

# A Prospective Study on the Prescription Pattern of Anti-Cancer Drugs in Breast Cancer Patients

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## ABSTRACT

**Background:** Cancer is a disease of uncontrolled division of cells in any part of the body. Breast Cancer (BC) is an emerging health issue among female population and accounts for 13% of the death worldwide. The objective of study was to evaluate the drug prescription pattern of BC patients in a tertiary care hospital of Bangalore. **Materials and Methods:** A prospective observational study was conducted for period of 6 months at a tertiary care hospital. The sampling was performed within day-care unit and in-patient department among BC patients meeting the inclusion criteria. A standard data collection form was designed and used to collect information. **Results:** A total of 52 patients satisfying inclusion criteria were enrolled in study. Majority of patients were age more than 50 years and in post-menopausal period. Most of the patients were diagnosed with stage IV of BC and were suffering from triple-negative and HER2+ tumours. The majority of patients received chemotherapy consists of adjuvant and dual drugs therapy. Most commonly prescribed anti-cancer drugs were paclitaxel (20.18%), cyclophosphamide (18.34%) and carboplatin (14.68%). 59.61% of drugs were prescribed from the National Essential Medicine List (NELM) 2022 and 63.46% from WHO essential drug list 2023. **Conclusion:** BC is a prevalent type of cancer which needs long term therapy and monitoring to evaluate and refine therapeutic regimen. The present study evaluated the prescription pattern of chemotherapeutic agents among BC patients and promote the rational use of drugs and reduce patient's sufferings.

**Keywords:** Breast cancer, Prescription pattern, Anti-cancer drugs, Chemotherapy, Chemotherapeutic regimens, Adjuvant, Neo-adjuvant therapy, WHO, NELM.

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## INTRODUCTION

Carcinoma is one of the most common causes of morbidity and mortality all over the world. Tumours are generally categorised based on the area of development and function. The general term use to describe a tumour is neoplasm, which means "new growth". Neoplasm indicates new growth and in ancient time it was referred as cancer as it resembles a crab, with "claws" holding into surrounding tissues.<sup>1</sup> A cancerous tissue undergoes various changes including loss of cohesiveness and destruction of normal cells around along with the loss of normal apoptosis or programmed cell death. The term "malignancy" has come from the malignant cell, the one which have potential to grow uncontrollably.<sup>2</sup> Tumours can be of two types: benign (non-carcinogenic) or malignant (carcinogenic). Benign are those which grow into large size but do not invade or spread into

surrounding tissues or other parts of body. Whereas, malignant are those which invade as well spread to other part of body through blood or lymph flow and that phenomenon is called as "metastasis".<sup>3</sup>

Breast Cancer (BC) is an arising health issue for both the developed as well as developing countries. As per the World Health Organization (WHO) report, BC is one of the most prominent health issues among women worldwide, which has also been the reason for the maximum death in women.<sup>4</sup>

According to the data of WHO survey about 2.1 million women get affected with BC every year and 11.1% of death has been reported of the total diseased number.<sup>5</sup> Studies conducted among the Indian female population revealed BC as the leading type of cancer followed by cervical cancer. In the year 2012, around 70,218 women died of BC in India and that was the highest number of BC-related death across the world that particular year.<sup>4</sup>

The Aetiology of BC correlated with certain factors like early menarche, late menopause, genetic and epigenetic reasons, family history of breast cancer, race and ethnicity, having dense breast tissue, drinking alcohol and being overweight or obese.<sup>6,7</sup>



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Breast cancer is diagnosed and staged as per the various scoring system and one of the standard scoring systems used is TNM system and it is described as:

T-Tumour, which describes the size and area of cancer cell.

N-Lymph node, which says whether cancer has spread to lymph node.

