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Safety of Topical Estrogen Use in Patients with a History of Breast Cancer

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Abstract

Introduction: *Genitourinary syndrome of menopause (GSM) is a very common condition in women with a history of breast cancer, especially those treated with anti-estrogen therapy. It is a health problem that has a major negative impact on the quality of life of patients who suffer from it, affecting their physical, social, sexual, and psychological health. Topical vaginal estrogens are very effective. However, there is controversy regarding their safety in patients with a history of breast cancer.*

Objectives: *To determine the safety of using topical vaginal estrogens for the treatment of GSM in patients with a history of breast cancer.*

Methodology: *A systematic review was conducted using the PubMed/MEDLINE, Cochrane Library, and EMBASE databases as sources of information, including articles published between 2010 and 2025 that evaluated the safety of topical vaginal estrogen use in patients with GSM and a history of breast cancer.*

Results: *The results suggest that the use of topical vaginal estrogens in these patients appears to be associated with transient elevations in serum estrogen levels, with subsequent normalization of these levels, as well as having no significant impact on the breast cancer recurrence rate and appearing to have a slight protective effect on the breast cancer-specific mortality rate.*

Conclusions: *The use of topical vaginal estrogens appears to be a safe option for the treatment of GSM in patients with a history of breast cancer.*

Keywords: *Vulvovaginal atrophy, Breast cancer, Topical vaginal estrogens, Safety, Genitourinary syndrome of menopause.*

1. Introduction

Breast cancer is the most commonly diagnosed cancer in women. In recent years, due to breast cancer screening programs and advances in treatment, particularly in adjuvant systemic therapies, there has been a significant increase in the number of patients surviving breast cancer (1).

Due to the high prevalence of breast cancer in the population and its high survival rates, early menopause and genitourinary syndrome of menopause (GSM) or vulvovaginal atrophy (VVA) are now common adverse effects that occur during the course of these treatments in breast cancer patients, especially in those treated with aromatase inhibitors AI (2). This is a health problem that has a major negative impact on the quality of life of patients who suffer from it, affecting their physical, social, sexual, and psychological health (3).

Hormone treatments, such as topical vaginal estrogens, are very useful for treating VVA; however, there is controversy over whether or not they are a safe option for patients with a history of breast cancer (4).

Therefore, the aim of this study was to conduct a systematic review to compile the information available in the scientific literature on the safety of topical vaginal estrogens in patients with a history of breast cancer, in order to determine the safety of this treatment in patients with VVA and a history of breast cancer.

2. Material And Method

A systematic review was conducted to determine the safety of topical vaginal estrogen for the treatment of vulvovaginal atrophy in patients with a history of breast cancer, by reviewing the literature published on the subject over the last 15 years, in accordance with the PRISMA statement.

2.1. Eligibility Criteria

2.1.1. Inclusion Criteria

- Studies published between 2010 and 2025.
- Analytical studies and experimental studies.
- Studies evaluating patients with vulvovaginal atrophy who have a history of breast cancer.
- Studies evaluating the safety of topical vaginal estrogens.
- Studies with a minimum follow-up time of 1 month.

2.1.2. Exclusion Criteria

- Descriptive studies.
- Review articles.
- Doctoral theses and final degree projects.
- Letters to the editor.
- Studies in which menopausal hormone replacement therapy is used in the group with the intervention of interest.

2.2. Sources of Information and Search Strategy

To conduct this systematic review, an exhaustive search of the scientific literature published on the subject between 2010 and 2025 was carried out, without language restrictions, in the following databases: PubMed/MEDLINE, Cochrane Library, and EMBASE.

Descriptors considered in the systematic review:

DeCS: Breast cancer, Cancer survivors, Atrophic vaginitis, Estrogens Safety.

MeSH: Breast cancer, Cancer survivors, Atrophic vaginitis, Estrogens, Safety.

In order to assess the validity (risk of bias) and quality of the studies, two methodological quality assessment scales were used. On the one hand, the Newcastle-Ottawa Scale (NOS) was used to assess the analytical studies included in the review (5), including only those analytical studies considered to be of good quality according to the NOS scale.

