

EDITORIAL

Long-term Adjuvant Tamoxifen Therapy and Decreases in Contralateral Breast Cancer

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Tamoxifen revolutionized personalized medicine as the first targeted therapy proven to save lives in cancer.¹ The paradigm change proposed to block the breast tumor estrogen receptor (ER), apply long-term adjuvant therapy to block estrogen-stimulated recurrences,^{1,2} and apply the potential of

tamoxifen to prevent breast cancer.³ These strategic recommendations were translated, during the past 3 decades, to clinical care.⁴ A meta-analysis⁵ of randomized clinical trials revealed that the strategic use of long-term adjuvant tamoxifen therapy is the key to therapeutic success. In addition, we now know that treating metastatic breast cancer (MBC) is only palliative at the end of life, but the same medicine saves lives if applied as long-term adjuvant therapy. Nevertheless, the question has to be asked whether the results would be the same outside the clinical trials process.

The report in this issue of *JAMA Oncology* by Gierach and coworkers⁶ is reassuring because all the rules derived, until now, from randomized clinical trial overview analyses hold true.⁶ The authors⁶ performed a retrospective cohort study of contralateral breast cancer (CBC) in a population of 7541 patients from the records at Kaiser Permanente Northwest and Colorado from 1990 to 2008 and followed up through 2011. The median range of observation was 6.3 years, and 248 patients were identified to have developed CBC. Both tamoxifen and aromatase inhibitors reduced CBC, and longer adjuvant therapy proved to be more beneficial than shorter therapy. The authors⁶ estimate that 4 or more years of adjuvant tamoxifen therapy will prevent 3 CBCs per 100 women by 10 years after first diagnosis of ER-positive breast cancer. The authors⁶ stress that patients with breast cancer who are undergoing long-term adjuvant endocrine therapy should be encouraged to complete the full course. Indeed, this conclusion is even more important because in the future adjuvant endocrine therapy will last for 10 years.^{7,8} However, the challenge is adherence. Simply stated, no medicine, no benefit. A previous report⁹ calculates the number of deaths caused by nonadherence with adjuvant tamoxifen therapy. Low adherence results in early recurrence, increased medical costs, and a much worse quality of life.⁹

Gierach and coworkers⁶ report the persistence of the protective effects of adjuvant tamoxifen after treatment stops on CBC risk and that this effect is dependent on the duration of tamoxifen therapy. The authors⁶ cite a Danish study¹⁰ that found that current users of tamoxifen had a reduced risk of CBC,¹⁰ but former use of tamoxifen had no effect on CBC. Importantly,

the adjuvant therapy used was only for a short period (median, 1-2.5 years).¹⁰ Persistence of the protective effects of tamoxifen using 5 years of treatment in high-risk populations is noted in the National Surgical Adjuvant Breast and Bowel Project trial¹¹ to reduce the risk of primary breast cancer in high-risk women. These data¹¹ are supported by the 96-month follow-up of the International Breast Cancer Intervention Study trial and the 20-year follow-up of the Royal Marsden Breast Cancer Prevention trial.¹² The rule is clear: long-term treatment with tamoxifen (5 years) produces a sustained beneficial effect in preventing breast cancer, whereas short-term therapy does not.

This clinical reality now presents the medical community with a paradox. Tamoxifen is a competitive inhibitor of estrogen action at the tumor ER. However, long-term adjuvant tamoxifen therapy^{1,2} must be continuous because failure of tamoxifen to block the tumor ER will result in recurrence. However, this laboratory strategy³ was not predictive for 5 years of adjuvant therapy. Patients survive without the benefit of tamoxifen blocking the ER to prevent recurrence. Herein lies the paradox. Tamoxifen is not cytotoxic, so where does the cytotoxicity of long-term tamoxifen therapy come from to protect patients after 5 years of adjuvant tamoxifen therapy?

The answer comes from laboratory research on the evolution of acquired resistance to tamoxifen.^{11,12} Investigation of ER-positive breast tumors transplanted into tamoxifen-treated ovariectomized athymic mice results in the development of acquired resistance to tamoxifen within 1 to 2 years.¹² Uniquely, breast tumors develop because of tamoxifen treatment not despite tamoxifen treatment, and tumors use tamoxifen or estrogen to maintain tumor growth.^{13,14} This biological knowledge is the scientific foundation for using an aromatase inhibitor (to prevent the postmenopausal patient from synthesizing estrogen) or fulvestrant (which destroys the tumor ER as a pure antiestrogen) as second-line therapies for MBC in which tamoxifen treatment has not worked. Antiestrogenic therapy is the strategy of choice because estrogen stimulates tamoxifen-resistant tumor growth.

