

NEW YORK-PRESBYTERIAN Oncology

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August 2003

Breast Cancer Survival: Assessing Risks and Outcomes

The slow but promising decline in breast cancer mortality over the past decade has provided an opportunity to shift the focus of research. At NewYork-Presbyterian Hospital, there is a new initiative to assess the effect of anticancer treatments on health outcomes other than control of malignancy.

Oncologic treatments can pose risks to the bones, heart, and cognitive function of patients undergoing them. The goal is to evaluate how therapies might be modified to improve these outcomes once the malignancy is cured.

“In some ways, we are now just trying to identify the right questions,” said Dawn Hershman, MD. “We need to identify the organs that are at risk, quantify the risk according to different therapeutic options, and then evaluate whether we can or should be modifying

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New Approaches in Breast Cancer Treatment and Staging

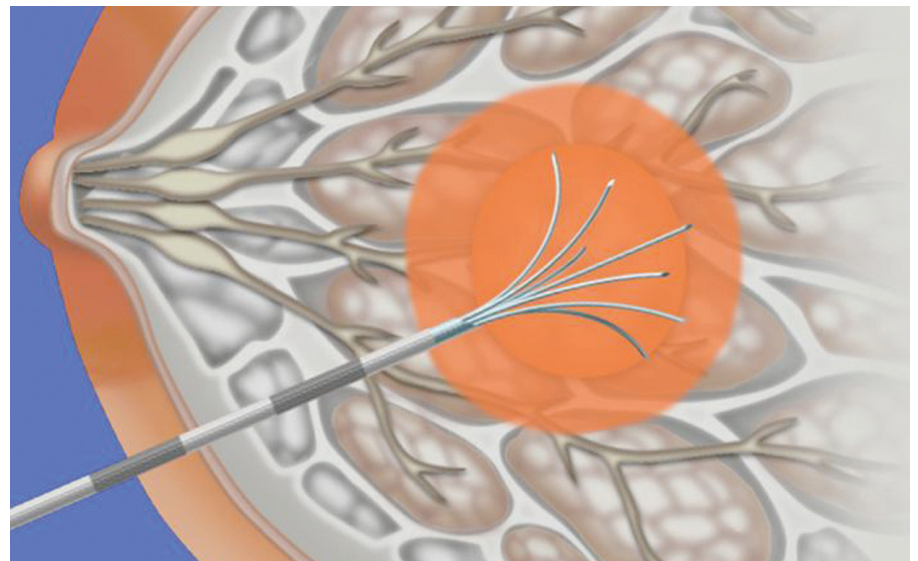
Researchers at Weill Cornell Breast Cancer Center are involved in studies of new ablation techniques and protocols at the forefront of breast cancer research. These techniques may eventually supplant the need for surgery in patients with small primary breast tumors, with bone marrow aspiration to detect micrometastases promising to be a powerful new prognostic tool in cancer staging.

Several ablation techniques are currently under investigation for the treatment of small primary breast tumors. One such technique is cryoablation, which involves the insertion of a small, ultrasound-guided probe into the tumor. The tip of the probe is chilled with argon gas to form an ice ball around the tumor, and then 2 cycles of freezing and thawing are conducted to ensure tumor cell death. One advantage of cryoablation therapy is that it doesn't require general anesthesia or sedation.

SPECIAL ISSUE FOCUS: BREAST CANCER UPDATE

“It can be done in the office, with the patient sitting up and alert,” explained Rache M. Simmons, MD, who is leading research into the efficacy of these relatively new approaches.

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In radiofrequency ablation, an ultrasound-guided electrode probe is inserted into a tumor, and another, larger electrode pad is placed on the skin surface.

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Patient Preferences and Outcomes: A Case for Quality-Adjusted Survival Analysis

Patients at high risk for cancer have unique needs, concerns, and expectations for their quality of life as they assess their future health and treatment options, and they rely heavily on their clinicians to guide them. At NewYork-Presbyterian Hospital, Victor R. Grann, MD, MPH, has focused much of his recent research on this aspect of physician-patient consultation.

“Determining patients’ expectations is a novel tool with potential to improve patient education and narrow any discrepancy between anticipated outcomes and reality,” said Dr. Grann. “It can empower patients to make informed treatment decisions.”

