about additional risk reduction through exercise and possibly through maintaining adequate vitamin D levels. In women who have the BRCA1 or BRCA2 gene, that is, women at very high risk of developing breast cancer, prophylactic mastectomy is an option that reduces the risk by 90 to 95 percent.

We also have several options for identifying breast cancers earlier. Digital mammography and breast self-exam are the standard approaches, although the latter has been shown to reduce risk only in women who are at high, not average, risk. Mammography may miss cancer in about 10 percent of patients, with an even

For patients who are found to be at high risk of developing breast cancer, we can offer two strategies: reducing risk and finding breast cancers earlier.

higher percentage in younger women and women with dense breast tissue. Tomosynthesis (three-dimensional breast imaging, explained in greater detail on page 3) may identify breast cancer earlier in those individuals. MRI is an option (particularly in women with dense breast tissue), with false negatives occurring in only about 3 to 5 percent of individuals. MRI imaging, however, will produce more false positives than mammography, which can lead to unnecessary biopsies, and it is not recommended as a stand-alone screening approach.

Special High-Risk Program

Our High-Risk Group Program, part of our larger Breast Cancer Program, includes a special database of all patients who have received genetic testing and are known to carry the BRCA1 or BRCA2 gene. We are already following these patients closely, but now we will be able to offer these patients additional options when they become available, such as enrollment in special clinical trials of new preventive drugs or new screening approaches to identify tumors at an early stage.

We are also in the midst of a retrospective study of all of our patients who were identified as carrying the BRCA1 or BRCA2 gene to see which risk reduction strategies they have chosen to use, including prophylactic mastectomy, and how they have fared.

Contact Us

To consult about high-risk breast cancer patients, contact Gladys Stefanek, NP, at **216-844-7874**, or Robert R. Shenk, MD, at **216-844-3026**.

Cardioprotection During Radiation Therapy

Researcher explores whether new techniques will benefit patients with breast cancer

■ By Janice Lyons, MD



Janice Lyons, MD, Director, Breast Cancer Services, Department of Radiation Oncology, UH Seidman Cancer Center; Director, Residency Program, Department of Radiation Oncology, UH Case Medical Center; and Associate Professor, Radiation Oncology, Case Western Reserve University School of Medicine

At UH Seidman Cancer Center at UH Case Medical Center, researchers are looking at newer radiation techniques that may provide better protection of the heart during radiation treatment for breast cancer.

Many women who are diagnosed with breast cancer undergo radiation therapy as part of their treatment plan. Areas that typically receive radiation include the breast after breast conserving surgery or the chest wall following mastectomy, with or without regional lymph node irradiation.

Adjuvant radiation provides a potential survival advantage and improvement in local cancer control. Women with node positive breast cancer may benefit from comprehensive nodal irradiation, which encompasses larger volumes of normal tissues, including the heart.

Breath-Holding Technique

A breath-holding technique called deep inspiration, which uses an active breathing control (ABC) device, is one promising strategy for reducing the cardiac radiation dose. The technique is used frequently at UH Seidman Cancer Center. By moving the heart down and away from the chest wall during treatment, deep inspiration appears to offer some protection.

A study recently conducted at UH Seidman Cancer Center at UH Case Medical Center compared treatment plans for patients using intensity modulated radiation therapy (IMRT), which is a technique frequently used for organ sparing, deep-inspiration breath hold using the ABC device, and standard techniques. Comparison showed that the ABC device was far superior for patients with early stage, left-sided breast cancer, in terms of reducing the mean dose to the lung (3.6 vs. 7.8 Gy) and the heart (2.8 vs. 8.6 Gy).

Cardiac Risk Difficult to Assess

Initial studies looking at the benefit of adjuvant radiation suggested a cancer specific survival advantage with the addition of radiation, but no advantage in overall survival. It has been difficult, however, to quantify the effects of radiation on the heart for many reasons. Until about 10 to 15 years ago, computerized tomography (CT) scanning was not routinely used in radiation planning; therefore, cardiac dose parameters were not available. Another confounding factor is that it often takes many years for the damage from radiation to be realized, and the treatments used may be outdated by the time the research is reanalyzed for cardiac risk. Despite these problems, we can point to a study of 4,456 women



Patient receiving deep-inspiration breath hold using ABC device during IMRT.

treated between 1954 and 1983 in which researchers found a 1.76-fold higher risk of cardiac disease and a 1.33-fold higher risk of dying from vascular disease among those treated for left-sided breast cancer as compared with those with right-sided breast cancer.

Other, more recent studies also confirm that the risk of radiation-related cardiac damage still exists, especially in cases of left-sided breast cancer. For example, in 2008, Taylor and colleagues evaluated the radiation plans of 50 patients with left-sided breast cancer and five with right-sided breast cancer. Although the radiation dose to all cardiac structures was 1.2 to 2 Gy for right-sided patients, in half of those treated for left-sided cancer, part of the heart received a dose higher than 20 Gy. This higher dose has been shown to raise the risk of coronary artery stenosis in the mid- and distal left anterior descending artery, a common site of atherosclerosis leading to heart attack.

