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Is anastrozole really better than tamoxifen for low-risk breast cancer?

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ABSTRACT

Objective: In 2002, the ATAC trial (Arimidex, Tamoxifen, Alone or in Combination) established anastrozole as the preferred adjuvant treatment over tamoxifen in postmenopausal women (disease-free survival at 89.4 % vs. 87.4 %) with hormone receptor-positive breast cancer (BC). The efficacy demonstrated in the ATAC trial led to the broader adoption of aromatase inhibitors in younger women. This practice necessitates using GnRH agonists or ovarian ablation to induce menopause, which causes significant side effects such as bone deterioration. Our study aimed to compare local recurrence (LR) and overall survival (OS) between anastrozole and tamoxifen for low Oncotype Recurrence Scores (RS). We hypothesize that there is little to no difference in LR and OS between the two medications in both pre- and postmenopausal women.

Methods: The TriNetX database was used to create retrospective cohort studies based on low (0–17) Oncotype RS. We conducted two studies comparing women <50 or >50 years old who were treated with either anastrozole or tamoxifen. All studies excluded Stage 4 or T4 tumors and had propensity scores matched by age, tumor stage, tumor size (T), and nodal status (N). Outcomes of interest were 10-year OS and LR.

Results: For patients aged >50, there were 1734 patients on anastrozole and 682 on tamoxifen, with 582 patients per cohort after matching. Within 10 years, 10 or fewer patients died, with no statistically significant difference in 10-year OS (KM analysis: 98 % vs. 97 %, p = 0.6). LR was 7.2 % in the anastrozole group and 7.6 % in the tamoxifen group, with no statistically significant difference (HR 1, 95 % CI, 0.69–1.65).

For patients aged <50, 94 received anastrozole and 270 received tamoxifen, with 82 matched patients included in the analysis. Within 10 years, no patients died, and 10 or fewer experienced LR. There was no significant difference in both 10-year OS (KM analysis: 100 % vs. 100 %, p = 1) and LR (12 % vs. 12 %, HR 2, 95 % CI, 0.59–6.56).

Conclusions: In both pre- and postmenopausal women, there is no difference in 10-year OS or LR between anastrozole and tamoxifen for BC patients with low Oncotype RS. We conclude that Stage 1–3, T1-T3 pre- and postmenopausal BC patients with Oncotype RS between 0 and 17 can safely choose either medication. This finding is of particular importance for premenopausal women who wish to avoid the adverse side effects of medically induced menopause and bone deterioration associated with the anastrozole and ovarian suppression approach.

1. Introduction

Over 200,000 U S. women are diagnosed with breast cancer (BC) annually, with 70 % being hormone receptor (HR)-positive tumors.[1,2] Recent studies have demonstrated a significant increase in BC rates among women under 50,[2,3] who represent approximately 30 % of HR-positive HER2-negative cases.[4] The 2002 ATAC (Arimidex, Tamoxifen, Alone or in Combination) trial was a landmark study that established anastrozole as the preferred adjuvant therapy over tamoxifen for postmenopausal women with HR-positive BC. The results showed that anastrozole had a higher disease-free survival (89.4 % versus 87.4 %), leading to its widespread use.[5] Subsequent studies have confirmed these findings,[6–9] leading to broader adoption of aromatase inhibitors (AIs) in premenopausal women.[10,11] However, in premenopausal patients, AIs stimulate ovarian function by disrupting hormonal feedback to the hypothalamus and pituitary, requiring combination with

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Gonadotropin-Releasing Hormone (GnRH) analogs or ovarian ablation to achieve menopausal estrogen levels. This combined approach exposes patients to detrimental side effects, including bone loss, arthralgia, and fractures.[5]

The aim of our study was to compare local recurrence (LR) and overall survival (OS) between anastrozole and tamoxifen for both pre- and postmenopausal women with low-risk BC (Oncotype Recurrence Score (RS) of less than 18). We hypothesize that there is minimal to no difference in LR or OS, and both patient groups can safely choose either medication.

2. Materials and methods

2.1. Data source

Data for this study were collected on October 19, 2024, from the TriNetX U.S. Collaborative Network, a global federated health research database with electronic medical records from over 115 million patients in 66 Health Care Organizations (HCOs). Available data include demographics, diagnoses (ICD-10-CM codes), procedures (ICD-10-PCS or CPT), medications (RxNorm, Veterans Affairs National Formulary, or Anatomical Therapeutic Chemical classification system), and laboratory tests (coded using Logical Observation Identifiers Names and Numbers). Oncological data used in this study were provided by the North American Association of Central Cancer Registries (NAACCR) International Classification of Diseases for Oncology (ICD-O) morphology codes. Participating HCOs include hospitals, clinics, and specialists serving both insured and uninsured patients.

