

Research Advocacy Network

OPTIONS

*News on Cancer Research and Therapy***Breast Cancer: Issue 1**

... From the Editor

We are delighted to welcome you to the premier issue of *Options: News on Cancer Research and Therapy*. This newsletter will provide the reader with coverage of the latest developments in cancer clinical research and treatment. Each issue will feature a particular disease condition, clinical problem, or approach to treatment. This inaugural issue focuses on early-stage breast cancer and adjuvant treatment. We are pleased to be able to bring you the results of a few studies reported at ASCO 2004. (See boxes.) Articles begin with a report on recently published studies, which provide further support for the treatment option called aromatase suppression. We include a snapshot of some of the most provocative research relating to treatment with chemotherapy

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New Options for Hormonal Treatment

Postmenopausal women with breast cancer who switched to the aromatase inhibitor exemestane (Aromasin) after receiving 2 to 3 years of the standard drug tamoxifen were significantly more likely to be free of cancer after 5 years than were those who stayed on tamoxifen, according to results of a study published in the March 11 issue of the prestigious *New England Journal of Medicine*. Five years of tamoxifen is the current standard of care for adjuvant hormone therapy in the treatment of postmenopausal women with estrogen-dependent disease.

More than 4700 postmenopausal women from the US, Europe, and South America with estrogen receptor-positive breast cancer participated in the study. All completed 2 to 3

years of adjuvant hormone therapy with tamoxifen and then were given either exemestane or tamoxifen for another 2 to 3 years. The women who received exemestane experienced significantly fewer cancer recurrences. In fact, their risk of cancer relapse was reduced by about 33%. Moreover, the side effects were mild. The results were striking, according to the researchers.

Chief investigator Charles Coombes, MD, Hammersmith Hospital, London, England, said, "Even though it is too soon to say that women should change their current regimen of adjuvant hormone therapy, this research may encourage doctors to reconsider their approach to treating a key breast cancer popula-

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Menopausal Symptoms Are Similar With Exemestane and Tamoxifen

Women receiving either exemestane or tamoxifen had similar menopausal symptoms, according to early results from an ongoing 5-year study comparing the effects of the 2 drugs on cancer-free survival in postmenopausal women with node-positive, early breast cancer. In fact, there were no differences in the severity of such symptoms as vaginal bleeding, mood swings, impaired word finding, energy levels, and hot flashes. Women on exemestane were more likely to have vaginal dryness and bone or muscle aches, while tamoxifen patients reported more cases of vaginal discharge. Overall, most symptoms were mild or moderate in nature, and many women said they experienced those symptoms at the start of the trial as well.

The contents of this newsletter are offered for your information only and should not be considered medical advice. Please discuss any of this information with your health care team in making treatment decisions.

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New Options for Hormonal Treatment

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tion: postmenopausal women with estrogen receptor–positive disease.” More studies will be necessary to

determine how best to use these new treatments.

Postmenopausal women with breast

cancer should consult with their physicians to determine if this agent would be appropriate for them. ■

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Exemestane Increases Bone Formation in Postmenopausal Women With Early Breast Cancer

Exemestane (Aromasin) is a steroidal aromatase inactivator that works through a different mechanism than other drugs in the class, and researchers have proposed that the compound may cause little or no bone loss. The renewal of bone is responsible for bone strength throughout life. Old bone is removed (resorption) and new bone is created (formation). The combination of resorption and formation is called bone remodeling. The results of one study concluded that exemestane does significantly reduce the amount of estrogen and increases the amount of resorption. Exemestane also increased bone formation, resulting in bone remodeling. There was no change in the bone mineral density of patients. The second study found that there was no bone loss in the spine but there was minor deterioration in the femoral neck. More research is needed to confirm these early findings that show that exemestane has only a small effect on bones.

Aromatase Inhibitor After Tamoxifen Improves Disease-Free Survival in Postmenopausal Women With Breast Cancer

In the first clinical trial to test the effectiveness of an aromatase inhibitor following 5 years of tamoxifen, postmenopausal women with breast cancer who received letrozole (Femara) were more likely to be free of disease after 2.5 years than women who were given placebo. In fact, the

benefit from letrozole was so great that the study was stopped early and reported immediately in the November 6, 2003, issue of the *New England Journal of Medicine*.