Recommendations for Radiation Oncologists

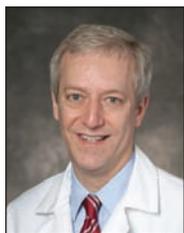
We still do not know the tolerance doses for radiation that reaches the heart and coronary arteries, although studies to determine these are under way. Until formal guidelines can be established, we recommend that radiation oncologists make efforts to protect the heart during radiation treatment for left-sided breast cancer to reduce the risk of long-term cardiac damage.

Contact Our Expert

To contact Janice Lyons, MD, directly, call **216-844-2536** or email **Janice.Lyons@UHhospitals.org**.



UH Seidman Cancer Center Physicians Earn Prestigious Designations



Neal J. Meropol,
MD

Dr. Meropol elected as medical oncologist representative to ASCO Board

Neal J. Meropol, MD, has been elected to the American Society of Clinical Oncology (ASCO) Board of Directors. His term will begin at the ASCO annual meeting in June.

Dr. Meropol is Chief, Division of Hematology and Oncology, UH Case Medical Center; Associate Director, Clinical Programs, UH Seidman Cancer Center; Professor of

Cancer Research and Therapeutics, Case Western Reserve University School of Medicine; and Associate Director, Clinical Research, Case Comprehensive Cancer Center. He also holds the Dr. Lester E. Coleman, Jr., endowed chair in Cancer Research and Therapeutics at UH Seidman Cancer Center.

Since joining ASCO in 1993, Dr. Meropol has served as Chair of the Cancer Research Committee and the Comparative Effectiveness Research Task Force. He was a member of the Cancer Education Committee and the Scientific Program Committee, and he currently serves on the Cost of Cancer Care Task Force and the Cancer Communications Committee. Dr. Meropol is a Co-Chair for the ASCO/American Association for Cancer Research Methods in Clinical Cancer Research workshop. In addition, he is Co-Chair of the National Cancer Institute Gastrointestinal Cancer Steering Committee and an elected member of the Eastern Cooperative Oncology Group Research and Education Foundation Board of Directors.

"Neal is a national leader in clinical research and has an outstanding record as a clinical and translational investigator, as well as a leader in the field of oncology. He is the first medical oncologist in Cleveland to assume this national leadership position in the 30-year history of the society," says **Stanton L. Gerson, MD**. "ASCO is a prestigious and highly respected organization. Having a Cleveland voice will benefit our community."

Nominees for positions on the ASCO board are solicited from ASCO membership and undergo an extensive vetting process by the Nominating Committee before ballot selection.



Afshin Dowlati, MD

Dr. Dowlati receives national recognition for advancements to oncology

Afshin Dowlati, MD, received the prestigious Michael C. Christian Oncology Development Lectureship and Award from the Cancer Therapy Evaluation Program (CTEP), part of the National Cancer Institute (NCI). Dr. Dowlati holds the Rosalie and Morton A. Cohen Chair in Lung Cancer and is the inaugural Lucile and

Robert H. Gries Endowed Director at the Center for Cancer Drug Development at UH Seidman Cancer Center. He is also Associate Professor of Medicine, Division of Hematology and Oncology, Case Western Reserve University School of Medicine.

Dr. Dowlati was honored for his scientific accomplishments, program-building, and mentorship of the next generation of clinical researchers in oncology.

CTEP established the Christian award in 2007 to honor the 20-year NCI career of Michael C. Christian. The award recognizes the contributions of individuals to the development of novel agents for cancer therapy. The selection committee seeks an outstanding North American midcareer academic investigator who has demonstrated innovation or introduced/investigated new hypotheses or technologies in conception, design or performance of early phase clinical trials.

The award and presentation occurred at the annual NCI CTEP Early Drug Development meeting in October 2012.

"This award is a true tribute to the national impact and stature of Dr. Dowlati's discoveries in cancer therapeutics," Dr. Gerson says. "Dr. Dowlati is a respected clinician and leader in developing novel treatments and has built our early phase cancer therapeutics program as well as our lung cancer program into one of the best in the nation. The program is one of the crown jewels of the UH Seidman Cancer Center and is known worldwide for its exemplary clinical care and cutting-edge research."



Image courtesy of Apple

Win an Apple iPad 2!

Your feedback is important to us. As a medical professional, your input is invaluable in helping us shape future issues of Innovations in Cancer. We want to know what's important to you. Do you want to read about leading-edge research, learn about the latest technology, or hear firsthand case studies of how others in your specialty are improving and saving lives? Tell us what you want to read about and your name will be entered to **win one of two Apple iPad 2s!** Simply visit **UHhospitals.org/innovations**.