On the other hand, the Jadad scale was used to assess the experimental studies included in the review (6). Only those experimental studies with a score of 3 or higher according to the Jadad scale were included.

2.3. Independent Variables

Anti-Estrogen Therapy: "Treatment used for breast cancer and related to the onset of VVA as a complication of the study."

Intervention: "Conditions of use of topical vaginal estrogens for the treatment of VVA in each study (dose, duration of treatment, and pharmaceutical form)."

Control: "Treatment with which the safety of topical vaginal estrogens as a treatment for VVA is compared in each study."

2.4. Dependent Variables

Serum estrogen levels: "Estrogen concentration in blood before and after treatment with topical vaginal estrogens (measured in pg/mL or pmol/L).

Breast cancer recurrence rate: "Number of patients who experience breast cancer recurrence per 100 patients." Mortality rate: "Number of patients who die specifically from breast cancer per 100 patients.

3. Results

According to the methodology described in the previous section, a total of 414 articles were identified, of which 109 were obtained from the PubMed/MEDLINE database, 55 from the Cochrane Library, and 250 from EMBASE.

The 414 articles identified using the search strategy underwent a screening process, in which 119 studies were excluded because they were duplicates, and a total of 238 articles were excluded after reviewing their titles and abstracts because they did not meet the objectives and eligibility criteria of this systematic review.

After this, a total of 57 articles were obtained, which were evaluated in full. Following this process, six articles were finally included and analyzed in this systematic review.

This process of study selection and data collection is summarized and outlined in the following PRISMA flow diagram:

