The Advanced Practice Nursing Role in a High-Risk Breast Cancer Clinic

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Purpose/Objectives: To describe the role of an oncology nurse practitioner in a breast cancer prevention clinic.

Data Sources: Published articles, abstracts, and book chapters and personal experience.

Data Synthesis: Validated risk assessment models and genetic screening can be used to assess an individual's risk for breast cancer. Lifestyle changes and medical interventions can reduce that risk.

Conclusions: Interventions for primary prevention of breast cancer soon may become one of the most effective means of reducing the incidence, morbidity, and mortality of breast cancer.

Implications for Nursing: Advanced practice nurses in the oncology setting are ideal healthcare providers to assess patients' risk of breast cancer, determine physical findings that can influence that risk, provide risk education, synthesize existing data, and make recommendations for surveillance, pharmacotherapy, lifestyle changes, and genetic counseling and testing. Limitations in the existing data in cancer prevention provide excellent opportunities for nursing research.

Key Points . . .

- ➤ The risk of developing breast cancer can be reduced in some women.
- ➤ Risk assessment and counseling about intervention options now can be considered a standard of care.
- ➤ Cancer risk assessment and counseling are appropriate roles for advanced practice nurses.
- ➤ Risk reduction intervention options include lifestyle modifications, tamoxifen, prophylactic mastectomy, and prophylactic oophorectomy.

The lifetime risk for breast cancer in the United States is 12%, which means that one in eight women will be affected. In 2002, approximately 203,500 women and 1,500 men in the United States were diagnosed with invasive breast cancer and 54,300 individuals were diagnosed with in situ breast cancer. An estimated 40,000 died from the disease in 2002 (American Cancer Society [ACS], 2002b).

The number of deaths attributed to breast cancer declined from 1992–1998 as a result of earlier detection and improved treatments (ACS, 2002b). Healthcare providers have long understood that early detection of breast cancer, including risk assessment, screenings, and self-examinations, increases long-term survival. Now, increasing evidence suggests that the risk of developing breast cancer also can be reduced (Prout, 2000). In fact, lifestyle changes, surgery, and medications may prevent cancer in selected women (Prout). Risk assessment and consultation are appropriate for anyone concerned about the risk of developing breast cancer. Interventions for primary prevention of breast cancer soon may become one of the most effective means of reducing the incidence, morbidity, and mortality of breast cancer. Risk assessments and counseling about intervention options now can be considered a standard of care (Knaus, 2002).

This article describes the role of the oncology nurse practitioner (NP) in a breast cancer prevention clinic. One NP supported by two board-certified medical oncologists opened this clinic in October 2000. Risk assessments, history and physical examinations, recommendations for surveillance and intervention, genetic counseling and testing, and education are included in the one- to two-hour office visit.

The high-risk breast cancer prevention clinic is held one to two days per month, depending on the number of patients scheduled. Patients may be self-referred or referred by a healthcare professional. The primary source of referrals to the clinic has been from surgeons and gynecologists. A significant number of patients have self-referred because they have relatives with breast cancer. This clinic has been advertised in a local newspaper, in grand rounds at a local hospital, in mailings to local physicians, and at several local health fairs.

This breast cancer prevention clinic seeks to provide comprehensive health education and individualized recommendations for patients who believe they are at risk for breast cancer. The goals of the clinic are listed in Figure 1.

Background

One of the major reasons women do not have mammograms or perform regular breast self-examinations (BSEs) is lack of clinician recommendation (Gulitz, Bustillo-Hernandez, & Kent, 1998). Although annual mammography is recommended for women over the age of 40 (ACS, 2002c), women aged 50 and older often are not encouraged to obtain breast screenings. In a comprehensive study completed in Florida, investigators found that primary care providers who are older than age 50, specialize in adult or geriatric care, or practice in a rural area were the providers who were most likely to miss

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- Provide accurate and up-to-date information about breast cancer risk and risk reduction interventions.
- Assess for a genetic predisposition to cancer, and offer genetic counseling as appropriate.
- Provide recommendations for surveillance.
- Provide information regarding other women's health issues, such as osteoporosis, menopause, and cardiac risk.
- Serve as a resource.
- Correct myths and alleviate unnecessary fears.
- Provide access to a healthcare network that can assist in the screening and early detection of cancer.

Figure 1. Goals of the High-Risk Cancer Clinic

these screening opportunities because of a combination of patient, provider, practice, and access barriers (Gulitz et al.). In fact, ACS (2002c) estimated that only 55.5% of women aged 40 or older in the United States had a mammogram and clinical breast examination in 2000.