M-Metastasis, which describes whether cancer has spread to other parts of body.<sup>8</sup>

Hormones such as oestrogen and progesterone also play a major role in the prognosis of the BC. Alterations in the homeostasis of these hormones in the body is responsible for the progression of this disease. In most of the breast cancer cells, Human Epidermal growth factor Receptor 2 (HER2) exhibit predominant expression in the patients suffering from breast cancer. The BC cells which do not show any kind of expression towards these receptors are termed as triple negative cancers.<sup>6</sup>

The major modalities that have been in practice for treatment of BC includes chemotherapy, hormonal therapy, immunotherapy, precision medicine or personalized medicine (a newer or developing approach), radiation therapy, stem cell transplant and surgery. The choice of any of this mentioned therapy depends upon various factors like patient factors, tumour factors and treatment factors.<sup>2,3,9,10</sup>

The term “chemotherapy” describes the medications given to the cancer patients, to stop the growth, invasion and dissemination of cancer cells to other tissue as well other parts of body.<sup>9</sup> Chemotherapy is the acts systematically to cure the disease or reduce its progression. Chemo-drugs usually act on rapidly dividing cells that is either it acts on the specific or non-specific cell cycle.<sup>10</sup> Treatments are based on the standard guidelines and recommendations like National Comprehensive Cancer Network (NCCN), European Society for Medical Oncology (ESMO), American Society of Clinical Oncology guidelines (ASCO), developed based on available clinical evidences and expert opinions.<sup>11</sup>

Selection of appropriate therapy is affected by various concerns including under-use, overuse or misuse of the prescribed drugs. Inappropriate drug selection leads to the raise in cost of medical care, increase adverse drug effects and increase patient mortality.<sup>9</sup> Irrational prescriptions and inappropriate use of drugs characterized by poly pharmacy, excessive use of oral drugs or injections and use of drugs with doubtful efficacy or indication has been the challenging feature of health care settings within the developing countries.<sup>12</sup> However, till date, there is no universally accepted guideline for better therapeutic management of cancer so it is required to explore the drug prescribing patterns of these cancer patients.<sup>6</sup>

A prescription pattern is a process to analyse the usage of drugs prescribed and to provide the relevant feedback to the prescribers

to bring awareness towards the proper use of drugs. Therefore, evaluation and monitoring of the prescription patterns of anticancer drugs and supportive drugs are necessary in the cancer patient.<sup>13</sup> Pharmacist play a significant role in the therapy by acting as a bridge between the patients and prescribers. The pharmacist involved with prescription analysis, they interact with their patients about their medications and address the following objectives:

To analyse the prescribed drugs with respect to their class, dose, dosage form and Route of Administration (ROA).

To determine and evaluate the usage of adjuvant drugs accompanied in the drug therapy of BC.

To analyse the anticancer drugs prescribed as per the National essential drug list.<sup>14</sup>

Periodic review of the drugs prescribed and their uses is the only way to prevent such a hazard to patients and also to ensure the safety and effectiveness of treatment.<sup>15</sup> This study was conducted to understand the prescription patterns of anticancer drugs in patients with breast cancer. The study aims to provide the recommendations and educational interventions to oncology treatment team to refine the therapeutic regimen of the breast cancer patients.<sup>11</sup> The present study focus describing the status of breast carcinoma and analyse the prescribing pattern of the anticancer drugs and along with the adjuvant drugs in a tertiary care hospital.

## MATERIALS AND METHODS

### Study Design

A 6-month prospective observational study was conducted at the Oncology Department of a tertiary care hospital in Bangalore to evaluate the pattern of prescription and chemotherapy treatment among female breast cancer patients. The study included 52 patients aged 19-75 years who were receiving chemotherapy, while excluding those who were pregnant, breastfeeding, undergoing surgery, or receiving radiation therapy. Demographic details and medical history were collected and recorded in a specially designed data collection form. The prescriptions were carefully assessed to identify and evaluate the pattern of prescription, providing insights into the management of breast cancer. The study aimed to analyse the chemotherapy treatment patterns among breast cancer patients, ultimately contributing to improved patient care and outcomes.

The sample size was fixed at 52 patients, taking into account several factors. Feasibility of recruiting patients within the 6-month timeframe, resource constraints such as data collection capacity were considered. The desired level of statistical power to ensure precise and confident results and insights from previous studies on breast cancer patients were taken into consideration to estimate the required sample size. By utilizing Cochran's formula,

it was determined that 52 patients would provide a representative and manageable dataset to achieve the study objectives while ensuring feasibility and validity.

**RESULTS**

Breast cancer is a leading cause of cancer-related deaths in women worldwide. Chemotherapy plays a crucial role in the treatment of breast cancer. This study aims to evaluate the demographic profile, clinical findings and prescribing patterns of breast cancer patients receiving chemotherapy.