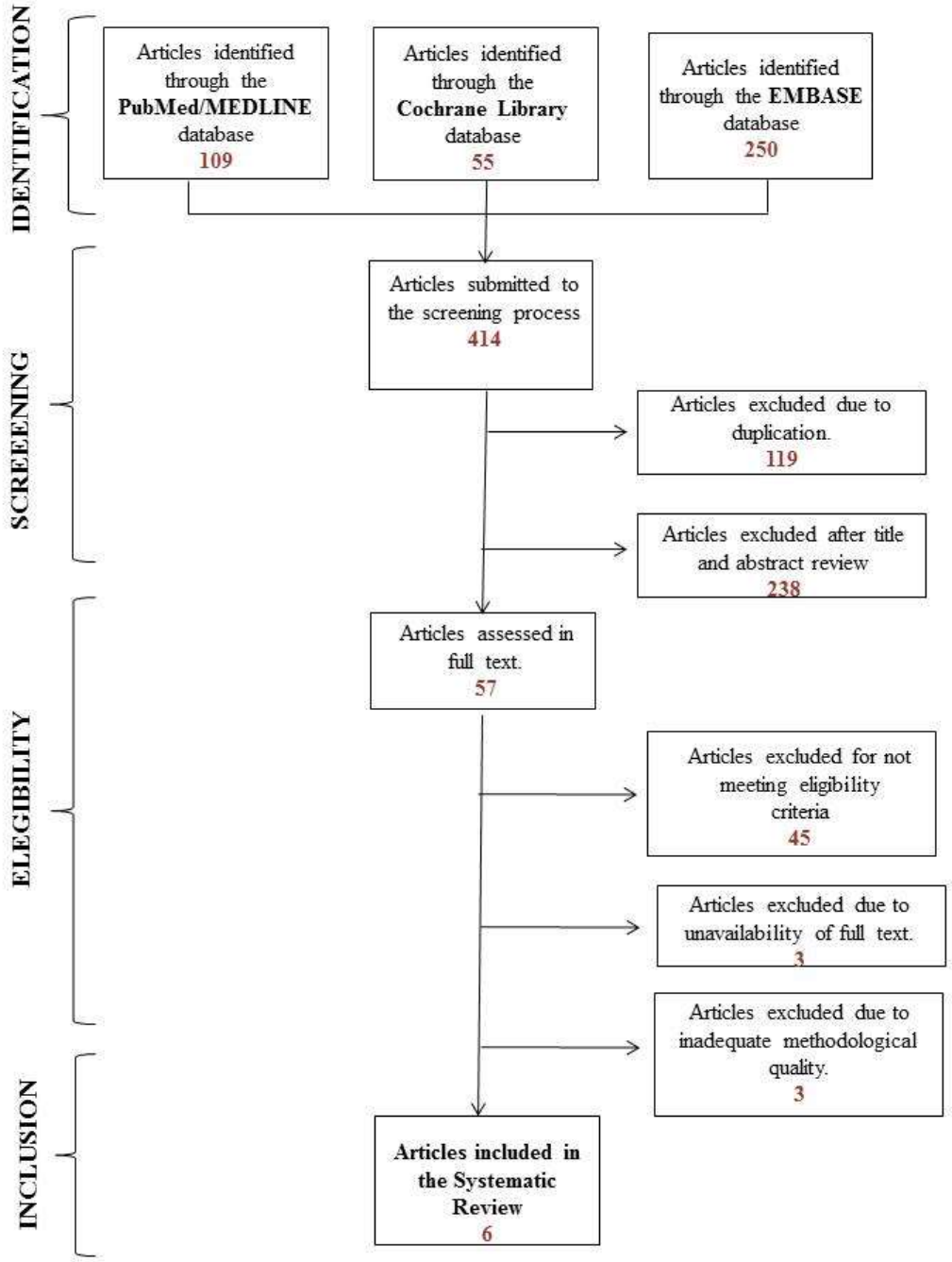

Figure 1. *PRISMA flow chart with the results of the study selection process studies and data collection process.*

The six articles included correspond to the works of Le Ray (7), Wills (8), Melisko (9), Hirschberg (10), Cold (11), and McVicker (12).

Table 1. *Description of the articles included in the systematic review.*

S.no	Título	Authors	Year	Journal
1	Local estrogen therapy and risk of breast cancer recurrence among hormone-treated patients: a nested case-control study	Le Ray et al. (7)	2012	Breast Cancer Research and Treatment.
2	Effects of vaginal estrogens on serum estradiol le vels in postmenopausal breast cancer survivors an d women at risk of breast cancer taking an aromat ase inhibitor or a selective estrogen receptor modulator	Wills et al (8).	2012	Journal of Oncology Practice.

3	Vaginal testosterone cream vs estradiol vaginal ring for vaginal dryness or decreased libido in women receiving aromatase inhibitors forearly-stage breast cancer: a randomized clinical trial	Melisko et al.(9)	2017	JAMA Oncology.
4	Efficacy and safety of ultra-low dose 0.005% estriol vaginal gel for the treatment of vulvovaginal atrophy in postmenopausal women with early breast cancer treated with nonsteroidal aromatase inhibitors: a phase II, randomized, double-blind, placebo-controlled trial	Hirschberg et al. (10)	2020	Menopause: The Jou rnal of The North American Menopause Society.
5	Systemic or vaginal hormone therapy after early breast cancer: a danish observational cohort study	Cold et al. (11)	2022	JNCI: Journal of the National Cancer Institute.
6	Vaginal estrogen therapy use and survival in females with breast cancer	McVicker et al. (12)	2024	JAMA Oncology.

The first article included (Le Ray et al., 2017) (7) presents a retrospective cohort design with a nested case-control analysis. It divides both cases and controls into three groups: a first group that received treatment with endocrine therapy alone (tamoxifen or AI), a second group that received simultaneous treatment with endocrine therapy and vaginal hormone therapy, and a third group that received vaginal hormone therapy after receiving endocrine therapy. It has a sample size of 10,933 patients.

The second article included in the systematic review (Wills et al., 2012) (8) is a cohort study of postmenopausal women with VVA who have hormone receptor-positive breast cancer or are at high risk of developing breast cancer and are receiving treatment with AI or SERM. The study has a sample size of 48 patients.

The third article included in the review (Melisko et al., 2017) (9) is a phase II randomized clinical trial involving postmenopausal women with VVA and hormone receptor-positive breast cancer in stages I to III who are being treated with AI. The sample size included in this clinical trial is 76 patients.

The fourth article included (Hirschberg et al., 2020) (10) is a phase II randomized clinical trial involving postmenopausal women with VVA and hormone receptor-positive breast cancer in stages I to IIIa undergoing AI treatment. The clinical trial had a sample size of 61 patients.