Breast Cancer Risk

Recognized risk factors for breast cancer include atypical hyperplasia or a history of benign breast disease, early menarche, late menopause, first live birth after the age of 30 or nulliparity, increasing age, female gender, and first-degree relatives with breast cancer (Byrne et al., 2001) (see Figure 2). The role of diet, hormone replacement therapy, oral and injectable contraceptives, breast density, obesity, and antiestrogens as risk factors is less clear (Nogueira & Appling, 2000).

Genetic Susceptibility

Two genes, *BRCA1* and *BRCA2*, have been identified in relation to breast cancer susceptibility. Only 5%–7% of patients with breast cancer have one of these gene mutations; however, genetic screening and counseling may identify those patients who could benefit from genetic testing (Armstrong, Eisen, & Weber, 2000). Counseling always should precede testing because of the many psychosocial, emotional, and ethical dilemmas that are possible for patients and practitioners (Freedman, 1998). Some dilemmas that may arise include (a) whether genetic information should be given to a relative, (b) moral concerns related to the management of risk information when no clinical interventions exist for a specific patient, (c) consideration of potential harm of risk reduction interventions for a problem that may never arise, and (d) whether the availability of new medical technologies or healthcare management strategies is dependent on insurance coverage.

Established factors
- Female gender
- Atypical hyperplasia
- Early menarche
- First live birth after age 30
- Nulliparity
- First-degree relative with breast cancer
- *BRCA1* or *BRCA2* mutation
- Drink more than one alcoholic beverage per day
- History of mantle radiation for Hodgkin's disease
- Increasing age

Unproven factors
- High-fat diet
- Hormone replacement therapy (controversial)
- Oral contraceptives
- Injectable contraceptives
- Breast density
- Obesity
- Antiestrogens
- Lack of exercise

Figure 2. Breast Cancer Risk Factors

Note. Based on information from Chantier & Jahanzeb, 2002.

BRCA-related cancers tend to occur at a younger age (i.e., less than age 50), and *BRCA1* carriers tend to be estrogen-receptor negative (King et al., 2001). A *BRCA1* or *BRCA2* mutation can incur a 60%–85% lifetime risk for breast cancer and a 15%–40% lifetime risk for ovarian cancer (Nogueira & Appling, 2000). These genes, particularly *BRCA2*, also may increase the risk for pancreatic cancer, prostate cancer, and melanoma (Pritchard & Goodwin, 2001).

Risk Reduction

The Breast Cancer Prevention Trial (BCPT) was a double-blind study that compared tamoxifen versus placebo in women who were determined to be at a higher risk of breast cancer based on the Gail model (Fisher et al., 1998). The investigators found that women aged 49 and older who took tamoxifen had up to a 49% reduction in the risk of breast cancer. The risk also was reduced in women with a history of lobular carcinoma in situ or atypical hyperplasia. As a result of this trial, tamoxifen is recognized as the first chemopreventive agent to reduce the risk of breast cancer development.

Lifestyle changes (e.g., low-fat diet, decrease in alcohol intake, daily exercise, smoking cessation) may decrease the risk of breast cancer. Consuming one or more alcoholic beverages per day is the best-evidenced dietary risk factor, most likely because of an interaction between alcohol and folate (Sellers et al., 2001). Consuming 2.5 alcoholic beverages per day may increase patients' relative risk by 1.41 (Rohan, Jain, Howe, & Miller, 2000).

Eating fruits and vegetables may lower breast cancer risk, and a low-fat diet that does not include high quantities of red meat has been touted as a means of risk reduction; however, cohort studies have been unable to establish a link (Smith-Warner et al., 2001). In an effort to establish this link, the Women's Health Initiative Dietary Modification Study, under the direction of the National Institutes of Health, currently is studying the effects of a low-fat and high fruit, vegetable, and grain diet on breast cancer, colorectal cancer, and heart disease in postmenopausal women (Greenwald, Sherwood, & McDonald, 1997; Prout, 2000).

Physical activity appears to influence breast cancer risk (Carpenter, Ross, Paganini-Hill, & Berstein, 1999). Previous studies may have been unclear about this relationship because of inaccurate measurements of physical activity (e.g., type, intensity, duration), lifetime exposure to physical activity, physiologic markers (e.g., heart rate, energy balance, hormonal levels), and site-specific cancer risk (Thune, 2000). Present guidelines are based on these observational studies and current knowledge of breast cancer biology. ACS (2002a) guidelines on nutrition and physical activity for cancer prevention recommended participating in vigorous physical activity at least four hours per week, avoiding or limiting alcoholic beverages to no more than one drink per day, and

minimizing lifetime weight gain through caloric restriction and regular physical activity.