Nearly 5200 postmenopausal women from the United States, Canada, and Belgium with early-

stage, estrogen receptor–positive breast cancer enrolled in the trial. All had completed a course of nearly 5 years of tamoxifen hormone therapy. They were to receive either letrozole or placebo for an anticipated 5 years. Letrozole patients experienced fewer cancer recurrences; overall, the risk of relapse dropped by 43%. Most women in the study tolerated the side effects. The primary side effects from letrozole were hot flashes (47.2%), joint pain (21.3%), inflammation of the joints (5.6%), and muscle pain or tenderness (11.8%). As a result of these dramatic results, the independent monitoring board in charge of the trial terminated the research after only 2.4 years.

Lead researcher Paul Goss, MD, Princess Margaret Hospital, Toronto, Canada, stated, “It is important to note that because the study was stopped

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Quality of Life Maintained in Postmenopausal Women With Early Breast Cancer Taking Letrozole

Women who were given letrozole (Femara) in the MA.17 trial had more low-grade hot flashes and bone and muscle pain than those who received a placebo. However, a closer examination of the evidence revealed that the aromatase inhibitor did not harm overall quality of life. A slightly greater percentage of women receiving letrozole experienced changes in physical function, pain, vitality, and menopausal symptoms, but the investigators said these complaints were expected, based on the small number of women who reported any side effects while receiving letrozole during the trial.

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early, we were not able to answer a number of questions. We do not know letrozole's effect on overall survival, how long to continue treatment, and how safe the drug is over time. However, postmenopausal women with hormone receptor-positive disease who have completed 5 years of adjuvant tamoxifen hormone therapy should be considered for letrozole."

Based on this study, women should discuss letrozole therapy with their physicians if they:

- are postmenopausal
- had early-stage breast cancer (stage I or II) that was positive for estrogen or progesterone receptors
- have been on tamoxifen for between 4.5 and 6 years
- are approaching the end of their 5 years of tamoxifen
- have recently ended tamoxifen therapy

Certain women are not candidates for letrozole. Those who:

- are premenopausal
- have yet to complete 5 years of tamoxifen therapy
- currently are taking anastrozole (Arimidex) as adjuvant hormone therapy instead of tamoxifen
- are newly diagnosed with estrogen receptor-positive breast cancer. The only approved hormonal treatments for new patients are tamoxifen and anastrozole. ■

San Antonio Highlights: The Latest Research Findings

Each year in December, cancer specialists from around the world gather in San Antonio for a 4-day review of the latest research in the prevention, detection and diagnosis, treatment, and prognosis of breast cancer. The San Antonio Breast Cancer Symposium is well recognized as one of the most important in the field. Last year, more than 50 patient advocates were in attendance. Here are some highlights from last year's meeting.

TAC Improves Survival

Many studies have shown that combinations of drugs known as taxanes (paclitaxel/Taxol and docetaxel/Taxotere) and anthracyclines (doxorubicin/Adriamycin and epirubicin/Ellence) are very effective in treating metastatic breast cancer. As a result, researchers have begun to study if they are also beneficial as adjuvant chemotherapy in women with early-stage disease. (Adjuvant chemotherapy is a course of drug

treatment that follows surgery. It is designed to prevent recurrence of the disease by helping to eliminate any remaining cancer cells.)

In 2002, researchers from the Breast Cancer International Research Group in Los Angeles reported that after 33 months, a combination of docetaxel (Taxotere) and doxorubicin (Adriamycin), along with another drug, cyclophosphamide (Cytosan or Neosar), which is known as TAC, reduced the risk of recurrence and death in women whose cancer had spread to their lymph nodes. The physicians compared TAC with a more traditional regimen of 5-fluorouracil (Adrucil or 5-FU), doxorubicin, and cyclophosphamide, called FAC. Last year in San Antonio, the scientists reported that the benefits of TAC are still seen after nearly 5 years: 75% of women receiving TAC were disease free, compared with 68% of those on FAC. Overall survival also was greater for women receiving TAC, although they were more likely to develop fevers and infections due to lower white blood cell levels. Based on these findings, TAC may be preferable for some patients. Women with breast cancer are encouraged to discuss this treatment option with their physicians.

