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RESEARCH ARTICLE

Drug Utilization Study of Anticancer Drugs in Breast Cancer Patients at a Tertiary Care Teaching Hospital

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Abstract: This study aimed to assess the drug utilization of anticancer drugs in breast cancer patients at a tertiary care teaching hospital. The objectives were to identify the most commonly prescribed chemotherapeutic drugs and to study the side-effect profile using the CTCAE grading. A prospective observational study was conducted in the medical oncology department. Data was collected from 93 patients and analyzed for prescribing patterns, drug utilization, and side-effects. The majority of patients were aged 46-55 years (48.38%) and in stage III cancer (62.36%). Luminal B was the most common molecular subtype (35.48%). Neoadjuvant therapy was administered to 59.13% of patients, while 40.86% received adjuvant therapy. Trastuzumab was the most frequently prescribed drug in both neoadjuvant (34.54%) and adjuvant (36.84%) therapies. Ondansetron, aprepitant, dexamethasone, and olanzapine were commonly used as supportive treatments. Side-effects were experienced by 76.34% of patients, with 71.83% having grade 1 and 28.16% having grade 2 side-effects. The most frequent side-effects were nausea, vomiting, and alopecia. The onset of side-effects was highest after the 3rd chemotherapy cycle (28.16%). The study provides valuable information about the prescribing patterns and side-effect profile of anticancer drugs in breast cancer patients.

Keywords: Breast cancer; Drug utilization; Anticancer drugs; Side-effects; CTCAE grading

1. Introduction

Breast cancer is a major global health concern and the most prevalent malignancy among women worldwide [1]. It is a heterogeneous disease with varying molecular subtypes, each requiring specific treatment approaches [2]. The global burden of breast cancer is substantial, with an estimated 2.3 million new cases and 685,000 deaths in 2020 [3]. In India, breast cancer is the most common cancer among women, with an incidence rate of 25.8 per 100,000 women and a mortality rate of 13.4 per 100,000 women [4].

The management of breast cancer is complex and involves a multidisciplinary approach, including surgery, radiation therapy, and systemic treatments such as chemotherapy, hormonal therapy, and targeted therapy [5]. The choice of treatment depends on various factors, including the stage of the disease, molecular subtype, patient characteristics, and treatment goals [6]. Chemotherapy plays a crucial role in the management of breast cancer, both in the neoadjuvant setting (before surgery) and the adjuvant setting (after surgery) [7]. Neoadjuvant chemotherapy aims to reduce tumor size, increase the likelihood of breast-conserving surgery, and provide prognostic information based on the tumor's response to treatment [8]. Adjuvant chemotherapy is administered to eradicate micrometastatic disease and reduce the risk of recurrence and mortality [9]. The selection of appropriate chemotherapeutic agents is based on the molecular subtype of breast cancer, which is determined by the expression of estrogen receptor (ER), progesterone receptor (PR), and human epidermal growth factor receptor 2 (HER2) [10]. The most common molecular subtypes are luminal A (ER+/PR+/HER2-), luminal B (ER+/PR+/HER2+), HER2-enriched (ER-/PR-/HER2+), and triple-negative (ER-/PR-/HER2-) [11]. Each subtype responds differently to chemotherapy, and the choice of drugs is tailored accordingly [12].

Drug utilization studies play a vital role in evaluating the prescribing patterns of anticancer drugs and assessing their appropriateness in clinical practice [13]. These studies help to identify the most commonly prescribed drugs, their dosages, and the duration of treatment [14]. Drug utilization research also provides insights into the adherence to treatment guidelines, which is crucial for ensuring optimal patient care and outcomes [15, 16].

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Moreover, drug utilization studies in oncology help to understand the effectiveness and safety of anticancer drugs in real-world settings [17]. These studies can provide valuable information on the adverse events associated with chemotherapy, which can have a significant impact on patients' quality of life [18]. The Common Terminology Criteria for Adverse Events (CTCAE) is a standardized classification system used to grade the severity of adverse events in cancer clinical trials and practice [19]. By incorporating CTCAE grading in drug utilization studies, researchers can assess the side-effect profiles of anticancer drugs and identify strategies to manage and prevent adverse events [20]. In addition to evaluating the prescribing patterns and safety of anticancer drugs, drug utilization studies can contribute to the optimization of healthcare resources [21]. Breast cancer treatment is associated with significant healthcare costs, and the rational use of drugs can help to reduce unnecessary expenses and improve the cost-effectiveness of cancer care [22]. By identifying the most cost-effective treatment options and minimizing the use of unnecessary or inappropriate drugs, drug utilization research can support the development of strategies to enhance the quality and affordability of cancer care [23]. The present study aims to assess the drug utilization patterns of anticancer drugs in breast cancer patients at a tertiary care teaching hospital in India.