2.2. Patient consent statement

This retrospective study is exempt from informed consent. The data reviewed is a secondary analysis of existing data, does not involve intervention or interaction with human subjects, and is de-identified as defined in Section §164.514(a) of the Health Insurance Portability and Accountability Act Privacy Rule. Data is directly retrieved from electronic health record systems of participating organizations in a systematic and standardized format.

2.3. Design of cohort

Using the TriNetX database, we created two retrospective cohort studies of women with breast cancer and low Oncotype RS (0–17), excluding Stage 4 and T4 cancers. Each study compared women on anastrozole versus tamoxifen: one in postmenopausal women and the other in premenopausal women. Women under 50 were classified as premenopausal and those over 50 as postmenopausal. While menopausal status is ideally determined by menstrual history or hormone levels, such data are not reliably captured in de-identified databases like TriNetX. Therefore, age 50 was used as a practical and commonly accepted surrogate marker, consistent with prior epidemiologic research reflecting the median age of natural menopause in the U.S.[12] Although detailed hormone receptor data are not consistently coded across institutions in TriNetX, selecting patients with a low Oncotype Recurrence Score (0–17) strongly implies a HR-positive population, as Oncotype DX testing is a validated prognostic assay for HR-positive, HER2-negative, early-stage breast cancer and is rarely used for HR-negative disease.[13]

The following codes were used:

- Breast cancer: ICD-10 C50
- Low Oncotype RS (0–17): NAACCR ICD-O 3906|0
- Anastrozole: RxNorm 84857
- Tamoxifen: RxNorm 10324

2.3.1. Outcomes

Outcomes were assessed over a 10-year follow-up period, starting from one day after the index event, which was initiation of anastrozole or tamoxifen. Overall survival (OS) was identified as "Deceased" status in Demographics, and local recurrence (LR) was coded using ICD-10-CM C77.3 and C79.81.

2.3.2. Statistical analyses

Statistical analyses were performed using the TriNetX platform. To minimize the effect of confounding factors, cohorts were matched 1:1 using TriNetX's built-in platform for covariate adjustment with the greedy nearest-neighbor algorithm. Covariates used for matching included age at index event, cancer stage (0–3), and tumor size (T1-T3). Of note, they do not represent the overall patient population characteristics and were not analyzed as study variables. Balance was assessed by standardized difference, with <0.1 indicating an acceptable match.[14] Kaplan-Meier (KM) curves were used to analyze 10-year OS, with significance defined as $p < 0.05$ by log-rank test. Hazard ratios (HR) and 95 % confidence intervals (CI) were reported for local recurrence.

3. Results

Table 1 shows covariate characteristics after propensity score matching for both post- and premenopausal women, with all matched covariates appropriately balanced (standardized difference <0.1).

3.1. Postmenopausal women

Among postmenopausal patients, there were 1734 on anastrozole and 682 on tamoxifen. After propensity matching, there were 542 patients per cohort (Fig. 1). For 10-year OS, there were 10 or fewer deaths among both cohorts. KM analysis demonstrated a 10-year survival probability of 98 % in the anastrozole cohort and 97 % in the tamoxifen cohort (log-rank $p = 0.60$) (Fig. 2). LR occurred in 7.2 % of anastrozole and 7.6 % of tamoxifen patients (HR 1.1 (95 % CI [0.69, 1.65])) (Table 2).

3.2. Premenopausal women

Among premenopausal patients, there were 94 on anastrozole and 270 on tamoxifen. After propensity matching, there were 82 patients per cohort (Fig. 1). The 10-year OS was 100 % in both groups with no deaths reported (log-rank $p = 1.0$) (Fig. 3). LR occurred in 12.2 % of patients in both cohorts, with a HR of 1.9 (95 % CI 0.59–6.56) (Table 2).

4. Discussion

Endocrine therapy is a crucial part of treatment for HR-positive BC patients, with tamoxifen and anastrozole as the two most prescribed options. Treatment choice depends on a variety of factors, including the patient's overall health, bone density, and menopausal status. Each treatment bears significant side effects which must be considered for each patient. Tamoxifen is associated with side effects such as endometrial cancer, thromboembolic disorders, and menopausal symptoms, while anastrozole is associated with bone deterioration.[15]

Historically, tamoxifen was the standard adjuvant endocrine therapy for both pre- and postmenopausal women. The ATAC trial and subsequent follow-up studies showed that anastrozole is more effective than tamoxifen in the adjuvant setting, prompting major guideline updates for BC treatment.[5,9] This led to the use of anastrozole in younger women, often combined with ovarian suppression to achieve postmenopausal estrogen levels.[10,11] However, this combined approach bears significant side effects related to bone loss, raising questions about its appropriateness for premenopausal patients.