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presented at the 2003 San Antonio Breast Cancer Symposium. Finally, *Options* includes a primer for patients who have just been diagnosed with breast cancer. It suggests ways to adjust to the emotional impact of the diagnosis, provides tips for communicating effectively with health care professionals, and includes additional resources to consider for further information and support services. Though intended for new patients, the helpful suggestions and advice should be of value to all. We hope this will give you a sense of the scope of new research currently being done at the nation's universities, scientific laboratories, and pharmaceutical companies.

We welcome and look forward to your feedback on this issue, as well as suggestions and contributions for forthcoming issues. Please write to *Options*, Research Advocacy Network, 309 East Rand Road, Suite 175, Arlington Heights, IL 60004; phone: 877.276.2187 or e-mail: options@researchadvocacy.org. We hope to hear from you. ■

San Antonio Highlights: The Latest Research Findings

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Waiting up to 12 Weeks to Begin Chemotherapy Does Not Affect Survival

When is the best time to begin adjuvant chemotherapy after breast cancer surgery? Researchers from the British Columbia Cancer Agency in Vancouver, Canada, used information from breast cancer and pharmacy databases to try to determine whether the start date of chemotherapy influenced how well patients responded to treatment.

In the study, the women were divided into 4 groups, based upon how soon chemotherapy was started after surgery: Group 1 (0–4 weeks), Group 2 (4–8 weeks), Group 3 (8–12 weeks), and Group 4 (12–24 weeks). Women in the first 3 groups had similar rates of survival, about 85%. However, women in Group 4, whose chemotherapy started after 3 months, fared significantly worse. Their survival rate was only 78%. Thus, it does not seem to matter when drug therapy begins, so long as the start of chemotherapy is not delayed past 12 weeks, the physicians said. These findings should reassure patients that waiting to gather more information, getting a second opinion, making arrangements for work or family needs during treatment, or just taking some time will not affect their survival.

New Gene-Based Test May Predict Breast Cancer Recurrence in Certain Patients

When clinicians plan treatment for breast cancer patients with estrogen receptor–positive, lymph node–negative disease, they use a number of factors to predict how the cancer will progress. Unfortunately, some of these factors, such as tumor size and the patient’s age, are not completely reliable, and others, such as tumor grade, vary from lab to lab. Thus, cancer specialists have long sought a better

means to determine if a patient’s cancer will return. Physicians from the National Surgical Adjuvant Breast and Bowel Project (NSABP), a research cooperative group in Pittsburgh, Pa, and Genomic Health, Inc, in Redwood City, Calif, used a new test, which analyzes 21 genes, a number of which are known to be related to breast cancer. At San Antonio, the team presented results that indicated that this new test may be helpful in predicting the likelihood of cancer recurrence in certain patients.

Nearly 700 women in the trial were divided into 3 risk groups — low, intermediate, and high — based on their “recurrence score,” which was drawn from their results on the gene test. The study showed that women in the low-risk group had the fewest new cancers, while those in the high-risk group had more than 3 times the rate of recurrence and lower survival rates. As a result, the researchers concluded that the gene test may more accurately predict cancer progression than age, tumor size, and tumor grade. However, there are

some limitations to the test. It is only for newly diagnosed patients who are estrogen receptor–positive and whose lymph nodes are negative. The test cannot be used in women who have already been diagnosed and begun treatment. Women who still have treatment decisions to make should consult their physicians to see if they are candidates for this test.

Survival Following Mastectomy and Chemotherapy: The African-American Experience

Does race predict survival in women with breast cancer? Researchers from the M.D. Anderson Cancer Center in Houston looked at data from a number of clinical trials in which Caucasian, Hispanic, and African-American women received a mastectomy and either postsurgical or presurgical chemotherapy. The results were striking. In both pre- and postsurgical groups, African-Americans did worse than either Hispanics or Caucasians — they had significantly lower survival rates, while Hispanic and Caucasian

About the Research Advocacy Network

The patient advocacy movement has changed the face of research. Patient advocates have provided invaluable input into medical research. The mission of the Research Advocacy Network (RAN) is to develop a network of advocates and researchers who can influence medical research from concept to patient care through education, support, and collaborations. One of the most important aspects of the research process is moving research results into clinical practice. RAN works to accomplish this goal in several ways: Fact Sheets were created to explain the results of the MA.17 trial and the exemestane studies; *Network News*, an e-newsletter, is published monthly and covers a variety of topics, including describing research results and tools for advocates; and this newsletter and its companion for health care providers, *UpDate*.