The fifth article included in the systematic review (Cold et al., 2022) (11) is a cohort study with a population of postmenopausal women with VVA and hormone receptor-positive breast cancer in non-metastatic stages who have undergone surgery and are receiving treatment with tamoxifen, IA, or without associated endocrine therapy. This cohort study had a sample size of 8,461 patients.

Finally, the study by McVicker (McVicker et al., 2024) (12) is a cohort study with a population of women between the ages of 40 and 79 with newly diagnosed breast cancer and no other invasive cancers, drawn from two cohorts, one in Scotland and one in Wales, followed until death or the end of the study. The sample size of this latter study consisted of a total of 49,237 women with breast cancer.

Once the articles have been described, the variables are analyzed:

In the study by Le Ray et al. 2017 (7), the use of AI or tamoxifen was considered as anti-estrogen therapies for the treatment of breast cancer in the patients included. The intervention studied was the use of vaginal hormone therapy in the form of estrogen creams and vaginal tablets, although the dose and duration of treatment were not specified. In this study, the control was the absence of vaginal hormone therapy.

With regard to the dependent variables considered, it only provides information on the breast cancer recurrence rate, as it explains that the breast cancer recurrence rate in patients undergoing endocrine therapy and simultaneous vaginal hormone treatment has a relative risk (RR) of 0.78, with a 95% confidence interval (95% CI) between 0.48 and 1.25. Likewise, the breast cancer recurrence rate in patients using vaginal hormone therapy after completing endocrine therapy has an RR of 0.97, with a 95% CI between 0.22 and 4.18.

In relation to the second article, the study by Wills et al. 2012, (8) treatment with AI or SERM was considered as anti-estrogen therapy for the treatment of breast cancer. Information on serum estrogen levels was obtained. On the one hand, the mean serum estradiol concentration in group 1, treated with vaginal estrogen tablets, was 4.2

pmol/L (prior to tablet application), 72 pmol/L (12 hours after application), and a return to the initial value was observed 24 hours after application.

On the other hand, the mean serum estradiol concentration in group 2, treated with an estrogen vaginal ring, was 14.2 pmol/L (prior to insertion), 10.2 pmol/L (at 30 days), and 30 pmol/L (at 60 days). It should be noted that the mean serum estradiol concentration in group 3, i.e., the control group, was 3.72 pmol/L.

As for the third article (Melisko et al., 2017) (9), patients undergoing AI treatment were included as antiestrogen therapy for the treatment of breast cancer. The intervention of interest in this study was the application of a vaginal ring that secretes 0.75?g of estradiol every 24 hours for 90 days. It should be noted that this article lacks a comparison group, and therefore has no control group.

This third article provides information on serum estrogen levels, showing that only four patients had a transient elevation in serum estrogen levels, which subsequently normalized during follow-up. No significant changes in serum estrogen levels were observed in the other patients followed during the study.

The fourth article (Hirschberg et al., 2020) (10) discusses the use of AI as an antiestrogenic therapy for breast cancer. The intervention of interest is the application of 1 gram of vaginal gel containing 50 µg of estriol every 24 hours for 3 weeks and then twice a week until week 12 of follow-up. In this study, the control consists of the use of a placebo in the form of vaginal moisturizers.

This clinical trial provides information on serum estrogen levels in these patients, showing that the mean serum estriol level prior to the intervention was 0.5 pg/mL in both groups, that the mean serum estriol level 1 week after starting the intervention was 3.9 pg/mL in the intervention group and 0.5 pg/mL in the control group, and that the mean serum estriol level 12 weeks after the start of the intervention was 0.5 pg/mL in both groups.

The fifth article (Cold et al., 2022) (11) considers the use of AI, tamoxifen, or even the absence of endocrine therapy for breast cancer as antiestrogen therapy. In this study, the intervention of interest is the use of topical vaginal estrogens. The control group is the untreated group. The breast cancer recurrence rate in patients with topical vaginal estrogen was 15.1% at 10 years, while the breast cancer recurrence rate in untreated patients was 19.2% at 10 years. The hazard ratio (HR) for the breast cancer recurrence rate in patients treated with topical vaginal estrogen was 1.08, with a 95% CI ranging from 0.89 to 1.32.

