Women and Breast Cancer: Trials, Tribulations and Tamoxifen

by Penni Mitchell

You'd think that if anyone would be excited about the prospect of Tamoxifen preventing breast cancer, it would be Nora Gambioli, executive director of the Canadian Breast Cancer Network (CBCN), a consumer advocacy organization whose board members are all breast cancer survivors. After all, many of them have also taken Tamoxifen, and like other Canadian breast cancer advocates, the organization is keen on research aimed at cancer prevention.

Last month, it was reported that researchers involved in a Washington-based study concluded that Tamoxifen can be used to prevent breast cancer among high risk women. However, Gambioli says the directors of the Network are "very cautious" about these conclusions.

"This is not the cure," Gambioli says of the preliminary results issued by the U.S. National Cancer Insitute (NCI), the sponsors of the study.

Initially, the Washington study was supposed to span seven years until the year 2000. However, it was called off two years early because the researchers felt they had achieved a "breakthrough" in cancer prevention.

British medical researchers were quick to offer a second opinion. They said it was premature to call off the study before its long-term effects could be determined, and they seem to have a point. Tamoxifen's ability to block cancer cells from growing is in fact not new; the drug has been used for 20 years to reduce recurrence of breast cancer among certain postmenopausal women with breast cancer.

Tamoxifen's success rate at preventing recurrence of breast cancer in postmenopausal women after surgery reaches a high of 40 percent; however, it is only half as effective for breast cancer patients under 50.

The study has raised more than the hopes of women who are being encouraged to believe that Tamoxifen is a magic bullet that will reduce their chances of getting breast cancer. It also raises critical questions about cancer research and the meaning of preventive medicine.

Chief among the questions is whether it is ethical to give symptomless women at risk for one type of cancer a drug that

will double the risk of another type of cancer, and increase other health risks.

The study involved 13,000 women determined to be "high-risk" because of their postmenopausal status, family history of breast cancer or being diagnosed to have precancerous cells. About 10 percent of the subjects were Canadian.

Half of the women were given Tamoxifen; half a placebo. A total of 1.8 percent (239 women) of the participants have been diagnosed with breast cancer since the study began in 1992. Among the 6,500 taking Tamoxifen, the breast cancer rate was 1.3 percent (85); in the control group of 6,500 it was 2.3 percent (154). In all, there were 69 more breast cancers diagnosed among the group taking a placebo, about 45 percent more.

If this were the end of the story, the findings may have lived up to their billing as a "medical breakthrough." But Tamoxifen, like most drugs, has negative as well as positive effects. In this study, Tamoxifen users had more than twice the rate of uterine cancer—five percent (33 cases) compared to two percent (14 cases)—in the control group.

The Tamoxifen link to uterine cancer is well known; in fact, it's the reason the Hamilton Regional Cancer Centre pulled out of the Washington study in 1992. As well, in 1994, the Washington study was temporarily halted following reports of four uterine cancer deaths in a different U.S. Tamoxifen study.

An earlier Swedish study also found uterine cancer rates six times higher among those who took Tamoxifen for two to five years—nearly two percent (23 out of 1,372) had uterine cancer compared to .04 percent (four out of 1,327) in the control group. In the Washington study, 17 women taking Tamoxifen were diagnosed with pulmonary embolisms (compared to six in the control group). Two of them died. The oncologists involved in the study dismissed these diseases as just side effects, and their opinion that the benefits outweigned the risks seemed irrefutable. One oncologist, whose bedside manner was particularly touching, remarked that even aspirin could kill you.

Unless the women involved in the study are tracked until their deaths, the beneficial effects of Tamoxifen in reducing overall breast cancer incidents compared to increasing uterine cancer incidents cannot be accurately assessed. The reaction of the Tamoxifen oncologists to the uterine cancer risk has been to state that uterine cancer is "easier to treat" than breast cancer—that is, with hysterectomies.

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The five-year survival rate of women with uterine cancer compare to women with breast cancer is about the same: 72 percent and 68 percent, respectively. With mortality rates for breast cancer continuing to decline, it begs the question: on what medical basis do these guys justify prescribing one type of cancer over another?

Even Zeneca Pharmaceuticals' own literature notes a small link to cancer of the liver, as well as "secondary tumors," birth defects and spontaneous abortions. Tamoxifen brought in about US$500 million per year to Zeneca, the company which was also the corporate mastermind behind the creation of Breast Cancer Awareness Month in the U.S. Other items in Zeneca's product line have also been questioned for their safety to individuals and the environment. The Women's Community Cancer Project in Massachusetts has linked Zeneca's herbicide Acetochlor to cancer, and reports that the company was charged with dumping DDTs and PCBs (two of the most carcinogenic substances known) into the Los Angeles and Long Beach harbors.

In contrast to the medical research establishment and the media's obsession with finding the "miracle cure" for breast cancer, women's health advocates are pressing for solutions to the root causes of the disease.

Last July at the World Conference on Breast Cancer in Kingston, Ontario, hundreds of breast cancer activists, researchers and authors demanded more publicly funded research on environmental causes of breast cancer and other forms of cancer in North America.

The CBCN itself is calling for a phase out of hormone-disrupting chemicals from the production and pollution created by pesticides, plastics and chlorine-based products in Canada. In spite of efforts to involve more cancer survivors in directing cancer research, Gambioli says she knows of no Canadian research currently underway on environmental causes of breast cancer.

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Side effects aside, the most notable limitation of Tamoxifen appears to be its long-term effectiveness. Reports on its use suggest that patients appear to become more resistant to its productive properties within about five years. Presumably, the researchers in the Washington NCI study were aware of the drug's time-limited benefits when they discontinued their drug study after five years. Tamoxifen is already being replaced in many cases by more effective anticancer drugs. Unless new markets for the drug are found, its days might be numbered.

Popular media is fuelling women's fears of getting breast cancer fear by citing merely being female as a risk factor for the disease. Similarly, since 80 percent of all breast cancers occur in women over 50, reaching menopause is now labeled a risk factor.

Even the category of "high-risk" appears to be a bit of a misnomer. It is not clear that women in the Washington study all had a strong family history of breast cancer (a mother or a sister). Of all women diagnosed with breast cancer, less than 10 percent of them have a strong family history of the disease, so targeting women whom researchers categorise as "high-risk" in fact leaves 90 percent of women who get breast cancer.

Based on what is known so far about Tamoxifen, its ability to block cancer cell growth may be temporary, simply delaying breast cancer while increasing risks for uterine cancer and pulmonary embolisms. Another question which would remain unanswered without follow-up study on the women in the Washington study is whether Tamoxifen benefits women later diagnosed with breast cancer who had been given the drug as preventive treatment.

One woman who phoned me when the Tamoxifen study was being sold to Canadian women as "new hope" in the fight against breast cancer was infuriated by the drug's link to conditions like blood clots in the lungs. "You can live without your tits," she said rather undiplomatically, "but you can't live without your lungs."

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