For a series of studies of patients at high risk for cancer, Dr. Grann and his team developed an expanded computerized decision model to predict the “quality-adjusted” survival benefits for those choosing particular courses of prophylactic treatment. The program endeavors to adjust traditional predictions of overall life expectancy in light of what the patient thinks about his or her particular health state at the time.

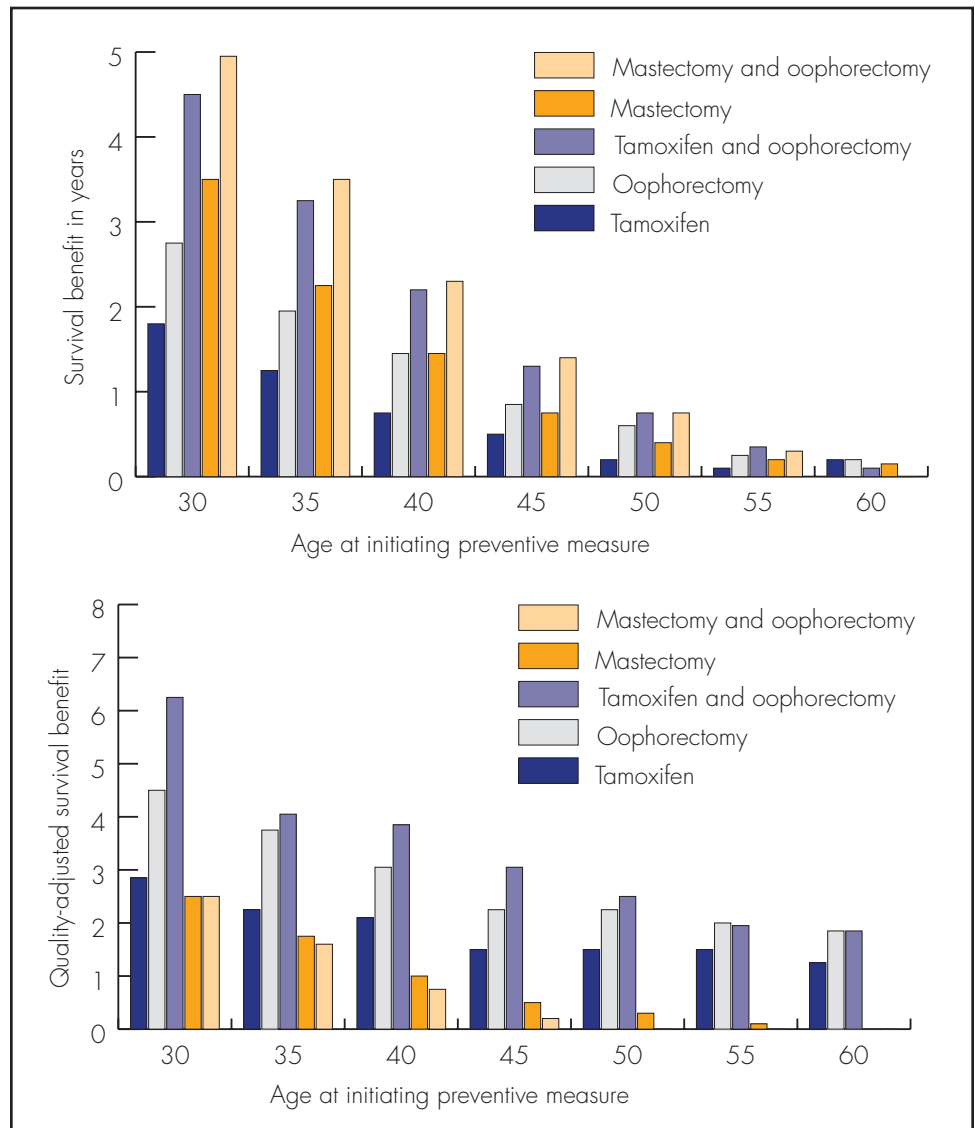
In one study—“Effect of Prevention Strategies on Survival and Quality-Adjusted Survival of Women with BRCA1/2 Mutations” (*J Clin Oncol* 2002;20:2520-2529)—Dr. Grann and his team found that women who test positive for BRCA1/2 mutations derive better survival benefits than previously reported from chemoprevention, prophylactic surgery, or a combination thereof. The study used as a model a 30-year-old woman who tested positive for a BRCA1/2 mutation and was found to be “at risk” for breast and ovarian cancer. According to Dr. Grann, researchers found that she could prolong her survival beyond that associated with conventional surveillance by taking preven-

tive measures, including tamoxifen treatment (1.8 years additional survival) and/or prophylactic oophorectomy/mastectomy (4.9 years additional survival).