Another modifiable risk factor for breast cancer is smoking. Several studies have suggested that passive and active exposure to tobacco smoke, particularly at a young age, may contribute to the development of breast cancer (Johnson, Hu, & Mao, 2000; Morabia, Bernstein, Heritier, & Khatchatrian, 1996). Smokers in families with a familial pattern of breast or ovarian cancer appear to be at an even higher risk (Couch et al., 2001).

Risk Assessment Tools

Two models commonly are used to assess breast cancer risk: the Gail model derived from the Breast Cancer Detection and Demonstration Project (Gail et al., 1989) and the Claus model derived from data collected in the Cancer and Steroid Hormone Study (Claus, Risch, & Thompson, 1994; McTiernan et al., 2001) (see Figure 3). Statisticians from the National Surgical Adjuvant Breast and Bowel Project (NSABP) modified the Gail model for use in the BCPT to include African American women. Other modifications included limiting the probability calculated to invasive breast cancer only and using updated mortality and population datasets (Euhus, 2001). The Gail model validated in different populations of women being screened for breast cancer risk and has been used in several large breast cancer prevention trials, including the NSABP for determining eligibility for the BCPT (Armstrong et al., 2000).

The modified Gail model—the Breast Cancer Risk Assessment Tool—is used initially to assess risk and is available from the National Cancer Institute. The Gail model is a multiple logistic regression tool that can be used to predict the five-year and lifetime rates of both invasive and noninvasive breast cancer associated with specific risk factor combinations. The modified Gail model assesses the number of first-degree relatives with breast cancer, race, age at menarche, age at first live birth or nulliparity, the number of breast biopsies, and the presence of atypical hyperplasia. A risk score then is calculated by multiplying the relative risk from these factors by an adjusted population risk for breast cancer (Euhus, 2001).

At times, however, the Gail model is not appropriate for patient assessment (McTiernan et al., 2001; Nogueira & Appling, 2000) because it actually may underestimate the risk of patients with a significant family history in second- or third-degree relatives or BRCA mutation carriers. The Gail model does not consider history of bilateral disease or the age at diagnosis of the affected relative. Although the tool accounts for atypical hyperplasia, it does not consider lobular carcinoma in situ. Euhus (2001) suggested that the Gail model overestimates the risk of women under the age of 35 who do not have regular mammography. Some researchers also question this model's applicability in non-Caucasian populations (Euhus). When the Gail model is believed to be inappropriate, the Claus model may be used. Occasionally, both the Claus and Gail models may be appropriate for patient assessment (McTiernan et al.).

The Claus model considers first- and second-degree relatives with breast cancer and the affected relatives' age at diagnosis. The Claus model is more useful in factoring in family history of breast cancer, but it does not assess bilateral breast or ovarian cancer. The tool also does not take into account nonfamily history (i.e., previous biopsies, age at menarche, and age at first birth). As with the Gail model, some question this model's applicability in non-Caucasian populations (Euhus, 2001).

A third model that may be used is the BRCAPRO (Berry et al., 2002). This is a statistical Bayesian probability model and software program that uses family history to calculate individual breast cancer probabilities based on whether a family carries a mutation in one of the BRCA genes. This model examines family history more thoroughly, but, like the Claus model, it neglects nonfamily history risk and factors included in the Gail model; BRCAPRO also may not address non-BRCA familial clustering (Euhus, 2001).

Using a variety of models is ideal because no single model integrates all applicable risk information. Clinicians then can draw on the strengths of each particular model. At the breast cancer prevention clinic, all three models are used at different times. A useful pedigree-drawing software program, CancerGene, can be used to run each of the models discussed. This program was developed and distributed by the University of Texas Southwestern Medical Center at Dallas for healthcare providers involved in cancer risk counseling. CancerGene calculates breast cancer risk using all three models by collecting family history and general risk factor information. The program draws a pedigree and calculates BRCA gene mutation probabilities. The prevention clinic uses CancerGene; the software may be obtained free of charge at www.swmed.edu/home_pages/cancergene.