2. Methodology

2.1. Study Design and Setting

A hospital-based prospective observational study was conducted in the Department of Medical Oncology at Sri Venkateswara Institute of Medical Sciences (SVIMS), a tertiary care teaching hospital in Tirupati, India. The study was carried out over a period of six months.

2.2. Study Population and Sample Size

The study included 93 breast cancer patients who were receiving chemotherapy at the Department of Medical Oncology during the study period. Patients above 18 years of age with biopsy-proven breast cancer and undergoing chemotherapy were included in the study. Patients below 18 years of age and those diagnosed with multiple malignancies were excluded.

2.3. Data Collection

A pre-designed data collection form was used to gather patient information, including demographic details, age, sex, chief complaints, past history, diagnosis, and treatment charts (drugs mentioned in chemotherapy cycles). Any side effects observed during chemotherapy were reported and graded using the Common Terminology Criteria for Adverse Events (CTCAE) version 3.0.

2.4. Ethical Considerations

The study was approved by the Institutional Ethics Committee (IEC) of SVIMS prior to its initiation. Informed consent was obtained from all the participants before their enrollment in the study.

2.5. Data Analysis

The collected data were analyzed using descriptive statistics. Demographic characteristics, prescribing patterns, drug utilization, and side effects were presented as numbers and percentages. The results were represented using tables, pie charts, and bar graphs.

3. Results and discussion

3.1. Demographic Characteristics

The study included 93 breast cancer patients, with the highest percentage (48.3%) in the age group of 46-55 years, followed by 20.4% in the 56-65 years age group (Table 1). The least represented age group was 25-35 years, with only 5.3% of patients. This age distribution is consistent with previous studies that have reported a higher incidence of breast cancer in middle-aged and older women [24, 25].

Table 1. Age distribution among the patients

Age (years)	No. Of patients	Percentage
25 – 35	05	5.37 %
36 – 45	18	19.35 %
46 – 55	45	48.38 %
56 – 65	19	20.43 %
66 – 75	06	6.45 %
Total	**93**	**100%**

3.2. Staging of Breast Cancer

The majority of patients (62.36%) were diagnosed with stage III breast cancer, while only 1.07% had stage I disease (Table 2). Among the stage III patients, 33.33% had stage IIIB, followed by 25.80% with stage IIIA. The high proportion of patients with advanced-stage disease highlights the need for early detection and screening programs to improve breast cancer outcomes in India [26, 27].

Table 2. Stages of breast cancer

Stages	No. Of patients	Percentage
I	01	1.07 %
A	00	-
B	01	1.07 %
II	26	27.95 %
A	13	13.97 %
B	13	13.97 %
III	58	62.36 %
A	24	25.80 %
B	31	33.33 %
C	03	3.22 %
IV	08	8.60 %
Total	**93**	**100 %**

3.3. Molecular Subtypes

Luminal B was the most common molecular subtype, accounting for 35.48% of patients, followed by HER2-enriched (32.25%) and luminal A (23.65%) subtypes (Table 3). Triple-negative breast cancer (TNBC) was the least common subtype, comprising 8.60% of patients. The distribution of molecular subtypes in this study is comparable to that reported in other Indian studies [28, 29]. The high proportion of luminal B and HER2-enriched subtypes emphasizes the importance of targeted therapies in the management of breast cancer [30].

Table 3. Results of molecular subtypes

Molecular subtypes	No. Of patients	Percentage
LUMINAL A	22	23.65%
LUMINAL B	33	35.48%
ENRICHED HER 2	30	32.25%
TNBC	8	8.60%
Total	**93**	**100%**

3.4. Type of Chemotherapy

Neoadjuvant chemotherapy was administered to 59.13% of patients, while 40.86% received adjuvant chemotherapy (Table 4). The higher proportion of patients receiving neoadjuvant therapy suggests a trend towards using chemotherapy to downstage tumors and increase the likelihood of breast-conserving surgery [31, 32].