This prospective observational study was conducted at a tertiary care hospital in Bangalore over a period of 6 months. 52 female patients diagnosed with breast cancer and receiving chemotherapy were included in the study. Demographic data, clinical findings and prescribing patterns were collected and analysed. The study findings are as follows.

**Demographic Data**

A total of 52 subjects studied, it was found that BC is more commonly (*n*=15, 28.84%) in the age group of 50-59 years followed by (*n*=14, 26.92%) in 60-69years, (*n*=8, 15.39%) in 40-49 and 30-39 years, (*n*=5, 9.62%) in 70-79 years and the least was found (*n*=2, 3.84%) in 19-29 years (Table 1).

**Clinical findings**

A total of 52 subjects studied, where the comparison of pre- and post-menopausal status of the patients was observed and which revealed that 18 patients (34.61%) were premenopausal of age

group 19-49 years and 34 (65.39%) were post-menopausal of age group 50-79 years (Table 1). Majority of the patients (18, 34.64%) were found to have none of the receptor positive, called as triple negative. Both estrogen and progesterone were found positive in 12 patients (23.07%). Only estrogen receptor+ve lesion was found in 4 cases (7.70%). 06 (11.53%) patients were found to be HER2 receptor positive. Triple positive was in 04 cases (7.70%) and estrogen and HER2 neu receptor were present in 08 cases (15.39%) (Table 1). Most of the BC patients were diagnosed with stage IV (*n*=18, 34.61%), followed by stage I (*n*=16, 30.77%) and stage II (*n*=12, 23.08%). The least number of patients were of stage III (*n*=06, 11.53). (Table 1).

**Types of therapy**

On the basis of types of chemotherapy received, 52 patients were grouped into three categories which include adjuvant therapy+surgery, adjuvant therapy+radiotherapy and neoadjuvant chemotherapy was observed in 23, 05 and 24 number of patients respectively. The neoadjuvant chemotherapy was highest, was given in 24 patients (46.15%). Adjuvant chemotherapy+radiotherapy was lowest given in 05 patients (9.61%) (Table 2). On the basis of the number of anti-cancer drugs received by the patients, the chemotherapy was categorised as mono, dual and triple therapy. Out of 52 patients 10 (19.23%) had received monotherapy, 27 (51.93%) had received dual therapy and 15 (28.84%) had received triple therapy, (Table 3).

**Prescribing pattern**

The prescribing patterns of the anti-cancer drugs were classified into two groups on the basis of different therapies received by the patients and they are either adjuvant chemotherapy or neo-adjuvant chemotherapy.

Table 4, shows that out of total of 52 subjects studied, 28 patients received adjuvant therapy. Where, dual-therapy was found to be most common regimen (*n*=17, 60.7%) followed by triple-therapy (8, 28.56%) and least was of mono-therapy regimen (*n*=3, 10.7).

Table 5, shows that out of 52 subjects studied 24 patients received neo-adjuvant therapy. Where, dual-therapy was found be most common regimen (*n*=10, 41.65%) followed by triple-therapy (*n*=7, 29.15%) and mono-therapy regimen (*n*=7, 29.15%).

The prescribing indicator shows the percentage of drugs prescribed from the WHO list of medicine and NLEM was

**Table 1: Demographics of the study population.**

Demographic details	Criteria	Number of patients (n=52), (%)
Age group (year)	19-29	02(3.84%)
	30-39	08(15.39%)
	40-49	08(15.39%)
	50-59	15(28.84%)
	60-69	14(26.92%)
	70-79	05(9.62%)
Menopausal status	Pre-menopause	18(34.61%)
	Post-menopause	34(65.39%)
Hormonal status	HR +ve	12(23.07%)
	ER +ve	04(7.70%)
	HER2 +ve	06(11.53%)
	ER+HER2 +ve	08(15.39%)
	Triple positive	04(7.70%)
	Triple negative	18(34.61%)
Stages of cancer	T1-2N0-1M0	16(30.77%)
	T3-4N0-1M0	12(23.08%)
	TanyN2-3M0	06(11.53%)
	Tany Nany M1	18(34.61%)

**Table 2: The number and percentage types of therapy received within the sample.**

Type of therapy	No. of patients	Percentage
Adjuvant+surgery	23	44.23
Adjuvant+radiotherapy	05	9.61
Neo-adjuvant	24	46.15
Total	52	100

63.46% and 59.61% respectively. All the cytotoxic drugs were prescribed in injection form with 100% value. The average number of drugs prescribed per prescription in this current study was 12.44, adjuvants/supportive medicines prescribed 10.34. and anti-cancer drugs prescribed per prescription was 2.16. (Table 6).