For more information, visit the RAN Web site at www.researchadvocacy.org or call 1-877-276-2187.

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women had about the same. One reason for the difference, the scientists suggested, might be that while Hispanic and Caucasian women shared similar tumor characteristics, such as size, stage, and estrogen receptor status (more were ER-positive), African-American women had more aggressive

disease. They had larger first tumors, more advanced tumors, and a higher rate of ER-negative disease. (These are 3 standard measures of cancer prognosis.) The researchers stated that race does predict the rate of survival in breast cancer. They called for more studies to try to find out why this is

true. Patients and doctors should take this information into consideration when making treatment decisions. In addition, it is especially important for African-American women to participate in screening programs and talk to their doctors about their risk of developing breast cancer. ■

Making Sense of the Studies

New research is helping physicians and patients better understand how to use adjuvant chemotherapy to extend the quality and length of life. Women with breast cancer face many treatment choices. One of the most important decisions concerns the use of adjuvant chemotherapy. This supplementary course of drug therapy is designed to help rid the body of any remaining cancer cells following surgery and is especially beneficial in women whose disease is in the early stages. Adjuvant chemotherapy is often given as a combination of drugs or a cocktail. A core component of the

combination may be a member of a class of medicines known as anthracyclines. These drugs, which include such agents as doxorubicin (Adriamycin) and epirubicin (Ellence), are among the most effective chemotherapies currently available.

New Combinations

For many years, physicians recommending adjuvant therapy relied upon a combination of 3 drugs, cyclophosphamide (Cytoxan or Neosar), methotrexate (Amethopterin or MTX), and fluorouracil (Acrucil or 5-FU), often referred to as CMF.

Recently, results from 2 large studies from Great Britain showed that adding epirubicin (Ellence) to CMF decreased the likelihood that cancer would return. The combination also improved survival. The studies, known as NEAT and SCTBG, tested how well women whose cancer had not spread to their lymph nodes fared when receiving epirubicin plus CMF. The researchers found that the addition of epirubicin made a significant difference in outcomes. Patients who were given both treatments were 30% less likely to see their cancer return than were women who received only CMF. They also were more likely to experience a marked increase in survival.

In assessing the results, one of the researchers, Christopher Poole, MD, from the University of Birmingham said, "Through clinical trials, chemotherapy combinations have been refined over the years, and survival rates have improved. The knowledge gleaned from these trials should help women with breast cancer increase their access to the best possible treatment options."

Long-term Survival

Looking at a slightly different combination of drugs, researchers from the National Cancer Institute of Canada found a similar benefit with the addition of epirubicin (Ellence), and this time, the advantage was still

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Dose-Dense Sequential Chemotherapy Improves Survival, Compared With Conventional Dosing: German AGO Trial

A large-scale German clinical trial involving nearly 1300 women with high-risk breast cancer (4 or more positive lymph nodes) has shown that higher doses of sequential, dose-dense chemotherapy (every 2 weeks) with epirubicin (Ellence), paclitaxel (Taxol), and cyclophosphamide (Cytoxan or Neosar) (ETC) significantly improves both disease-free and overall survival, compared with a treatment plan using conventional (lower) doses of the same drugs (EC followed by T for 4 cycles given every 3 weeks). After more than 2 years of follow-up, the shorter, more intense dosing schedule reduced the risk of relapse by 36%, a highly significant finding, the investigators said. The dose-dense regimen that included higher doses of chemotherapy (thus a more "intense" regimen in addition to "dose dense") was fairly well tolerated, and patients did not experience any unusual or severe side effects, including cardiotoxicity. However, this interesting study cannot answer the question, Was it the increased dose of the drugs given in the ETC arm or the fact that they were given every 2 weeks instead of every 3 weeks that resulted in the improved results? Longer follow-up will be important to determine if there are long-term side effects due to the high doses of drugs given in this dose intense/dose-dense regimen.