The breast cancer-specific mortality rate in patients with topical vaginal estrogen was 25.4% at 15 years, while the breast cancer-specific mortality rate in untreated patients was 44.3% at 15 years. The HR for breast cancer-specific mortality in patients treated with topical vaginal estrogen was 0.88, with a 95% CI ranging from 0.77 to 0.99.

Finally, the study by McVicker et al., 2024, (12) considers the use of AI, tamoxifen, oophorectomy, and other antiestrogenic treatments as antiestrogenic therapies for breast cancer. The intervention of interest in this study was the use of topical vaginal estrogens.

The breast cancer-specific mortality rate in patients with topical vaginal estrogens was 4.7%, while the breast cancer-specific mortality rate in patients without hormone therapy was 12.2%. Thus, the HR for breast cancer-specific mortality in patients with topical vaginal estrogen was 0.77, with a 95% CI between 0.63 and 0.94. It is noted that there appears to be no increase in breast cancer recurrence in patients treated with topical vaginal estrogen.

Table 2. *Summary of conclusions from the articles included in the systematic review. Own elaboration.*

Authors	Statistical Test Used	Conclusions
Le Ray Et Al. 2012 (7)	**Conditional Logistic Regression.**	This article concludes that the use of vaginal hormone treatments (estrogen creams and vaginal tablets) is not associated with an increased risk of breast cancer recurrence in patients receiving endocrine treatments (tamoxifen or AI) for breast cancer. It argues that treatment with topical vaginal estrogen should be considered in patients with breast cancer who have symptoms of VVA, as it is not associated with an increased risk of breast cancer recurrence.

Wills Et Al. 2012 (8)	1. **Student´S T-Test For Paired Data.**	This publication concludes that the use of topical vaginal estrogen in patients with VVA and a history of breast cancer is associated with increased serum estradiol levels, and therefore recommends that these therapies should be used with caution in this type of pacient.
	2. **Wilcoxon Signed-Rank Test**	However, it is noted that, in the case of vaginal estrogen tablets, these elevation appear to be transient.
Melisko Et Al. 2017 (9)	**Student´S T-Test**	It concludes that the use of an estradiol vaginal ring is an effective and safe option for the treatment of VVA in patients with a history os breast cancer. Only four patiens followed in this study had transient elevations in serum estrogen levels, which subsequently normalized.
Hirschberg Et Al. 2020 (10)	1. Differences Between The Two Groups:	This scientific work concludes that the use of 0,005% estriol vaginal gel is an effective and safe option for the treatment of VVA in patients with a history of breast cancer. It is determined that there is no significant impact of treatment on serum estrogen levels (with a transient elevation at the start of treatment followed by normalization).
	Mann – Whitney U Test	
	2. Differences Between Time Points Within Each Group:	
	Wilcoxon Test	
	(Intention-To-No-Treat Analysis)	
	1. For Breast Cancer Recurrence Rate:	This article concludes that the use of topical vaginal estrogens is an effective and safe option for the treatment of VVA in patients with a history of breast cancer. It is determined that this therapy has no significant impact on either the breast cancer recurrence rate or the mortality rate in these patients.
	Fine Y Gray´S Compteing Risk Model	
Cold Et Al. 2022 (11)	2. For The Mortality Rate:	However, there is discussion of the posibility that in a subgroup of patients receiving combined treatment with AI and topical vaginal estrogens, there may be a slight increase in the recurrence rate of breast cancer, but without affecting the mortality rate.
	Poisson Regression	
	Cox Regression	This publication concludes that there is no evidence of an increase in breast cancer-specific mortality in patients with a history of breast cancer who receive topical vaginal estrogen treatment for VVA, and that the mortality rate in these patients even appears to decrease compared to those who do not use hormone therapy.
Mcvicker Et Al. 2024 (12)	The Results Of The Two Cohorts Were Combined Using **Random Effects Meta-Analysis Models.**	It argues that these treatments can be used in patients with VVA and a histoy of breast cancer if non-hormonal treatments are unsucessful.

4. Discussion

The results of Le Ray et al. (7) suggest that topical vaginal estrogens are not associated with an increased rate of breast cancer recurrence, so it appears that they could be a safe option in patients with a history of breast cancer.