Table 1
Baseline covariate characteristics of the propensity-matched study population, postmenopausal and premenopausal women on tamoxifen versus anastrozole. Bold font represents a standardized difference <0.1.
*TriNetX rounds all patient counts from 1 to 10 as 10 to prevent patient reidentification. We report a value range of 1–10 as ≤ 10.

Variables	Postmenopausal Tamoxifen (n = 542)	Postmenopausal Anastrozole (n = 542)	Std. Diff.	Premenopausal Tamoxifen (n = 82)	Premenopausal Anastrozole (n = 82)	Std. Diff.
Age at index, years (mean ± SD)	60.6 ± 9.9	60.7 ± 9.5	**0.0116**	43.1 ± 4.2	43.4 ± 4.3	**0.0721**
Stage, n (%)						
0	26 (4.8 %)	21 (3.9 %)	**0.0453**	≤10 (12.2 %)	≤10 (12.2 %)	–
1	522 (96.3 %)	520 (95.9 %)	**0.0191**	77 (93.9 %)	78 (95.1 %)	**0.0536**
2	52 (9.6 %)	55 (10.1 %)	**0.0186**	≤10 (12.2 %)	≤10 (12.2 %)	–
3	≤10 (1.8 %)	≤10 (1.8 %)	–	≤10 (12.2 %)	≤10 (12.2 %)	–
Tumor size, n (%)						
T1	445 (82.1 %)	428 (79 %)	**0.0793**	67 (81.7 %)	66 (80.5 %)	**0.0312**
T2	183 (33.7 %)	209 (38.6 %)	0.1000	26 (31.7 %)	29 (35.4 %)	**0.0776**
T3	24 (4.4 %)	30 (5.5 %)	**0.0509**	≤10 (12.2 %)	≤10 (12.2 %)	–
Nodal status, n (%)						
N0	513 (94.6 %)	511 (94.3 %)	**0.0191**	77 (93.9 %)	77 (93.9 %)	–
N1	118 (21.8 %)	119 (22 %)	**0.0045**	20 (24.4 %)	18 (22 %)	**0.0578**
N2	≤10 (1.8 %)	≤10 (1.8 %)	–	≤10 (12.2 %)	≤10 (12.2 %)	–