The BRCA Mutation Guide (Myriad Genetics, Inc., Salt Lake City, UT) is a slide rule similar to a body surface area calculator and is used to measure the risks of having a genetic mutation (i.e., *BRCA1* or *BRCA2*) for breast cancer. The slide rule takes into account the number of relatives with breast cancer diagnosed before the age of 50 and ovarian cancer diagnosed at any age. The data reflected from these calculations were derived from observations of deleterious mutations by Myriad Genetics,

Gail Model
- Multiple logistic regression model
- Considers first-degree relatives only
- Does not consider age at diagnosis
- Does not account for bilateral breast cancer
- May underestimate risk in a BRCA carrier; therefore, use is not appropriate when a strong suggestion of an inherited cancer syndrome exists.
- Five-year and lifetime risk calculations
- Validated in different populations
- Not adequately tested in non-Caucasians
- Women younger than age 35 are screened inadequately.
- Computer-based software, calculators, and Web links available

Claus Model
- Assumes an autosomal dominant trait
- Considers first- and second-degree relatives
- Considers age of relative with breast cancer
- Does not account for bilateral breast cancer
- Does not assess nonfamily history risk factors
- Ten-year and lifetime risk calculations
- May only be used for women with first- or second-degree relatives with breast cancer
- No independent validation
- Not adequately tested in non-Caucasians
- Not appropriate when a strong suggestion of an inherited cancer syndrome exists

Figure 3. Characteristics of the Gail and Claus Models

Note. Based on information from Euhus, 2001; McTiernan et al., 2001.

Inc., through its clinical testing service (Myriad Genetics, Inc., 2001). Although these data have not been independently verified, this provides an easily obtained gross screening that gives providers a basis on which to begin discussion about genetic counseling and testing.

The Breast Cancer Prevention Clinic Visit

Educating the medical community about the need to screen every woman and the ability to reduce the risk of breast cancer is vital to the acceptance and use of the high-risk breast cancer clinic. Using the Gail model, clinicians can perform a simple risk assessment in no more than one to three minutes. Thus, this assessment could be offered to all women (Prout, 2000). However, the counseling and recommendations for risk reduction that should follow the initial assessment can take more than 90 minutes for women found to be at high risk. Referral to a high-risk cancer clinic can relieve primary care providers of this time-consuming obligation.

Women may self-refer or be referred to the clinic by a physician. Any woman who is concerned about her risk for breast cancer should be given the opportunity for professional risk assessment and consultation. Prior to the visit, patients are asked to provide copies of mammogram and pathology reports and gather pertinent personal and family medical history.

Upon arrival to the clinic, patients are asked to complete a risk survey that supplies information in assessing breast cancer risk by the modified Gail model (see Figure 4). A member of the nursing staff takes a comprehensive medical, psychological, social, and family history; vital signs; and a list of current medications while the NP completes the risk assessment using the modified Gail model and/or the Claus model. The estimated risk of carrying a genetic mutation also is calculated. Copies of the risk assessments are printed for patients and their medical records.

The NP carefully reviews the medical history with patients. Any occurrence of depression, anxiety, or psychological distress is assessed by the NP during the interview and examination because the presence of any of these factors may influence patient adherence to surveillance and therapeutic interventions (Brain, Norman, Gray, & Mansel, 1999). A detailed to comprehensive physical examination as defined by the evaluation and management codes (Centers for Medicare and Medicaid Services, 1997) is performed.

1. Have you ever had breast cancer?
2. Have you had a breast biopsy with a diagnosis of lobular carcinoma in situ or ductal carcinoma in situ?
3. How old are you?
4. At what age did you start your period?
5. How old were you when your first child was born?
6. How many of your sisters, daughters, or mother have had breast cancer?
7. Have you ever had a breast biopsy? If so, how many? If so, has any biopsy shown atypical hyperplasia?
8. What is your race?
9. Have you had any relatives diagnosed with breast cancer or ovarian cancer under the age of 50?
10. Is there any history of male breast cancer in your family?

Figure 4. Risk Survey Questions

Note. Based on information from Gail et al., 1989; Myriad Genetics, Inc., 2001.

BSE is discussed in detail because any woman can perform this examination with adequate education. No costs or availability issues are incurred with this screening method. However, in the author's experience, some women are afraid to perform BSE because they do not know what they are feeling, they always feel lumps, or they are afraid they might find something. Fear about breast cancer risk can lead to either hyper- or hypovigilant BSE (Brain et al., 1999). A thorough clinical breast examination is performed while the NP points out different areas of breast tissue, allowing the patient to palpate them. The NP must emphasize that patients should know their breasts well enough to detect significant changes, but not necessarily know what type of tissue is being palpated. The NP provides patients with a BSE shower card and detailed written instructions with pictures to take home. During this portion of the visit, many false notions and fears about BSE, breast anatomy, and breast cancer biology are dispelled.