The study highlights the demographic profile and clinical findings of breast cancer patients receiving chemotherapy. The majority of patients was in the 50-59 age group and had triple-negative receptor status. Neoadjuvant chemotherapy was the most common treatment approach. The study also highlights the prescribing patterns of anti-cancer drugs, with a high percentage of drugs prescribed from the WHO list of essential medicines and NLEM.

## DISCUSSION

The current study involving 52 female patients, the majority of patients belonged to age group of 50-59 years, i.e., 28.84% and 60-69 years, i.e., 26.92% and least were in age group of 19-29 i.e., 3.84%, as shown in Table 1. This indicates that prevalence of developing BC was high in female of older age group i.e., above 50 years.

Similar finding was seen in study conducted by Vinodkumar Mugada *et al*, where study reviewed that according to the National institute of health study, the changes in biochemical process which is responsible to control genes and hormonal changes gets

**Table 3: The number and percentage types of chemotherapy received within the sample.**

Type of Chemotherapy	No. of patients	Percentage
Mono-therapy	10	19.23
Dual-therapy	27	51.93
Triple-therapy	15	28.84
Total	52	100

**Table 4: Distribution of drug based on adjuvant therapy.**

Drug therapy type	Name of drugs	No. of prescription n, (%)
Mono-therapy	Paclitaxel	2 (7.14%)
	Sachituzumab	1 (3.57%)
Dual-therapy	Epirubicin+cyclophosphamide	4 (14.28%)
	Paclitaxel+carboplatin	4 (14.28%)
	Doxorubicin+cyclophosphamide	4 (14.28%)
	Docetaxel+cyclophosphamide	2 (7.14%)
	Gemcitabine+carboplatin	1 (3.57%)
	Bevacizumab+cyclophosphamide	1 (3.57%)
	Paclitaxel+trastuzumab	1 (3.57%)
Triple-therapy	Doxorubicin+cyclophosphamide+paclitaxel	3 (10.71%)
	Trastuzumab+docetaxel+carboplatin	3 (10.71%)
	Trastuzumab+paclitaxel+zoledronic acid	2 (7.14%)

altered with older age which may be responsible for the increased risk of breast cancer.<sup>12</sup>

Similarly, it was observed that 34 (65.39%) patients were post-menopausal and 18 (34.61%) patients were in pre-menopausal. This indicates, the population under post-menopausal status has high risk of developing BC. In the study conducted by Gnaga paudel *et al*, stated that early menarche and late menopause are considered as the markers of BC risk. As the participants who were above 20 years, the period of early menarche, incidence of BC was not observed at high rate.<sup>16</sup>

In the study, majority of patients ( $n=18$ , 34.61%) found triple negative hormonal status. Whereas 12 (23.07%) patients were found to have both Estrogen and progesterone positive. Only HER2 receptor was found positive among 06 (11.53%) patients. With triple positive hormonal status was found in only 04 patients (7.70%), as presented in Table 1. Similar study was conducted by Anjan Adhikari, which reveals that hormones plays a major role in the prognosis of this BC. Success of hormone-targeted therapy depends on the nature of these receptors. However, few BC cells fail to express any types of receptors are termed as triple negative cancers. As poor prognosis of the disease was observed among triple negative BC as no hormone-targeted therapy is useful.<sup>6</sup> In the study, according to TNM system of staging, majority were diagnosed with Stage IV ( $n=18$ , 34.61%) followed by Stage I (16, 30.77%) and Stage II (12, 23.08%). Whereas least diagnosis was of Stage III (6, 11.53%). This indicate that the maximum number of enrolled patients were having metastatic breast cancer cells.