Additional transplantation of ER-positive breast tumors with early acquired resistance to tamoxifen into tamoxifen-treated athymic mice for up to 5 years replicates the clinical strategy of 5 years of adjuvant therapy.¹¹ Tamoxifen-stimulated growth continues, but paradoxically physiologic estrogen has a significant antitumor effect.¹¹ Estrogen is cytotoxic, and tumors disappear completely. Yao and coworkers¹⁵ proposed 2 clinical applications: (i) physiologic estrogen to treat MBC af-

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Table of Contents Long Term Tamoxifen Treatment For Breast Cancer

1. Understanding the eBook Long Term Tamoxifen Treatment For Breast Cancer
 - The Rise of Digital Reading Long Term Tamoxifen Treatment For Breast Cancer
 - Advantages of eBooks Over Traditional Books
2. Identifying Long Term Tamoxifen Treatment For Breast Cancer
 - Exploring Different Genres
 - Considering Fiction vs. Non-Fiction
 - Determining Your Reading Goals
3. Choosing the Right eBook Platform
 - Popular eBook Platforms
 - Features to Look for in an Long Term Tamoxifen Treatment For Breast Cancer
 - User-Friendly Interface
4. Exploring eBook Recommendations from Long Term Tamoxifen Treatment For Breast Cancer

- Personalized Recommendations
- Long Term Tamoxifen Treatment For Breast Cancer User Reviews and Ratings
- Long Term Tamoxifen Treatment For Breast Cancer and Bestseller Lists
- 5. Accessing Long Term Tamoxifen Treatment For Breast Cancer Free and Paid eBooks
 - Long Term Tamoxifen Treatment For Breast Cancer Public Domain eBooks
 - Long Term Tamoxifen Treatment For Breast Cancer eBook Subscription Services
 - Long Term Tamoxifen Treatment For Breast Cancer Budget-Friendly Options
- 6. Navigating Long Term Tamoxifen Treatment For Breast Cancer eBook Formats
 - ePub, PDF, MOBI, and More
 - Long Term Tamoxifen Treatment For Breast Cancer Compatibility with Devices
 - Long Term Tamoxifen Treatment For Breast Cancer Enhanced eBook Features
- 7. Enhancing Your Reading Experience
 - Adjustable Fonts and Text Sizes of Long Term Tamoxifen Treatment For Breast Cancer
 - Highlighting and Note-Taking Long Term Tamoxifen Treatment For Breast Cancer
 - Interactive Elements Long Term Tamoxifen Treatment For Breast Cancer
- 8. Staying Engaged with Long Term Tamoxifen Treatment For Breast Cancer
 - Joining Online Reading Communities
 - Participating in Virtual Book Clubs
 - Following Authors and Publishers Long Term Tamoxifen Treatment For Breast Cancer
- 9. Balancing eBooks and Physical Books Long Term Tamoxifen Treatment For Breast Cancer
 - Benefits of a Digital Library
 - Creating a Diverse Reading Collection Long Term Tamoxifen Treatment For Breast Cancer
- 10. Overcoming Reading Challenges
 - Dealing with Digital Eye Strain
 - Minimizing Distractions
 - Managing Screen Time
- 11. Cultivating a Reading Routine Long Term Tamoxifen Treatment For Breast Cancer
 - Setting Reading Goals Long Term Tamoxifen Treatment For Breast Cancer
 - Carving Out Dedicated Reading Time
- 12. Sourcing Reliable Information of Long Term Tamoxifen Treatment For Breast Cancer

- Fact-Checking eBook Content of Long Term Tamoxifen Treatment For Breast Cancer
- Distinguishing Credible Sources
- 13. Promoting Lifelong Learning
 - Utilizing eBooks for Skill Development
 - Exploring Educational eBooks
- 14. Embracing eBook Trends
 - Integration of Multimedia Elements
 - Interactive and Gamified eBooks

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