Mammography questions are discussed during this time as well, including a concern that has surfaced recently resulting from the publication of a research letter by Olsen and Gotzsche (2001). Their meta-analysis concluded that mass mammography screening trials do not provide any survival benefit and that screening actually leads to more aggressive treatment, which is a waste of health resources. Olsen and Gotzsche's article has been soundly refuted by ACS, the American College of Obstetricians and Gynecologists, and the Oncology Nursing Society, as well as by at least seven other leading medical organizations (ACS, 2002a). The U.S. Preventive Services Task Force (1997) recommended that women over the age of 40 have regular mammograms every one to two years. Patients over the age of 40 who visit the high-risk clinic are advised to have mammography at least yearly.

Following the physical examination, the NP reviews the risk assessment and findings from patients' history and physical examination. Pharmacologic interventions are discussed, if appropriate, as well as lifestyle changes. Recommendations for regular surveillance are given. Information on other health issues (e.g., osteoporosis, menopause, cardiovascular disease) is given as appropriate. Other potential resources are identified, such as Web sites, support groups, and health societies (e.g., ACS, the National Cancer Institute). All verbal information is provided in written form as well.

Surveillance

The oncology NP makes individualized recommendations for surveillance using guidelines for screening of high-risk patients from the National Comprehensive Cancer Network (NCCN). NCCN (2002) defined high risk as a five-year risk of invasive breast cancer greater than 1.7% (per the Gail model) or a strong family history or genetic predisposition as defined in the American Society of Clinical Oncology Guidelines. For those with a strong family history or genetic predisposition and who are 25 years of age or younger, annual physical examination and mammography is recommended. Patients who have received prior thoracic radiation therapy and are younger than 25 years of age should have annual physical examinations, and BSE should be encouraged. If they are 25 years of age or older, annual mammography and a physical examination every six months should be performed beginning 8–10 years after radiation therapy. Those patients 35 years of age and older with a five-year risk of invasive cancer

greater than 1.7% per the Gail model should schedule mammography and a physical examination annually. For patients younger than age 25 who have a strong family history of breast cancer or a genetic predisposition for the disease, an annual physical examination should be performed. For women older than age 25 with a strong family history of breast cancer or a genetic predisposition for the disease, annual mammography and a physical examination should be performed every six months, beginning 5–10 years prior to the earliest age of the youngest relative diagnosed with breast cancer. Patients with a BRCA mutation should have annual mammography and a physical examination every six months, beginning at age 25. In all of these patients, BSE should be encouraged and risk reduction strategies should be considered. Clinical breast examinations are recommended at least yearly for everyone and are recommended more frequently if a history of atypical hyperplasia or lobular carcinoma in situ is present or a clinically nonsuspicious lesion is being monitored.

The limitations of clinical breast examinations, mammography, and BSE are reviewed with patients, and the importance of the combination of surveillance methods is emphasized. Patients are reminded to seek timely attention anytime a lump causes worry. Other surveillance recommendations might include annual physical examinations, pelvic examinations, Pap tests, bone density tests, and other general screening tests as recommended by ACS (2002c) (e.g., fecal occult blood testing, colonoscopy).

Intervention Recommendations

Few clinical trials have studied the effects of risk factor modification on breast cancer occurrence. High-fat diets, lack of exercise, alcohol consumption, and smoking are thought to be risk factors in the development of breast cancer and may have interactive effects (Prout, 2000).

Beneficial changes in diet include lowering the total percentage of daily dietary fat and consuming more fruits and vegetables (Byers et al., 2002). Body mass index is calculated, and target weight is set if weight loss is recommended. Modifications in fat, protein, and carbohydrate calories are recommended. If patients are candidates for pharmacologic, behavioral, or surgical interventions for obesity, referrals can be made. Dietary changes are acknowledged to be part of a healthy lifestyle and not touted as a definitive means of risk reduction because epidemiologic studies have not provided conclusive evidence of the association between diet and breast cancer (Greenwald et al., 1997).

At least 30 minutes of exercise per day is recommended for most patients. Weight-bearing exercise, such as walking, is ideal because it can help to prevent osteoporosis (Curry & Hogstel, 2001). Smoking cessation is discussed if applicable. All smokers are asked about their smoking history and their desire to quit. Quit kits are given to those who wish to stop smoking. The quit kit contains information about the risks of smoking and benefits of quitting, as well as tips for quitting and information about nicotine replacement and pharmacologic interventions.