Using patients’ preference ratings of cancer-related states obtained from another of his studies—“The Quality of Life Associated with Prophylactic Treatments for Women with BRCA1/2 Mutations” (*Cancer J Sci Am*

1999;5:283-292)—Dr. Grann and his team developed a measurement for quality-adjusted life years that took into account treatment efficacy, cancer risk, and “time trade-off” preferences (the number of years of a specified life expectancy the respondent is willing to trade to be free of the state described).

When adjusted for quality of life, the 30-year-old patient’s rating of survival



benefits from treatment with noninvasive tamoxifen or both tamoxifen and oophorectomy leapt to 2.8 years and 6.3 years, respectively, meaning she preferred these options, and their impact on her quality of life, to the alternatives. Research has shown the latter treatment course can reduce the risk of breast cancer by as much as 84%—provided intervention is initiated during a woman’s most productive and active years. In contrast, the quality-adjusted life year rating for highly invasive (and life-altering) procedures such as mastectomy or mastectomy-oophorectomy dropped to 2.6 years, even though these treatments may reduce the risk of breast cancer by as much as 90% (see chart, page 2). Overall, Dr. Grann finds that quality-of-life adjusted treatment preferences are influenced by the patient’s ethnicity, education, religion, marital status, and degree of risk to self and children.

“I was interested in what patients could expect [from various treatments] if they had tested positive for BRCA1/2,” Dr. Grann explained. “If you look at tamoxifen, which reduces the risk of breast cancer by 50%, the women we’ve studied rate that option much higher if they are at risk for breast cancer, even though the survival rate is lower.”

Ultimately Dr. Grann hopes his work will become the basis for establishing genetic screening as a standardized medical procedure for high-risk patients. With genetic information at their disposal, he said, patients at high risk can better decide whether or not to pursue preventive care—provided they are suitably informed about the options available. Unfortunately, many patients hesitate to undergo genetic testing, and many physicians hesitate to offer it, because of concerns related to insurance coverage.

“People are fearful of losing insurance, not being able to obtain health insurance, or being unable to get coverage after they change jobs, if genetic testing discovers a risk of cancer,” Dr. Grann noted. “That needs to change. Knowledge is a good thing. If a patient is at increased risk, and if he or she is willing to take protective action, he or she can do so.”

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NewYork-Presbyterian Oncology is a publication of the Cancer Centers of NewYork-Presbyterian Hospital. The Cancer Centers are at the forefront of cancer screening and diagnosis, and basic science and clinical research. The Cancer Centers serve over 6,500 new cancer patients each year, who receive state-of-the-art multidisciplinary care. The Cancer Centers include the Herbert Irving Comprehensive Cancer Center at Columbia Presbyterian Medical Center and the NewYork Weill Cornell Cancer Center, which are respectively comprised of physicians from the Columbia University College of Physicians & Surgeons and the Weill Medical College of Cornell University.

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Breast Cancer Radiation Offers Greatest Benefit at Least Exposure

In conjunction with an important study to evaluate the cosmetic effect of breast irradiation on women with different skin colors, research initiatives at NewYork-Presbyterian Hospital may contribute to new definitions of optimal breast radiotherapy in women who are candidates for conservative therapy on the basis of high likelihood of survival.

“With the advances in mammography, ultrasound, and magnetic resonance imaging (MRI), we have new opportunities to take a much more targeted approach. If we can avoid whole breast radiotherapy, we can minimize a host of problems and achieve a better outcome for the patient,” said Mary Katherine Hayes, MD. “We have several initiatives under way or planned with the MammoSite system, including a study on ductal carcinoma in situ. We hope these trials will define a conservative approach.”

Sandra Russo, MD, PhD, MPH, reports similar results with accelerated partial breast irradiation. The advances have been dependent on increasingly sophisticated imaging to select patients who are candidates for more localized radiotherapy. If clinical trials can prove that these imaging techniques identify patients at the lowest risk for occult microscopic malignancies, image-guided partial breast irradiation may be an option for a select group of patients.