Table 4. Type of chemotherapy among the patients

Chemotherapy	No. Of patients	Percentage
NEO-ADJUVANT	55	59.13%
ADJUVANT	38	40.86%
TOTAL	**93**	**100 %**

3.5. Commonly Prescribed Chemotherapeutic Regimens

In the neoadjuvant setting, trastuzumab was the most commonly prescribed drug (34.54%), followed by doxorubicin plus cyclophosphamide (AC) and paclitaxel (16.36% each) (Table 5). This finding highlights the widespread use of trastuzumab in HER2-positive breast cancer, which has significantly improved outcomes in this subtype [33, 34]. In the adjuvant setting, trastuzumab was again the most frequently prescribed drug (36.84%), followed by the AC regimen (15.78%) (Table 6). The use of trastuzumab in both neoadjuvant and adjuvant settings underscores its importance in the management of HER2-positive breast cancer [35].

Table 5. Various treatment regimens used in neo-adjuvant therapy

Treatment regimen	No. Of patients	Percentage
Docetaxel+Carbolplatin+Trastuzumab	6	10.90%
Paclitaxel+Trastuzumab	3	5.45%
Adriamycin+Cyclophosphamide	9	16.36%
Docetaxel+Trastuzumab	3	5.45%
Gemcitabin+Carboplatin	2	3.63%
Trastuzumab	19	34.54%
Docetaxel	2	3.63%
Paclitaxel	9	16.36%
Capecitabine	1	1.81%
Capecitabine+Trastuzumab	1	1.81%
Total	**55**	**100%**

Table 6. Various treatment regimens used in adjuvant therapy

Treatment regimen	No. Of patients	Percentage
Adriamycin+Cyclophosphamide	6	15.78%
Docetaxel+Cyclophosphamide	2	5.26%
Docetaxel+Carboplatin +Trastuzumab	5	13.15%
Trastuzumab	14	36.84%
Gemcitabine+Trastuzumab	2	5.26%
Paclitaxel	2	5.26%
Capecitabine	1	2.63%
Docetaxel	2	5.26%
Docetaxel+Trastuzumab	2	5.26%
Paclitaxel+Trastuzumab	2	5.26%
Total	**38**	**100%**

3.6. Side Effects and CTCAE Grading

Among the 93 patients, 71 (76.34%) experienced side effects during chemotherapy. Of these, 51 patients (71.83%) had grade 1 side effects, while 20 patients (28.16%) had grade 2 side effects according to the CTCAE grading system (Figure 1). The most frequently observed side effects were nausea, vomiting, and alopecia (Table 7). These findings are consistent with the known side-effect profiles of the chemotherapeutic agents used in this study [36, 37]. The high incidence of side effects emphasizes the need for effective supportive care measures to manage these adverse events and improve patients' quality of life [38].