In current study, 23(44.23%) had received adjuvant therapy and surgery. Whereas 5 (9.61%) patients had received adjuvant therapy with radiotherapy. Others 24 (46.15%) had received neo-adjuvant therapy, as presented in Table 2. The majority of patients had received combination of anti-cancer drugs, either mono-chemotherapy, dual chemotherapy or triple chemotherapy. Out of total subjects, 27 patients (51.93%) had received dual-therapy, whereas 15 patients, (28.84) had received

**Table 5: Distribution of drug based on neo-adjuvant therapy.**

Drug therapy type	Name of drugs	No. of prescription n, (%)
Mono-therapy	Paclitaxel	5 (20.83%)
	Trastuzumab	2 (8.33%)
Dual-therapy	Epirubicin+cyclophosphamide	2 (8.33%)
	Paclitaxel+carboplatin	3 (12.50%)
	Doxorubicin+cyclophosphamide	3 (12.50%)
	Paclitaxel+trastuzumab	1 (4.16%)
	Trastuzumab+vinorelbine	1 (4.16%)
Triple-therapy	Paclitaxel+doxorubicin+ cyclophosphamide	1 (4.16%)
	Trastuzumab+docetaxel+carboplatin	5 (20.83%)
	Oxaliplatin+ calcium leucovorin +5 fluorouracil	1 (4.16%)

**Table 6: WHO prescribing indicators.**

Sl. No.	Prescribing Indicators	In patients
1	Average number of anti-cancer drugs per prescription.	2.16
2	Average number of adjuvant drugs per prescription.	10.34
3	Average number of drugs per prescription.	12.44
4	Percentage of encounter with anticancer injectable prescribed.	100%
5	Percentage of anticancer drugs prescribed by generic name.	100%
6	Percentage of drugs Prescribed from National essential list of medicine 2022.	59.61%
7	Percentage of drugs Prescribed from WHO Model List of Essential Medicines-23 <sup>rd</sup> List (2023).	63.46%

triple therapy. The least number of patients, 10(19.23%) had received monotherapy. It indicates that the prescribed regimens to patients, combined regimen had greater efficacy and safety in treatment of metastatic breast cancer.

Different types of anti-cancer drugs were prescribed where, majorly prescribed drug is Paclitaxel (22,20.8%), followed by cyclophosphamide (20,18.34%) and carboplatin (16,14.68%). Another highly prescribed drug was Trastuzumab (15,13.76%) from class monoclonal antibodies (HER2 inhibitor). Monoclonal antibodies play major role in treatment of BC cells as they are hormonal targeting agents. A similar study was conducted by Renuka L. Kadam *et al*, which shows that taxanes group of drugs were highly preferred drugs in treatment of BC, due to excellent clinical outcome and desirable pharmacokinetic properties.<sup>16</sup>

The drug distribution based on adjuvant chemotherapy as presented in Table 4 shows that; majorly combined dual-therapy was epirubicin+cyclophosphamide (14.28%), paclitaxel+carboplatin (14.28%) and doxorubicin+cyclophosphamide (14.28%). Under triple-therapy, doxorubicin+paclitaxel+cyclophosphamide (3,10.71%) and trastuzumab+docetaxel+carboplatin (3, 10.17%) was prescribed. Table 5 shows distribution of drug based on the neo-adjuvant chemotherapy. Here, paclitaxel and trastuzumab were prescribed as monotherapy. Most commonly prescribed dual-therapy were paclitaxel+carboplatin and doxorubicin+cyclophosphamide (25%). For triple therapy, trastuzumab+docetaxel+carboplatin was most commonly prescribed regimen (20.83%). Cyclophosphamide is the most commonly used drug in combination with other chemotherapy drugs under both adjuvant and neo-adjuvant therapy. A similar study was conducted by Ganga Paudel *et al*, it shows that according to NCCN guideline version 111, use of cyclophosphamide drugs before and after surgery helps to decrease the risk of early-stage BC recurrence, shrink large advanced-stage BC tumors and treat advanced-stage BC.<sup>13</sup>

WHO prescribing indicators were used to access the prescription pattern of drugs among breast cancer patients, as a result percentage of drugs prescribed from NELM 2022 was 59.61% and from WHO-model list of essential medicines 2023 was 63.4%. This indicates that selection of drugs from list of essential medicine assures safety and provides maximum benefits at a lower cost. The average number anti-cancer drugs and adjuvant drugs per prescription was found 2.16 and 12.44 respectively. All the anti-cancer drugs were prescribed in generic name and were 100% injectable. The average number of drugs prescribed per prescription was 10.34.