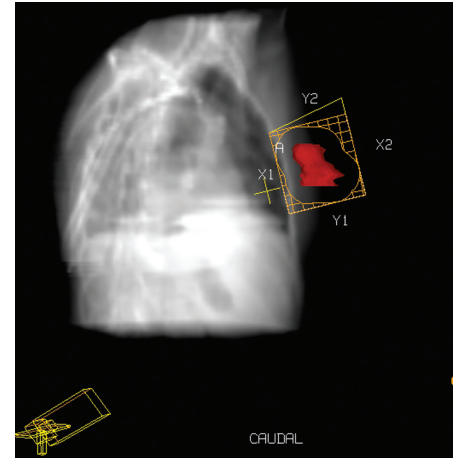
“After lumpectomy, all patients may not require whole breast radiotherapy,” said Dr. Russo. “In carefully selected patients, we will be testing whether accelerated partial breast radiotherapy, which involves administering a relatively higher daily dose of radiotherapy once or twice a day over 1 to 2 weeks, is sufficient. If we could reduce the time needed for a course of radiotherapy and are able to obtain the same outcome, this may lead

to more patients receiving a breast-conservative approach.”

Patient selection is the key variable for both initiatives. The MammoSite technology, which involves implanting a catheter and balloon for targeted and localized delivery of radiotherapy, requires a large enough breast to accommodate the device. In addition, the studies in early breast cancer are being confined to women over age 45 with suitably small and focal tumors. In these patients, the radiotherapy is delivered on an outpatient basis twice per day for 5 days, after which the balloon and catheter are removed. Compared to a conventional irradiation course of 6 weeks, this represents a large reduction in the demands of therapy.

“At the present time, more than 350 MammoSite procedures have been performed. We will collect 5-year follow-up data on these patients and compare them with those receiving standard radiation treatment before MammoSite is used as a conventional treatment,” Dr. Hayes observed. “If we carefully select women who are at low risk and have highly confined lesions, I think we can successfully localize therapy to reduce the morbidity of this therapy.”

The concern with partial breast irradiation is that occult microscopic lesions outside of the lumpectomy bed and not visualized on mammography, breast ultrasound, or breast MRI will not be treated. However, Dr. Russo pointed out that the majority of recurrences after conservative surgery and whole breast radiotherapy occur within the same quadrant of the breast as the original tumor. If patients with occult breast lesions distant from the primary tumor site can be excluded by use of multimodality breast imaging, partial breast irradiation may be as effective in preventing breast recurrences as the



Simulated radiation therapy treatment-planning film with computed tomography-defined volume of the lumpectomy cavity (volume in red). Margin is added around the lumpectomy cavity to define the area that will require treatment with radiation therapy.

conventional whole breast approach.

Researchers are currently enrolling patients in clinical trials of partial breast irradiation. These trials are needed to establish the long-term data required for changes in conservative management.

“Reducing the volume of breast tissue requiring tumoricidal doses of radiation may make it possible to administer larger doses of radiation per fraction without significant toxicity,” said Dr. Russo. Moreover, such sophisticated delivery systems as 3-dimensional conformal radiation therapy and intensity-modulated radiation therapy may have substantial advantages for delivering localized radiation to the lumpectomy bed.

“Intensity-modulated radiation therapy uses computerized algorithms to deliver more conformal radiation therapy, improving dose uniformity within the treatment area,” Dr. Russo added.