If patients are found to have a five-year risk of invasive breast cancer greater than 1.7% by the Gail model, tamoxifen may be discussed. Tamoxifen is the first drug to be approved by the U.S. Food and Drug Administration for breast cancer risk reduction (Prout, 2000). The drug has antiestrogenic and antiproliferative effects in the breast and acts by binding to estrogen receptors. In the 1990s, tamoxifen was found to decrease the development of breast cancer in high-risk women by almost 50% (Fisher et al., 1998).

Benefits and risks of tamoxifen are reviewed with patients when presenting this option. Side effects and adverse effects are discussed (see Figure 5). Patients' current medications are reviewed, and a drug interaction check is performed to assess for any drug-drug interactions with tamoxifen. Cost is discussed, and application may be made to the pharmaceutical company for financial assistance if needed. Tamoxifen may be contraindicated in women of childbearing age or those with a history of thrombosis, poorly controlled hypertension, atrial fibrillation, or another comorbid disease (Brown & Lippman, 2000). Women's risk of endometrial cancer, thrombotic events, and cataracts should be assessed prior to tamoxifen initiation. If women begin taking tamoxifen, follow-up should include a history and physical examination every 6–12 months (may be performed by the primary care provider), annual pelvic examination and age-appropriate Pap test, annual ophthalmic examination (or more frequently if cataracts or vision problems exist), and bone density examinations periodically, particularly if patients are premenopausal (NCCN, 2002).

Although tamoxifen can reduce the risk of developing breast cancer, effects on breast cancer mortality remains unknown (Leris & Mokbel, 2001). The decision to use a pharmacologic agent in disease prevention should be made jointly by patients and healthcare providers. The risk-benefit ratio must be weighed carefully. Gail et al. (1999) and Brown and Lippman (2000) presented several factors to consider in determining whether to place a patient on tamoxifen. Some of these factors include consideration of comorbid diseases, potential drug-drug interactions, patient preferences, and the presence of an intact uterus.

In *BRCA1* or *BRCA2* mutation carriers, the benefits of tamoxifen are less clear. In the BCPT, tamoxifen did not seem to reduce the risk of breast cancer in *BRCA2* carriers; however, the benefit to *BRCA1* carriers was not determined (King et al., 2001). This is because *BRCA1* cancers frequently are estrogen-receptor negative. Cancers that are estrogen-receptor negative generally will not respond to tamoxifen. However, the number of patients with mutations in this study (n = 19) made this a statistically nonsignificant finding (King et al.).

If appropriate, participation in a clinical trial may be discussed. Studies such as the study of tamoxifen and raloxifene (STAR) trial and the ongoing Women's Health Institute studies may answer some of the difficult questions that healthcare providers face today, such as (a) Do safer drugs for breast cancer chemoprevention exist? (b) Does chemoprevention halt cancer or treat a very early case? and (c) Do certain

- Hot flashes
- Increased risk for endometrial carcinoma (relative risk 2.3 per 1,000 women)
- Vaginal discharge
- Ocular changes
- Menstrual irregularities
- Hair loss
- Fluid retention
- Thromboembolic events
- Rash
- Nausea

Figure 5. Adverse Reactions to Tamoxifen

Note. Based on information from Brown & Lippman, 2000.

lifestyle changes definitively reduce the risk of cancer? The STAR trial is a randomized, double-blind study that compares the effectiveness of tamoxifen with raloxifene in high-risk, postmenopausal women. This trial also monitors fractures, thrombotic events, cataracts, and the quality of life of women taking each agent (Rhodes, Hartmann, & Perez, 2000). Raloxifene is not recommended for breast cancer risk reduction by the breast cancer prevention clinic outside of a clinical trial (NCCN, 2002; Rhodes et al.).

Comorbid diseases such as diabetes, osteoporosis, cardiac disease, or hypertension may influence treatment recommendations. For example, an obese woman who smokes may be at higher risk for endometrial cancer or thromboembolus, perhaps making the risks of tamoxifen prevention outweigh the potential benefits (Bernstein et al., 1999). Although not an absolute contraindication, should this patient decide to take tamoxifen, she may require closer surveillance for endometrial cancer and more detailed information on the signs and symptoms of a blood clot. Likewise, the risks of early menopause (whether pharmacologic or surgically induced) must be weighed against the benefits of the reduced risk of breast cancer. One risk of early menopause may be osteoporosis.