**LIMITATIONS OF THE STUDY**

All the studies that are being carried out has its own limitation and boundaries. Being an observational study, this study also encountered certain limitations including:

Conduction of the study in a single centre limits the extension of finding results.

The study period for assessing the prescription was limited, a 6 month to be carried out.

The BC patients were mostly day-care patients so it was difficult to get the information once the patient discharged.

The present study evaluated a relatively small population i.e., 52 participants.

Some patients hesitated to provide information regarding past-medical history.

There was less communication with the patients because of language barriers.

## POTENTIAL DIRECTIONS FOR FUTURE RESEARCH

The data generated from this study has significant potential for various applications, including:

**Pharmacoeconomic analysis:** Informing cost-effectiveness and budgetary decisions related to anti-cancer drugs.

**Chemotherapy optimization:** Analyzing dose modification and dilution factors to enhance infusion efficacy and safety.

**Adjuvant drug evaluation:** Assessing the efficacy and safety of adjuvant drugs, including their interactions with other medications.

**Personalized medicine:** Guiding the use of adjuvant drugs in patients with concomitant diseases and concurrent medications, to optimize treatment outcomes.

These applications can ultimately contribute to improved cancer treatment strategies, enhanced patient care and more efficient healthcare resource allocation.

## CONCLUSION

This study investigated the prescription patterns of anti-cancer and adjuvant drugs in breast cancer patients undergoing chemotherapy at a tertiary care hospital. The findings revealed a significant correlation between age and BC prevalence, with a higher incidence observed in patients above 50 years. The maximum patients were under post-menopausal status. The major risk factors for the development of BC are hormonal status in female, however, the study has shown a high occurrence of triple-negative BC. For the treatment of hormone-positive BC, anti-cancer drugs like trastuzumab, bevacizumab and Sacituzumab.

The treatment regimen include of adjuvant and neoadjuvant chemotherapy and the selection of drugs was based on different stage of cancerous cell. Prescribing patterns of anticancer drugs was

maximum in combined therapy i.e., dual therapy and triple-therapy in comparison with monotherapy. The most commonly used monotherapy drug was paclitaxel. The most frequently used combination regimens were taxanes+Cyclophosphamide or platinum analogs+cyclophosphamide. The majorly prescribed antineoplastic agents were paclitaxel, cyclophosphamide, doxorubicin, carboplatin and docetaxel.

WHO prescribing indicator shows that 59.61% of the total anti-cancer drugs was prescribed from National essential list of medicine 2022 and 63.46% were from WHO Model list of essential medicine 2023.

This study provides an in-depth analysis of the current state of breast carcinoma management, with a focus on the prescribing patterns of anticancer drugs. The primary objective is to inform evidence-based recommendations and educational interventions for the oncology department team, ultimately refining the therapeutic regimens for breast cancer patients.

Furthermore, this study highlights the crucial role of hospital-based monitoring of rational use of anticancer drugs by clinical pharmacists. By emphasizing the importance of monitoring, analysing and reporting the therapeutic regimen, this study promotes drug safety, efficacy and optimal patient care. The findings of this study have significant implications for healthcare professionals, policymakers and researchers, contributing to the advancement of breast cancer management and patient outcomes.

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## ETHICAL CONSIDERATIONS

This study did not require ethical approval because it was an observational study that did not involve any intervention, treatment, or administration of medication. The research was conducted by observing and analysing existing data, without modifying any treatment plans or affecting the participants' care in any way.

## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**WHO:** World health organisation; **BC:** Breast cancer; **NPI:** Nottingham prognostic index; **TNM:** Tumour, lymph node and metastasis; **HER2:** Human epidermal growth factor receptor 2; **NCCN:** National Comprehensive Cancer Network; **ESMO:** European Society for Medical Oncology; **ASCO:** American Society of Clinical Oncology guidelines; **ADRs:** Adverse drug reactions; **HCP:** Health care professional; **RT:** Radiotherapy; **ER:** Estrogen; **PR:** Progesterone; **HR:** Hormonal receptor.

## SUMMARY

The authors declare that they have no conflict of interest in this study. No financial support or sponsorship was received from any organization or individual that could influence the outcomes of this research. All authors have reviewed and agreed on the manuscript's content, and there are no potential conflicts of interest to disclose.

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