According to Dr. Hayes, the improved
see Radiation, page 8

Staging

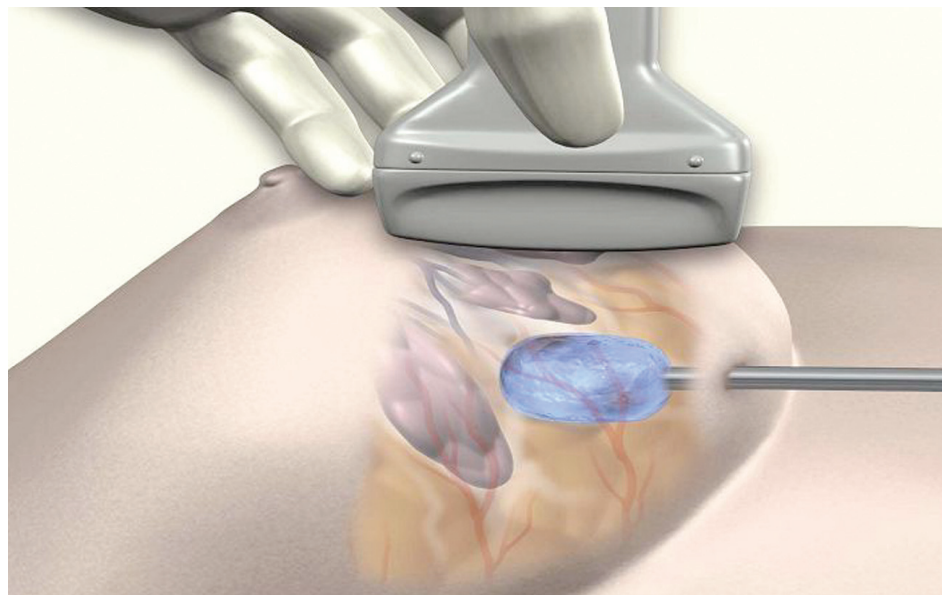
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The Weill Cornell Breast Cancer Center is also embarking on a protocol involving focused magnetic resonance angiogram for small tumor ablation. No probe is necessary because the ultrasound works transcutaneously.

“An advantage to this technique is that you can cater the ablation zone to the shape of the tumor,” said Dr. Simmons. “Not all tumors are spherical; with focused ultrasound, you can make irregular shapes to fit the shape of the tumor.”

Radiofrequency ablation, like focused ultrasound, uses heat to destroy the tumor cells. With radiofrequency ablation, an ultrasound-guided electrode probe is inserted into a tumor, and another, larger electrode pad is placed on the skin surface.

As the ions in the tissue attempt to follow the high-frequency current between the electrodes, the tissue heats up and gets hottest where the current is greatest, at the small electrode in the tumor. Weill Cornell Breast Cancer



Cryoablation involves the insertion of a small, ultrasound-guided probe into the tumor.

Dr. Simmons is also studying new tools in breast cancer staging. Bone marrow aspiration promises to be an important prognostic supplement to tumor and axillary node staging. The procedure is minor, and is usually performed while the patient is sedated or under general anesthesia for breast cancer surgery (ie, lumpectomy or node dissection). Bone marrow aspirate,

need for more aggressive therapy than might be indicated based on sentinel node evaluation or tumor size. “With bone marrow aspiration, we may be able to tease out which of these patients, otherwise thought to have a good prognosis, may actually have circulating tumor cells and are at a higher risk of relapse and decreased survival,” explained Dr. Simmons. “If we can offer these women up-front chemotherapy, it might make a huge difference as far as their prognosis.”

Marrow aspiration can also be performed after treatment to determine the efficacy of a particular chemotherapy regimen or to check for disease recurrence. “We are also thinking about repeating the bone marrow aspiration 6 months after treatment, because there are data that suggest that some patients who were negative initially will turn positive, or who are positive and will stay positive,” said Dr. Simmons.

This information will allow the physician to tailor chemotherapy treatment more quickly to the response of the patient. “The more information, the better,” she added.

“We may be able to tease out which patients, otherwise thought to have a good prognosis, may actually have circulating tumor cells and are at a higher risk of relapse and decreased survival.”

—Rache M. Simmons, MD

Center was part of a recently completed study on radiofrequency ablation. Results from the study were very promising; radiofrequency ablation was shown to be effective in treating small, primary breast tumors.

Tumor ablation is an advance in the evolution of minimally invasive treatment for breast cancer. Potentially, early breast cancers may be treatable one day without surgery at all. “In 10 years’ time, ablation may replace lumpectomies entirely when treating small, primary breast cancers,” Dr. Simmons said.

obtained from the anterior iliac crest of each hip, is then processed in the lab for cytopspins that are stained for polymerase chain analysis to detect micrometastases.

