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NIH Convenes Panel on Adjuvant Therapy for Women with Localized Breast Cancer

After three days of presentations on and discussions about the current research on adjuvant therapy for breast cancer, a panel of experts convened by the National Institutes of Health released a draft consensus statement on Adjuvant Therapy for Breast Cancer on Nov. 3, 2000. The last consensus statement on adjuvant therapy was released in 1990.

Adjuvant therapies are those used following surgery. The two types of adjuvant systemic therapies—those that affect the entire body—are chemotherapy and hormone therapy. Radiation is a local form of adjuvant therapy.

The panel only looked at the use of adjuvant therapy for localized invasive disease. The use of adjuvant therapy for women diagnosed with ductal carcinoma in situ (DCIS) or with metastatic disease was not discussed.

The panel revised the lifetime statistical chance of a woman getting breast cancer, concluding, "If current breast cancer rates remain constant, a woman born today has a one in ten chance of developing breast cancer." The previous risk—and the one most women are familiar with—was calculated as one in eight. The panel also noted that deaths from breast cancer have decreased in the United States and they attributed this, in part, to the improved use of adjuvant therapy.

Recommendations and Conclusions

Hormonal Therapy

Hormonal therapy is used to keep the breast from getting estrogen, which can promote tumor growth. The most commonly used form of hormone therapy is tamoxifen, which blocks estrogen receptors. The panel concluded that:

- Hormonal therapy should be recommended for women whose tumors have estrogen or progesterone receptors, regardless of a woman's age, menopausal status, HER2 status (also sometimes referred to as HER-2 or Her-2/neu or erb-b2), lymph node involvement, or tumor size. If there is not enough tissue to determine receptor status, then the tumor should be assumed to be estrogen receptor-positive, especially in postmenopausal women.

- Tamoxifen should not be recommended for women whose tumors do not have estrogen or progesterone receptors. Further, in these women, tamoxifen does not reduce the risk of developing breast cancer in the other breast.

- Only two groups of women with receptor-positive tumors might consider not using tamoxifen: women with small tumors (less than 10mm) who still want the benefits of estrogen, and elderly women with small tumors who have a history of blood clots.

- Tamoxifen should only be given for five years.

Chemotherapy

Chemotherapy is used to kill cancer cells, but it also damages other cells in the body, which is why it can lead to side effects such as hair loss, weight loss, loss of appetite, nausea and vomiting, mouth sores, and menopause in premenopausal women. The panel concluded that:

- Using two types of chemotherapy is better than using one type alone, and that treatment should be given in four to six cycles. Longer treatments are more toxic and do not appear to lengthen survival.

- Chemotherapy treatments that contain an anthracycline, such as doxorubicin and epirubicin, offer a slightly better outcome than do those chemotherapy combinations that do not contain them. But patients must also take into account that the anthracyclines are more toxic.

- There is no evidence that high-dose chemotherapy with stem cell improves outcome. This procedure should only be performed as part of a randomized clinical trial.

- Although the taxanes (docetaxel, paclitaxel) have been shown to be effective in women with metastatic disease, the panel could not "definitively recommend" these drugs for women with node-positive localized breast cancer. Women with node-negative tumors should only receive taxanes in a clinical trial setting.

- Women who use both tamoxifen and combination chemotherapy may further reduce their risk of recurrence, especially if they are premenopausal.

- More information is needed to determine which group of women might do just as well without chemotherapy. The only women who may consider not using chemotherapy are those who have node-negative cancers less than 1cm in diameter and women over 70 who have other serious illnesses or who might not be able to tolerate the drugs' toxicity.

Radiation

As methods of providing radiation therapy have improved, allowing for radiation to be delivered to the chest without causing extensive damage to the heart, interest in the use of radiation post-mastectomy has been renewed. Recent randomized trials and a meta-analysis—an analysis of the results of many studies—found that women who receive radiation after a mastectomy have better survival rates than women who do not. Women must remain aware, however, that radiation remains associated with an increased risk of arm edema, a condition where fluid accumulates in the tissue and causes the arm to swell. The panel concluded that:

- The women most likely to benefit from radiation post-mastectomy are those who have four or more positive lymph nodes or an advanced primary tumor. Based on the information currently available, the panel could not say whether women with one to three positive lymph nodes would benefit from radiation. Randomized clinical trials currently underway may provide an answer in the near future.

- Radiation therapy should not be given at the same time as chemotherapy regimens that contain anthracycline, and radiation therapy should be given within six months of the mastectomy.

To read the entire draft statement, visit the NIH Consensus Development website at:
http://consensus.nih.gov