Early menopause and oophorectomy are two of the most frequently identified risk factors for osteoporosis (Curry & Hogstel, 2001). Osteoporosis prevention, diagnosis, and treatment are discussed in the clinic, and a bone density study may be considered. A nonstatistically significant decrease in fractures was noted in association with tamoxifen in the BCPT (Fisher et al., 1998). Calcium, bisphosphonates (e.g., alendronate, risedronate), and weight-bearing exercise may be recommended.

Intervention-induced menopause or chemoprevention (e.g., tamoxifen) can induce hot flashes and vaginal symptoms (e.g., dryness, atrophy, discharge). In fact, 45%–67% of women taking tamoxifen experience moderate hot flashes (Brown & Lippman, 2000; Prout, 2000). Vitamin E, oral clonidine (0.1 mg per day) or a clonidine patch, venlafaxine, or lifestyle changes may be recommended for hot flashes (Loprinzi et al., 2000; Pandya et al., 2000). Vaginal moisturizers or an estradiol-releasing silicone vaginal ring may be recommended for vaginal symptoms (Prout).

The risks and benefits of hormone replacement therapy are discussed with patients on an individual basis. A causal relationship between female hormones and breast cancer may be based on duration of use, dose response, and other factors, making the increased risk comparable to that of delayed menopause (Colditz, 1999). Osteoporosis, heart disease, hyperlipidemia, menopausal symptomology, and comorbid diseases are taken into consideration before discontinuing hormone replacement therapy.

Surgery such as bilateral prophylactic mastectomy may be discussed in very high-risk women, such as *BRCA1* or *BRCA2* carriers or women with lobular carcinoma in situ. Bilateral prophylactic mastectomy may reduce breast cancer risk by as much as 90% in these women (Grann et al., 2000; Khurana, Loosmann, Numann, & Khan, 2000). However, surgical morbidity, psychosocial issues, economic considerations, and quality of life must be addressed if this option is considered. If performed, prophylactic mastectomies should be complete, simple bilateral mastectomies and include the nipple, areola, axillary tail, and pectoral fascia, leaving as little breast tissue behind as possible (Willemsen, Kaas, Peterse, & Rutgers, 1998). Patients must be aware that this surgery, just like any preventive intervention, will not completely eliminate the risk of developing breast cancer (Geller et al., 1998).

Bilateral prophylactic oophorectomy also may be discussed. Performing this surgery in patients younger than age 35 appears to reduce the risk of breast cancer in *BRCA1* mutation carriers (King et al., 2001).

Genetic Counseling and Testing

Only 5%–10% of women with breast cancer actually have an inherited genetic mutation (Curry & Fentiman, 1999; Nogueira & Appling, 2000). In addition to *BRCA1* and *BRCA2*, several genetic mutations influence breast cancer development (e.g., Cowden's disease, Li Fraumeni syndrome, ataxia-telangiectasia) (Curry & Fentiman). Genetic testing has become more acceptable to many clinicians because of the availability of effective preventive measures. The American Society of Clinical Oncology (1996) recommended genetic testing be offered only when the likelihood of a positive test is greater than 10%, the test can be interpreted adequately, and the test results will influence medical management.

Genetic testing may raise financial, social, ethical, and legal concerns for patients and healthcare providers. Patients must understand that genetic testing information is strictly confidential and that the results will not be shared outside of the patient-provider relationship. A shadow file (i.e., a file that is kept separate from the patient's medical file and inaccessible to anyone without the patient's written consent) may be kept to prevent possible socioeconomic discrimination.

Reimbursement

Managed care integrates financing, cost-containment strategies, and business principles with the delivery of healthcare services (Blackburn, 1998). Prevention of a serious illness is the best way to contain healthcare costs. Estimation of cost-effectiveness using data from the BCPT indicates that risk reduction therapy with tamoxifen fits within current guidelines for cost-effective practices (Prout, 2000; Smith & Hillner, 2000). However, coverage of preventive medicine is sadly lacking throughout the healthcare system (Flach & Jennings-Dozier, 2000). The success of new preventive technologies may depend on whether insurance companies provide coverage for them. Patient compliance is reduced when insurers do not provide coverage for increased surveillance or prophylactic interventions. The disparity in health care among populations may be more readily apparent in preventive services than treatment services (Flach & Jennings-Dozier). Increased surveillance for high-risk patients often requires written justification from healthcare providers to insurance providers to ensure coverage; however, this is no guarantee that insurance providers will pay for the added surveillance.