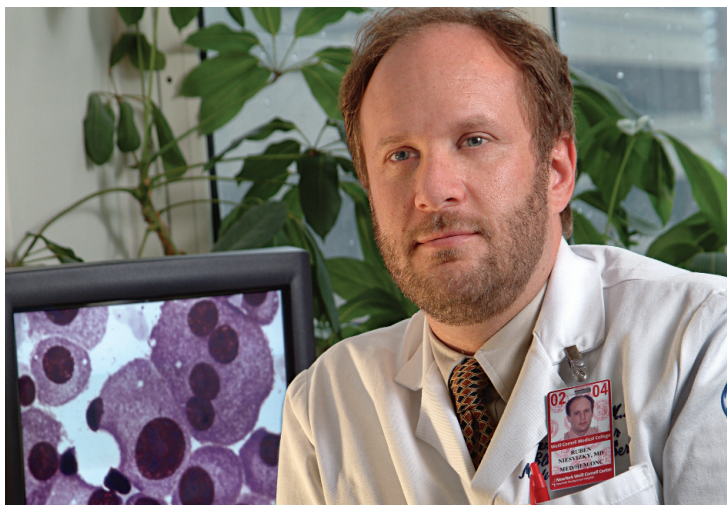
Traditionally, the decision to treat the patient with chemotherapy has been based on tumor size and axillary node involvement. However, approximately one third of patients with small tumors who are node negative nonetheless have recurring breast cancer. Detection of micrometastases through bone marrow aspiration can alert the physician to the

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Investigating Novel Multiple Myeloma Therapies

Although multiple myeloma has been a challenging malignancy, the development of novel small-molecule drugs, monoclonal antibodies, and second-generation chemotherapies has produced some forward strides. At NewYork Weill Cornell Medical Center, an ambitious set of clinical trials is accepting patients at virtually every stage of the disease into therapeutic regimens aimed at defining the leading edge of optimal care.

“We have maintained a strong focus on drug development,” said Ruben Niesvizky, MD. “There are many new agents in the pipeline, including those in Phase III trials with substantial clinical promise.” Although trials evaluating drugs in late stages of



Ruben Niesvizky, MD: “We have maintained a strong focus on drug development. There are many new agents in the pipeline.”

Phase II trial with a histone deacetylase inhibitor, which targets an enzyme that is important to proliferation of several different types of malignant cells,” Dr.

to be both more active and better tolerated than its parent thalidomide, making it easier to use and potentially increasing its therapeutic index. Both drugs are being evaluated in relapsed or refractory multiple myeloma, but some promising activity may move these into use at earlier stages.

“We are doing some work with new strategies in newly diagnosed multiple myeloma, including a trial in which patients are being randomized to thalidomide plus dexamethasone or dexamethasone alone, with or without clarithromycin,” Dr. Niesvizky noted. “The goal in multiple myeloma, like many other malignancies, is to define an optimal therapeutic approach and then build on it by altering doses, changing schedules, or adding drugs.”

NewYork Weill Cornell Medical Center is able to participate in so many clinical trials because of the size of its multiple myeloma program. As a leading referral center, the Hospital manages a diverse patient population and can accommodate a range of patient desires relative to innovative treatment strategies. This has resulted in a systematic approach to redefining therapeutic standards.

“Multiple myeloma is a difficult disease to treat, but we have a growing number of options to offer,” Dr. Niesvizky observed. “This is a strength, as we constantly search for more effective therapies to improve care.”

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“The goal in multiple myeloma, like many other malignancies, is to define an optimal therapeutic approach and then build on it by altering doses, changing schedules, or adding drugs.”

—Ruben Niesvizky, MD

clinical development are typically multi-center collaborations, it is not uncommon for NewYork-Presbyterian Hospital to be the largest single recruitment center. In Phase I studies, work at the Hospital is defining future therapeutic directions.

“We have a Phase I study underway with a radiolabeled molecule that has substantial theoretical promise, and a

Niesvizky said. NewYork Weill Cornell Medical Center, he added, is the only institution currently involved in testing of the histone deacetylase inhibitor in multiple myeloma.

Closer to mainstream use are PS-341 and the new-generation thalidomide CC-5013. Both are in Phase III trials. Bortezomib is a new small-molecule proteasome inhibitor. CC-5013 appears

Survival

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therapy or supportive care in order to reduce these risks.”

Investigators are developing methods of evaluating the adverse effects of current therapies on the cardiovascular system and the brain, but change in bone density and long-term risk of fracture is an area of particular focus. Because of their malignancy, women with breast cancer are not candidates for the hormone replacement therapy that can modify the risk of osteoporosis, even though their risk for bone loss may be increased by current interventions.

“As we move patients from tamoxifen, a therapy that provides some protection

against bone loss, to the aromatase inhibitors, some of which may actually exacerbate bone loss, this is an issue that

domized trial of bisphosphonates in women at high risk who are being treated for an early stage of breast cancer.