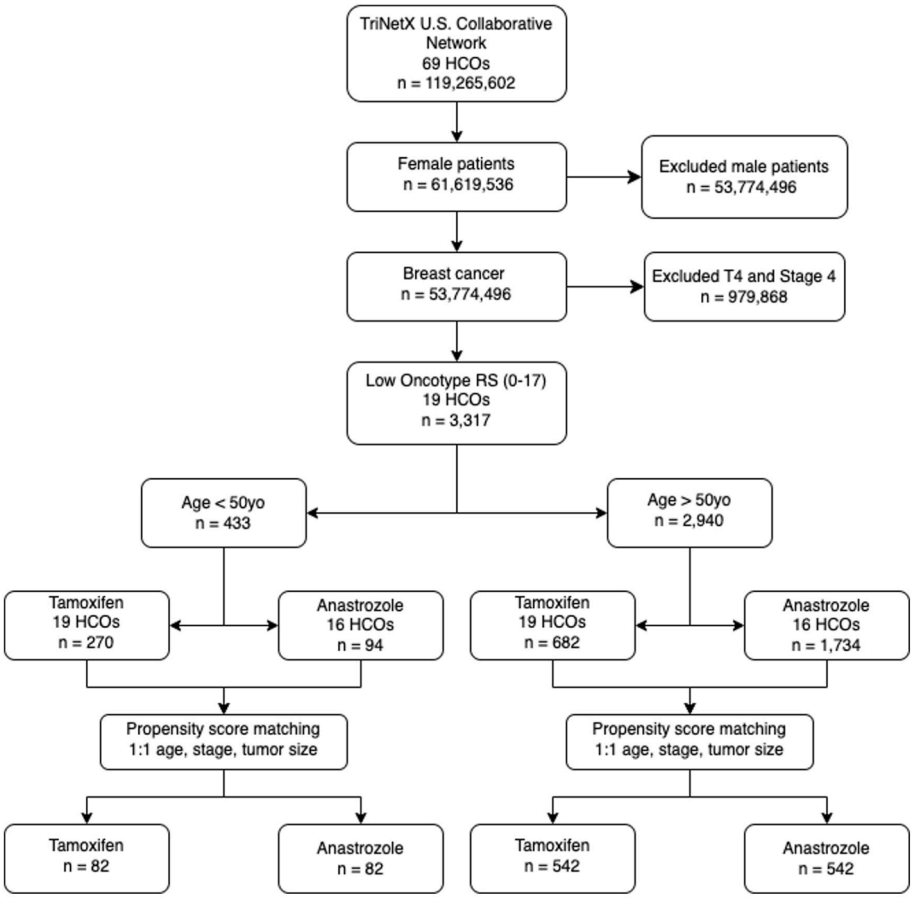

Fig. 1. Flow diagram of cohort construction for female breast cancer patients who were on either tamoxifen or anastrozole. Female patients either >50 or <50 years old with Stage I-III, T1-T3 breast cancer were identified, separated by tamoxifen or anastrozole use, then propensity-matched.

Our study found no difference in 10-year OS or LR between anastrozole and tamoxifen for both pre- and postmenopausal women with low Oncotype RS, suggesting that either medication is safe. Treatment should be individualized based on tumor biology, cancer stage, comorbidities, and patient preference. These factors should guide not only the type of endocrine therapy but also its duration. Clinical trials have shown that extending AI therapy to 10 years compared to five improves disease-free survival and reduces contralateral BC risk.[16,17] However, multiple studies have reported no improvement in OS.[17–21] Our study supports these findings, confirming no difference in 10-year OS and additionally demonstrating no difference in LR. This may reflect the inherently low baseline recurrence risk in patients with early-stage BC, which may limit the measurable impact of anastrozole over tamoxifen. Additionally, improvements in multidisciplinary care, surgical technique, and radiation therapy may contribute to reducing LR, further lowering the observable differences between the two medications.

While extending AI treatment by an additional five years may offer modest benefits for some women, this must be carefully weighed against

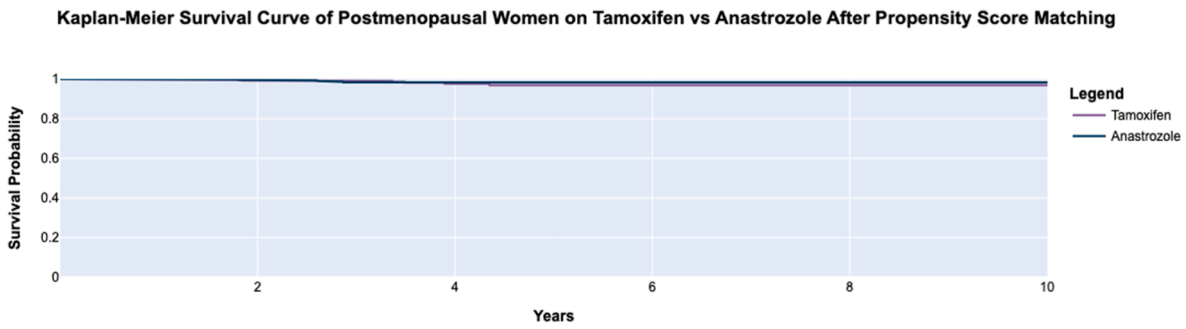

Fig. 2. Kaplan–Meier survival curve of postmenopausal women on tamoxifen versus anastrozole after propensity score matching. Abbreviations: x^2, chi-squared test; df, degrees of freedom.

Table 2
Comparison of propensity-matched female postmenopausal and premenopausal breast cancer patients on tamoxifen versus anastrozole
Bold font indicates a statistically significant value.

Outcome	Menopausal Status	Tamoxifen (n, %)	Anastrozole (n, %)	HR (95 % CI)	Risk Difference P-value
Mortality, n (%)	Postmenopausal	≤10 (1.8 %)	≤10 (1.8 %)	1.3 (0.46, 3.82)	0.32
	Premenopausal	0 (0 %)	0 (0 %)	–	–
Local recurrence, n (%)	Postmenopausal	41 (7.6 %)	39 (7.2 %)	1.1 (0.69, 1.65)	0.68
	Premenopausal	≤10 (12.2 %)	≤10 (12.2 %)	1.9 (0.59, 6.56)	0.83

