ELSEVIER

EJC Supplements Vol 2 No. 9 (2004) 17–18

EJC Supplements

www.ejconline.com

E2. Tamoxifen use for breast cancer chemoprevention among U.S. women

Andrew N. Freedman [a,*], Barry I. Graubard [b], Worta McCaskill-Stevens [c], Mitchell H. Gail [b], Rachel Ballard-Barbash [a]

[a] *Division of Cancer Control and Population Sciences, National Cancer Institute, Bethesda, MD, USA*
[b] *Division of Cancer Epidemiology and Genetics, National Cancer Institute, Bethesda, MD, USA*
[c] *Division of Cancer Prevention, National Cancer Institute, Bethesda, MD, USA*

In 1998, the Breast Cancer Prevention Trial (BCPT) demonstrated that tamoxifen reduced the risk of invasive breast cancer by 49% among women with no previous history of the disease. The United States (U.S.) Food and Drug Administration (FDA) approved tamoxifen for breast cancer chemoprevention for women aged 35 years or older with a 5-year breast cancer risk of at least 1.67%, as defined by the ''Gail'' Breast Cancer Risk Assessment Model [1]. Such women are eligible in the U.S. to take tamoxifen for chemoprevention. Freedman and colleagues [2] estimated that over 10 million women in the U.S. between the ages of 35 and 79 were eligible to take tamoxifen for breast cancer chemoprevention in 2000.

Unfortunately, tamoxifen use has been associated with adverse outcomes, including excesses of endometrial cancer, pulmonary embolism, stroke, deep vein thrombosis, and cataracts, and not all eligible women have a positive benefit/risk ratio. Using a benefit/risk index for tamoxifen chemoprevention [3], Freedman and colleagues [2] estimated that 2.4 million U.S. would have a net benefit from taking the drug.

To obtain a nationally representative estimate of the numbers of women taking tamoxifen for breast cancer chemoprevention, we analysed data from the year 2000 National Health Interview Survey (NHIS) Cancer Control Module [4–6]. Only 13 of 6569 (0.2%, 95% Confidence Interval (CI) 0.1–0.3%) white women without a previous history of breast cancer, age 40 to 79 years or older reported they were currently taking tamoxifen. We estimated that among 42 197 968 white women age 40–79 years in the U.S., only 70 681 (95% CI 36 284–123 984) were taking tamoxifen for chemoprevention. Samples were too small to give reliable estimates for black and Hispanic women. Since women were not asked about the reason for taking tamoxifen, our estimates may exceed the actual numbers of women taking tamoxifen for chemoprevention, because some women who reported taking tamoxifen may have failed to report a previous diagnosis of breast cancer.

Thus, in the year 2000, two years after the FDA's approval of tamoxifen for chemoprevention, few white women were using the drug for chemoprevention compared with the large numbers eligible and even compared with the more modest numbers estimated to have a positive benefit/risk index. Women in the U.S. may be unaware of the availability of a drug to prevent breast cancer. Women may also be unaware of the risks and benefits. In a community sample of women aged 40–55 years, 23% were interested in taking a drug to prevent breast cancer without specific information on risks and benefits, even though only 8% of these women were at high risk [7]. Some physicians may be unclear about when to recommend chemoprevention, may be unfamiliar with available benefit/risk analyses, and may not want to carry out the long-term follow-up necessary for serious adverse events from tamoxifen.

In 2002, the U.S. Preventive Services Task Force recommended that clinicians routinely discuss chemoprevention with women at high risk of breast cancer and low risk of adverse effects. A woman's decision to take tamoxifen to prevent breast cancer is complex and involves how she weighs her disease risks and benefits, as well as her comorbidities, personal values, preferences, lifestyle, and specific medical situation. The data presented here indicate a need for educating healthcare

*Corresponding author. Address: National Cancer Institute, EPN 4005 MSC 7344, 6130 Executive Blvd., Bethesda, MD 20892-7344, USA.

E-mail address: Andrew_Freedman@nih.gov (A.N. Freedman).

1359-6349/$ - see front matter
doi:10.1016/j.ejcsup.2004.08.002

professionals and for providing tools to help assess the risks and benefits of tamoxifen for chemoprevention in their patients.

References

1. Gail MH, Brinton LA, Byar DP, Corle DK, Green SB, Schairer C, *et al.* Projecting individualized probabilities of developing breast cancer for white females who are being examined annually. *J Natl Cancer Inst* 1989, **81,** 1879–1886.
2. Freedman AN, Graubard BI, Rao SR, McCaskill-Stevens W, Ballard-Barbash R, Gail MH. Estimates of the number of U.S. women who could benefit from tamoxifen for breast cancer prevention. *JNCI* 2003, **95,** 526–532.
3. Gail MH, Costantino JP, Bryant J, Croyle R, Freedman L, Helzlsouer K, *et al.* Weighing the risks and benefits of tamoxifen treatment for preventing breast cancer. *J Natl Cancer Inst* 1999, **91,** 1829–1846.
4. National Center for Health Statistics. National Health Interview Survey (NHIS). Centers for Disease Control and Prevention, U.S. Department of Health and Human Services. [Last accessed July 22, 2002.] Available at: http://www.cdc.gov/NCHS/nhis.htm.
5. Botman SL, Moore TF, Moriarity CL, Parsons VL. Design and estimation for the National Health Interview Survey, 1995B2004. National Center for Health Statistics. Natl Vital Stat Rep 2000, p. 1B31.
6. Korn EL, Graubard BI. Analysis of health surveys. Sec 3.2. New York: Wiley; 1999. p.22–8, 64–68.
7. Bastian LA, Lipkus IM, Kuchibhatla MN, Weng HH, Halabi S, Ryan PD, Skinner CS, Rimer BK. Women's interest in chemoprevention for breast cancer. *Arch Intern Med* 2001, **161,** 1639–1644.