“We do not really know who to screen, when to screen, how often to screen, or what level of bone density we should use as a marker for the need for treatment. In fact, we may never be able to answer all the relevant questions. But knowing what questions we should be asking is a step forward.”

—Dawn Hershman, MD

A Take on ATAC

The Anastrozole, Tamoxifen, Alone or in Combination trial (ATAC) was launched in 1996 to determine which of the following pharmacologic therapies for breast cancer treatment is most effective: anastrozole alone, tamoxifen alone, or anastrozole and tamoxifen together. More than 9,300 women with early-stage disease are participating in the double-blind study.

The study is designed to give treatment to every participant for 5 years, or until she experiences a recurrence of breast cancer. Women joined the study gradually, over the course of 4 years, beginning in July 1996 and ending in March 2000. Early results from the trial were first reported in 2001, with an update in 2002. Final results are scheduled to be completed in 2005.

Based on the early study findings, anastrozole was approved by the US Food and Drug Administration in September 2002 for treating postmenopausal women with early-stage, hormone-receptor-positive breast cancer.

deserves to be addressed,” Dr. Hershman observed. “When we are talking about long-term survival, we need to get a handle on the relative risks of osteoporosis, weigh these in the context of the efficacy of the therapies, and evaluate what changes we might make in management to modify these risks.”

Among the issues prompting researchers such as Dr. Hershman to take a closer look at the risk posed by adjuvant breast cancer therapies for osteoporosis were the results of the Anastrozole, Tamoxifen, Alone or in Combination trial. The initial findings in the trial associated anastrozole with a prolonged disease-free survival and the reduced risk of contralateral breast cancer relative to tamoxifen.

The hazard ratio for disease-free survival, as reported at the last San Antonio Breast Cancer Symposium, was 0.83 ($P=.013$). The odds ratio reduction of cancer in the contralateral breast was 58% ($P=.007$). Results are preliminary, with follow-up for only 3 of the planned 5 years, but preferential use of anastrozole, which reduces the availability of estrogen and may adversely affect bone density, has important implications for the noncancer risk of osteoporosis in long-term survivors.

Prophylactic strategies for osteoporosis are already being explored at NewYork-Presbyterian Hospital through a ran-

The strategy is to preserve bone quality to reduce the rate of fracture in survivors as they age into the period of greatest risk. However, even if the therapy is effective, Dr. Hershman will be working to address the question of when and in whom prophylaxis of bone loss should be considered.

“We do not really know who to screen, when to screen, how often to screen, or what level of bone density we should use as a marker for the need for treatment,” Dr. Hershman acknowledged. “In fact, we may never be able to answer all the relevant questions. But knowing what questions we should be asking is a step forward.”

As the proportion of women who survive breast cancer increases, efforts to reduce the health risks posed by cancer therapies is becoming a significant concern. By evaluating how to adjust cancer therapies to minimize short- and long-term risks, it is hoped that ongoing studies at NewYork-Presbyterian Hospital will lead to substantial improvements in the quality of life of survivors.

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Radiation

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delivery systems are important, but it is the improvements in the imaging systems that have pushed forward the attempts to localize therapy.

As work towards a conservative approach proceeds, a new effort to characterize the cosmetic impact of external-beam radiotherapy may revise the definition of an optimal result. In a recently funded pilot study, the first systematic evaluation of skin discoloration from radiotherapy may outline the final hurdle to optimal breast conservation. Skin discoloration from radiotherapy may seem a minor problem relative to breast cancer survival, but as survival is similar between women managed with breast conservation and those who undergo mastectomy, the issue of preserving optimal appearance of the breast in women who choose conservation deserves more

systematic evaluation.

“One of the goals of breast-conservation therapy is to preserve a cosmetically acceptable and intact breast, but there is relatively little objective data on what *cosmetically acceptable* means, particularly in regard to changes in skin color,” noted Shermian Woodhouse, MD, MPH. “In women with skin of different hues and tones, this may mean different things, and this is what we will address in the pilot study.”

Once data on skin color changes are collected, using a narrow-band spectrophotometer to measure skin color objectively, a larger trial is anticipated in which these data will be correlated with patient and physician perceptions of outcome. The intention is to use these data to consider potential treatment modifications that might yield benefits.

“Potentially, these data could be used in the process of developing new regimens to reduce skin and soft tissue toxicity,” Dr. Woodhouse explained.

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