Making Sense of the Studies

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evident as late as 10 years after treatment. More than 700 pre- and perimenopausal women whose cancer had spread to the lymph nodes received either classic CMF or a combination of cyclophosphamide (Cytoxan or Neosar), epirubicin (Ellence), and fluorouracil (Adrucil or 5-FU), known as CEF. Even after a decade, women who took CEF had significantly fewer cancer recurrences and a higher overall survival rate. While undergoing any course of chemotherapy can be a hardship, both physically and mentally, the knowledge that current treatments can help extend life over a long period of time can prove to be a source of comfort and strength for many women.

New Dosing Options

Timing, it is said, is everything, even in breast cancer therapy. Today, many clinicians are accelerating the course of treatment in the hope of improving the outcomes for patients. Instead of using the traditional 3-week course of treatment, doctors are giving the same amount of chemotherapy in a 2-week cycle. This approach, called dose-dense chemotherapy, is increasingly being used at leading hospitals around the country.

Researchers from the Cancer and Leukemia Group B, a cooperative group that conducts large clinical trials, looked at whether dose-dense adjuvant chemotherapy was better

than the standard schedule. They found that it was: after 4 years, 82% of the women in the dose-dense group were free of cancer, compared with 75% in the standard 3-week group. Of course, different women will respond differently to treatment. For a large portion of the population, dose-dense chemotherapy may increase their chances of remaining cancer free by about 10%.

While this study is very promising, the dose-dense method has not yet been evaluated over a long period of time, so doctors do not yet know the long-term rate of recurrence and all of the possible side effects. The approach also is expensive: dose-dense therapy can nearly double the cost of cancer care because of the addition of special drugs required to fight the higher rate of infection associated with this treatment method.

Dose-dense treatment is an important option for women with early-stage breast cancer, and they should discuss it with their physician. Besides the potential survival advantage, it helps women get on with their lives more quickly.

Does Age Make A Difference?

Many older women with newly diagnosed breast cancer do not receive adjuvant chemotherapy. Some are apprehensive and choose not to undergo the rigors of treatment.

However, others who are willing to face the difficult physical challenges may be denied care because doctors perceive that the effectiveness of chemotherapy in prolonging life diminishes with age. A recent study from the research team at the Cancer and Leukemia Group B cooperative group may help change some of these attitudes. The team analyzed data from nearly 6500 breast cancer patients who were enrolled in a number of the group's clinical trials. All received a variety of different doses and schedules of treatment. Looking at the length of time that the patients remained free of disease, the researchers found that clinical factors such as smaller tumor size and a lower number of positive lymph nodes were crucial predictors of outcome. Age, however, was not. Thus, even though older women in these trials had more advanced disease, they responded as well to treatment — and received similar benefits — as did younger women.

The decision to receive chemotherapy depends on many things: overall health, potential benefits, possible side effects, and the patient's preferences. This study suggests there is no scientific reason for women to be discouraged from receiving chemotherapy based on age alone. In making their decision, older women and their doctors should review carefully the benefits and risks of treatment. ■

“What do I do now?”—Getting Started on the Journey

A diagnosis of breast cancer can hit a woman like a clap of thunder. In a heartbeat, her life changes, irrevocably and forever. The rush of emotions tugs the mind in different

directions, leaving one feeling at sea, lost and hopeless. Soon, the thoughts and sensations settle, coalescing into a single question, “What do I do now?” The good news, the experts

say, is that helpful answers can be found.

“Newly diagnosed patients with breast cancer often go into overload,” said Terri Pedace, RN, research

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coordinator at Franciscan Skemp Healthcare in LaCrosse, Wisconsin, and a 5-year breast cancer survivor. “The implications are so overwhelming that it’s hard to know where to start.”

The most important thing, she said, is to have an accurate diagnosis. Once the condition has been confirmed, then the real decisions must be made.

In seeking the best possible treatment, patients should look for 3 “features” in their medical care, according to Debu Tripathy, MD, a medical oncologist and director of the breast cancer research program at the Uni-

versity of Texas Southwestern Medical Center in Dallas.