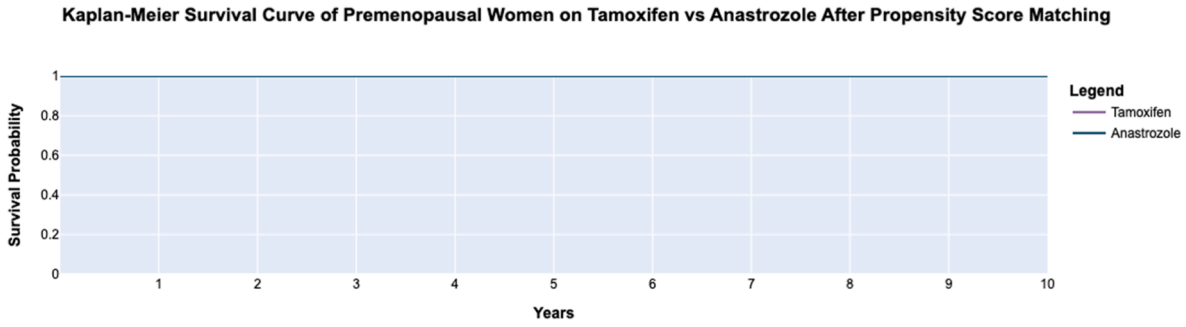

Fig. 3. Kaplan–Meier survival curve of premenopausal women on tamoxifen versus anastrozole after propensity score matching. Abbreviations: x^2, chi-squared test; df, degrees of freedom.

the associated risks and side effects, such as bone deterioration.[22] In addition to the physical impact of such side effects, studies have shown that women under 50 undergoing BC treatment experience greater psychosocial challenges.[23] This raises the question of how to identify the most suitable treatment for each patient and whether therapy compliance should be factored into the decision-making process. These results again highlight the need for a balanced and individualized approach when determining the type and duration of endocrine therapy.

We acknowledge several limitations due to the study's retrospective nature and reliance on electronic records from multiple institutions, which could lead to potential misdiagnosis, inaccurate coding, and documentation errors. The TriNetX platform lacks data to evaluate disease-specific survival and details on baseline disease status, grading, and nodal involvement. The study utilized age as a surrogate marker for menopausal status, consistent with epidemiologic research, but lacked confirmation via menstrual history or hormone levels. Similarly, it was not possible to determine whether premenopausal women on anastrozole received concurrent ovarian suppression or the duration of endocrine therapy. Furthermore, database coding limitations prevented consistent accounting for local and systemic adjuvant therapies, including the type of surgery, radiation delivery, or use of chemotherapy. However, because inclusion was restricted to patients with a low Oncotype RS (0–17), the majority of this population was likely at low risk for recurrence and had a low probability of receiving chemotherapy. Despite these limitations, the strength of our study stems from the analysis of a large and diverse multicenter database with a nationally validated set of outcome data and a rigorous audit process.

A multidisciplinary approach and shared decision-making between patients and physicians are essential when considering the type and duration of endocrine therapy. Discussions should address the benefits of reducing BC recurrence and preventing secondary cancers, as well as the potential impact of treatment-related side effects. Future prospective studies with more granular data on menopausal status, hormone receptor expression, and therapy adherence are warranted to validate these findings and further refine endocrine therapy selection for women with early-stage, low Oncotype RS BC.

5. Conclusion

For both pre- and postmenopausal women with breast cancer and low Oncotype RS, no differences were observed in 10-year OS or LR between anastrozole and tamoxifen. Based on these retrospective findings, our results support the consideration that Stage 1–3, T1-T3 breast cancer patients with an Oncotype RS of 0–17 can safely discuss either medication with their physician. This is particularly significant for premenopausal women who may prefer to avoid the side effects of medically induced menopause and bone loss associated with the anastrozole and ovarian suppression approach. The selection of endocrine

therapy should be individualized, considering the biology of the cancer as well as the patient's comorbidities and preference. Decisions regarding the type and duration of treatment should ensure that the benefits outweigh the risks for each patient.

10-Year Survival Probability		Log-Rank Test		
Tamoxifen ($n = 82$)	Anastrozole ($n = 82$)	x^2	df	p-value
100 %	100 %	0	1	1.0

CRediT authorship contribution statement

Jennifer Den: Writing – review & editing, Writing – original draft, Visualization, Investigation, Data curation, Conceptualization. **Caroline Baughn:** Writing – review & editing, Writing – original draft, Investigation, Data curation. **V. Suzanne Klimberg:** Writing – review & editing, Visualization, Validation, Supervision, Investigation, Conceptualization.

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10-Year Survival Probability		Log-Rank Test		
Tamoxifen ($n = 542$)	Anastrozole ($n = 542$)	x^2	df	p-value
97 %	98 %	0.271	1	0.60

Declaration of interest

The authors have no affiliation with any organization with a direct or indirect financial interest in the subject matter discussed in the manuscript. The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper. The authors declare they have no financial interests/personal relationships which may be considered as potential competing interests.

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