The success of new medical technologies or healthcare management strategies frequently depends on cost-effectiveness. The role of the advanced practice nurse in the high-risk breast cancer clinic is multifaceted and time consuming. Advanced practice nurses often find it difficult to accurately define their cost-effectiveness, partly because the time spent with patients often is not reimbursable. The positive outcomes of advanced practice interventions, such as patient satisfaction, attainment and application of knowledge by patients, and long-term quality of life or increased survival, are very difficult to quantify.

The NP is reimbursed by Medicare Part B at 80% of the lesser charge or 85% of the physicians' fee schedule when billing under the NP's own Medicare number (Towers, 1999). Medicare does not require oncologists to be on-site for NP reimbursement, but in the breast cancer prevention clinic, at least one oncologist is available for consultation as needed. Most private insurances recognize NPs and reimburse at varying rates (Towers).

Follow-Up

If patients decide to take tamoxifen, a follow-up visit is scheduled four to six weeks later and then annually to evaluate symptomology. Some patients (i.e., those with genetic predisposition or lobular carcinoma in situ) are seen every six months for breast examinations either in the high-risk clinic or by their primary care provider. While on tamoxifen therapy, the management of side effects is important to ensure adherence to the recommended five years of daily therapy (Prout, 2000). At each appointment, new scientific data and changes in the individual risk profile are reviewed and therapeutic changes are made as necessary. Patients may need encouragement to continue taking a chemopreventive medication and adhering to a healthier lifestyle. Patients whose risk is borderline or who decline intervention may be reevaluated within three to five years or sooner if risk factors change.

Implications for Nursing

Breast cancer prevention clinics such as the one described in this article have highlighted areas of needed research. Limitations of existing data provide excellent opportunities for nurses in cancer prevention. Areas of research that need to be studied further include (a) reducing risk across different racial populations, (b) evaluating the effects of prophylactic mastectomy and oophorectomy, (c) finding a more comprehensive screening tool, (d) evaluating the cost-effectiveness of preventive health care, (e) determining the optimal tamoxifen therapy duration and the age at which to start therapy, (f) determining whether the mechanism of action of tamoxifen is actual prevention of disease or the treatment of subclinical disease, (g) evaluating the effectiveness of chemopreventive strategies in hereditary breast cancer, (h) determining the best strategies to facilitate screening processes, (i) determining the effects of hormones (e.g., hormone replacement, birth control) on breast cancer, and (j) evaluating healthy lifestyle changes on the risk of breast cancer. Advanced practice nurses in oncology are ideal members of the healthcare team to implement nursing research in these areas using their health-assessment and decision-making skills. Nursing research in these areas can improve patient care and patient outcomes, as well as advance the nursing profession.

Ethical issues in the clinical practice of cancer prevention may arise. Most of the risk factors that are under an individual's control (e.g., exercise, maintenance of a healthy weight) are part of a healthy lifestyle and are not proven to prevent cancer. Although clinicians should encourage healthy lifestyles, they should avoid providing false reassurances to patients regarding positive effects on patients' cancer risk.

Another issue that may arise is in the difference between risk reduction and prevention. The explanations and use of these terms may be confusing to the public. "Risk reduction" implies a risk still is present and is the more accurate term to use in the high-risk clinic when counseling patients. Patients may interpret "prevention" to mean that if certain interventions are completed, no risk will exist for that disease and that mammograms and BSE are not necessary.

The NP's role in the high-risk clinic is mainly that of educator and facilitator. When patients receive accurate, current, and relevant information, they will be empowered to autonomously make important healthcare decisions. Managed care is changing the classic medical-nursing healthcare model and creating unique opportunities for advanced practice nurses to contribute to the oncology field. The NP, as a clinician, educator, researcher, counselor, healthcare liaison, ethicist, consultant, mentor, and patient advocate, is an ideal healthcare provider to facilitate lifestyle changes and screening practices. The NP provides a needed service, closing the circle to provide continuity of care in patients at risk for breast cancer.

The limitations of the existing data regarding breast cancer risk reduction therapies are important to recognize. These deficits can make it difficult for clinicians to make recommendations, and they often complicate patient decision making. Patients can play a more active and autonomous role in decision making with comprehensive information from clinicians. Shared decision-making processes must be based on the best data available and should include a comprehensive risk assessment and an understanding of the options available, risks and benefits of each option, limitations of current knowledge, and patient preferences (Prout, 2000). The next decade will bring much more data about pharmacologic options and other methods of risk reduction. Risk reduction clinics such as the one described will prove to be cost-effective and will set a new standard for chronic disease prevention.

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