The study by Wills et al. (8), supports the idea that the use of topical vaginal estrogens could be associated with an increase in serum estrogen levels, so they should be used with caution in patients with a history of breast cancer. However, it also notes that, in the case of vaginal estrogen tablets, these increases appear to be transient.

Melisko et al (9) argue that only in some cases are topical vaginal estrogens associated with an increase in serum estrogen levels, although these levels subsequently normalize, thus appearing to be a safe option in patients with a history of breast cancer. For their part, the article by Hirschberg et al. (10), also reinforces the idea that topical vaginal estrogens do not have a significant impact on serum estrogen levels, with an elevation in levels, but transient, with subsequent normalization.

Cold et al. (11), support the conclusion that topical vaginal estrogens do not have a significant impact on either the breast cancer recurrence rate or the breast cancer-specific mortality rate, and may even have a slight protective effect on the mortality rate.

Finally, McVicker et al. (12), suggest that topical vaginal estrogen would be a safe option in patients with a history of breast cancer, as there

is no increase in breast cancer-specific mortality in patients using topical vaginal estrogen, and there even appears to be a decrease in breast cancer-specific mortality in these patients compared to those who do not use hormone therapy.

The results obtained in this systematic review therefore support the safety of using topical vaginal estrogens specifically for the treatment of VVA in patients with a history of breast cancer.

We expand the discussion with regard to other recent publications dealing with the management of VVA in patients with a history of breast cancer:

One publication of interest is the meta-analysis by Pavlovic (13) published in 2019, which addresses the safety of local hormone therapy for DCIS in patients with estrogen receptor-positive breast cancer receiving adjuvant therapy with aromatase inhibitors (AIs).

This meta-analysis includes clinical trials, observational cohort studies, cross-sectional studies, and case series evaluating women with early-stage estrogen receptor-positive breast cancer who had received AI treatment after breast cancer surgery and had developed VVA, undergoing local hormone therapy for this condition.

The articles included in the meta-analysis use different local hormone treatment options, such as topical vaginal estrogens, but also topical vaginal androgens such as testosterone. However, this systematic review focuses solely on topical vaginal estrogens.

Regarding the results of the meta-analysis, it is mentioned that when the study was conducted, it was ultimately impossible to evaluate the breast cancer recurrence rate and the breast cancer-specific mortality rate due to the lack of articles discussing this at the time the meta-analysis was performed.

This contrasts with the present systematic review, which has determined that the breast cancer recurrence rate is not significantly altered by the use of topical vaginal estrogens and that the breast cancer-specific mortality rate is slightly reduced by the use of topical vaginal estrogens.

Pavlovic's meta-analysis (13) supports the safety of using local hormone therapy to manage VVA in patients with a history of breast cancer, and the results obtained in this systematic review suggest that the use of topical vaginal estrogens could be a safe option for treating VVA in patients with a history of breast cancer.

Finally, another recent publication of interest is that of Comini et al. 2024 (14), consisting of a systematic review and meta-analysis on the safety and impact on serum estradiol levels of hormonal treatments for the management of VVA in patients with a history of breast cancer. A total of 17 studies published between 2003 and 2022 were included. The articles evaluated in the meta-analysis by Comini et al. (14) consider different hormonal treatment options as interventions, including topical vaginal estrogens, intravaginal testosterone, oral ospemifene, and oral DHEA. However, the present systematic review has focused solely on determining specifically and more specifically the safety of topical vaginal estrogens for the treatment of VVA in patients with a history of breast cancer.

With regard to the results obtained in the study by Comini et al., 2024, (14) serum estradiol levels did not change or increased very slightly compared to normal levels in postmenopausal women using low-dose topical vaginal estrogens. It also reports that serum estradiol levels showed more significant elevations in patients treated with intravaginal testosterone.

Regarding the recurrence rate of breast cancer, the study by Comini et al. (14) concludes that this still needs to be evaluated, so the lowest possible doses of hormone treatments should be considered in the context of their efficacy.

5. Conclusions

Based on the evidence available to date, the use of topical vaginal estrogens for the treatment of VVA (GSM) in patients with a history of breast cancer appears to be a safe option, as it is not associated with a significant increase in the breast cancer recurrence rate.

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