“Experience, the ability to communicate effectively, and good team work are absolutely essential,” Dr. Tripathy said. “Patients should look for an experienced breast cancer provider who can effectively communicate what the diagnosis means; what the treatment options are, both the pros and cons; what the latest research findings are; and where there might be suitable clinical trials.”

Teamwork!

Cancer care is best delivered in a team setting, Dr. Tripathy added. The

team, which might include a surgeon, oncologist, radiologist, primary care physician, oncology nurses, and other allied health care professionals, need not even be at the same center, so long as they work together to create the best possible treatment plan, individualized to the “preferences, issues, and clinical features of each patient.”

During the early stages, most breast cancer patients are desperate for accurate information. However, many women can be overwhelmed by the avalanche of information available today, both from traditional sources and from the Internet (see sidebar).

“We need to be careful about not giving out so much information that patients become confused,” said Ms. Pedace. The goal should be to provide the information women need when they need it and to offer reassurance. “I’ve found, both as a nurse and as a patient, that it’s best to tailor the information to a woman’s needs at the time, to her readiness to hear,” she added.

Key Questions

What are the critical questions for patients to ask? At the outset, Dr. Tripathy said, there are 6 primary uncertainties that need to be addressed:

- What is my diagnosis? Are any additional studies needed for confirmation?
- If it is cancer, what is the size of the tumor, the stage, and the type of cell?
- What are my surgical treatment options (lumpectomy or mastectomy)? Is breast reconstruction appropriate?
- What other treatments (chemotherapy, hormonal therapy, radiation) will I need?
- Will there be any side effects? How will they affect me?

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Where to Look for Information

Here are several useful resources available to women looking for breast cancer information.

On the Internet:

- **Susan G. Komen Breast Cancer Foundation:** www.komen.org; 1-800-I’M AWARE
- **The American Cancer Society:** www.cancer.org; 1-800-ACS-2345
- **Cancer Information Service:** <http://cis.nci.nih.gov>; 1-800-4 CANCER
- **The Wellness Community:** www.thewellnesscommunity.org; 1-888-793-WELL
- **Y-ME National Breast Cancer Organization:** www.y-me.org; 1-800-221-2141
- **The National Breast Cancer Coalition:** www.natlbcc.org; 1-800-622-2838

Research nurse and breast cancer survivor Terri Pedace also recommends the following books:

- *Dr. Susan Love’s Breast Book*, by Susan Love, MD
- *Minding the Body, Mending the Mind*, by Joan Borysenko
- *Spinning Straw into Gold*, by Ronnie Kaye
- *It’s Not About the Bike*, by Lance Armstrong

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“What do I do now?”—Getting Started on the Journey

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- What is the prognosis or likely outcome, and how will additional treatments affect it?

Each patient likely will have other questions and concerns. Ms. Pedace advises women to “write them all down.” She recalled a recent conversation with a friend. While sitting in the doctor’s office, the woman was so numb she could not think of anything to ask. As women sort through the reality of the disease, writing down key questions can help organize their thoughts and help providers direct them to the best resources, Ms. Pedace said.

Families and other caregivers can help. Both Dr. Tripathy and Ms. Pedace agreed that the most impor-

tant thing is to keep people you trust in a close circle of support.

An Emotional Roller Coaster

“There are a lot of ups and downs due to the emotional changes people with cancer undergo,” Dr. Tripathy said. “Families should form a team, with one person serving as a contact point for communication with the medical team. Also, if young children are involved, family members can help explain and clarify what Mom is going through.”

“This can be a very frightening experience to go through alone,” said Ms. Pedace. “Women need other sources of support. Plus, family members and friends can provide another pair of ears during doctor’s visits and treatment sessions. Patients don’t always

remember everything they’re told.”

In the end, the best advice for women about to make “the long journey,” as Ms. Pedace called it, is to focus on what is really important in life.

“Sometimes women get so wrapped up in cancer issues that being a cancer patient becomes an identity,” said Ms. Pedace. “It is important to continue to live, to enjoy life, to find a sense of normalcy. The journey can be more tolerable if one is able to find comfort in the love and support of family and friends.

“Certainly, no one chooses to have bad things happen. However, a person does have control over how she responds to the experience. Recognize your limits, focus only on what is important, and be thankful for what you have.” ■

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