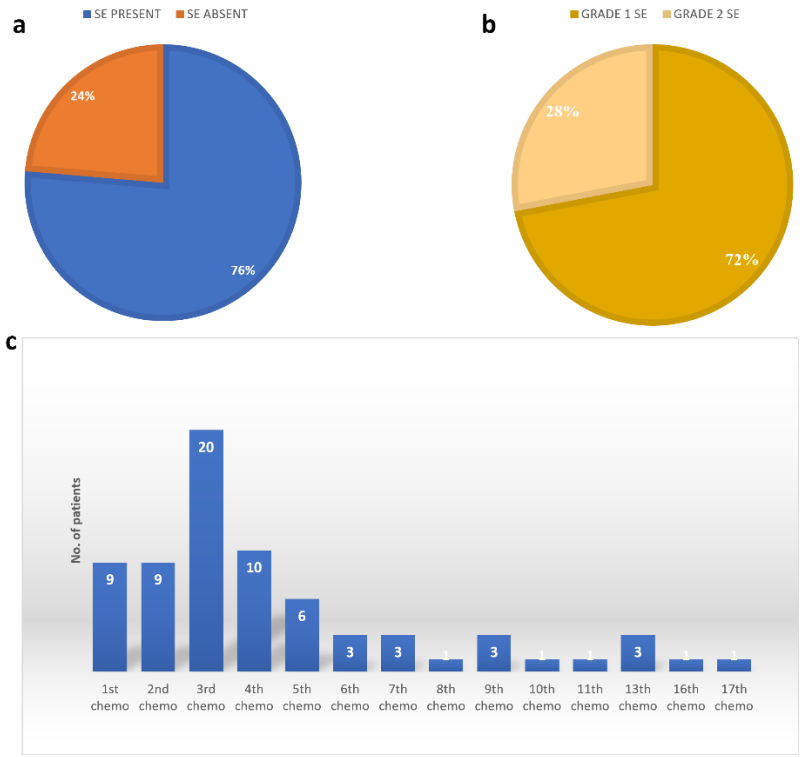

Figure 1a. Frequency of side effects (SE) b. Frequency of grade 1 and grade 2 side effects c. onset of adverse effects among the patients

Table 7. Frequency of side effects in patients

Side effects	No. Of patients
Alopecia	10
Nausea and Vomiting	12
Parasthesia	8
Diarrhea	7
Mucositis	3
Myalgia	3
Fever and cold	8
Abdominal pain	4
Skin allergy	4
Body pain	7
Headache	6
Swelling of lower limbs	3
Burning micturation	2
Anemia	1
tremors	1
Eye disorders	2

3.7. Discussion

This study aimed to assess the drug utilization patterns of anticancer drugs and evaluate the side-effect profiles using CTCAE grading in breast cancer patients at a tertiary care teaching hospital in India. The findings provide valuable insights into the current practices and challenges in the management of breast cancer in this setting. The age distribution of patients in this study is consistent with the epidemiology of breast cancer in India, where the majority of cases are diagnosed in middle-aged and older women [24, 25]. The high proportion of patients with advanced-stage disease (62.36% with stage III) highlights the need for improved early detection and screening programs in India [26, 27]. Late-stage diagnosis is a significant challenge in developing countries, leading to poorer outcomes and increased mortality [27].

The distribution of molecular subtypes in this study, with luminal B (35.48%) and HER2-enriched (32.25%) being the most common, is comparable to that reported in other Indian studies [28, 29]. The high proportion of these subtypes emphasizes the importance of targeted therapies, such as trastuzumab, in the management of breast cancer [30]. Trastuzumab was the most frequently prescribed drug in both neoadjuvant (34.54%) and adjuvant (36.84%) settings, highlighting its crucial role in the treatment of HER2-positive breast cancer [33-35]. The higher proportion of patients receiving neoadjuvant chemotherapy (59.13%) compared to adjuvant chemotherapy (40.86%) suggests a trend towards using chemotherapy to downstage tumors and increase the likelihood of breast-conserving surgery [31, 32]. This approach is in line with current treatment guidelines and has been shown to improve surgical outcomes and quality of life for patients [31].

The high incidence of side effects (76.34%) observed in this study, with the majority being grade 1 (71.83%) according to CTCAE grading, underscores the importance of effective supportive care measures to manage these adverse events [38]. Nausea, vomiting, and alopecia were the most frequently reported side effects, which is consistent with the known side-effect profiles of the chemotherapeutic agents used [36, 37]. Effective management of these side effects is crucial for maintaining patients' quality of life and adherence to treatment [38]. The results of this study should be interpreted in light of certain limitations. First, the sample size was relatively small, and the study was conducted at a single center, which may limit the generalizability of the findings. Second, the

study did not evaluate long-term outcomes, such as survival and quality of life, which are important considerations in the management of breast cancer. Future studies with larger sample sizes and longer follow-up periods are needed to validate these findings and assess the impact of drug utilization patterns on long-term outcomes.

Despite these limitations, this study provides valuable real-world data on the prescribing patterns and side-effect profiles of anticancer drugs in breast cancer patients in India. The findings can inform clinical decision-making and support the development of evidence-based treatment guidelines tailored to the Indian context. Moreover, the high incidence of side effects highlights the need for effective supportive care measures and patient education to manage these adverse events and improve treatment adherence

4. Conclusion

This drug utilization study assessed the prescribing patterns and side-effect profiles of anticancer drugs in breast cancer patients at a tertiary care teaching hospital in India. The majority of patients had advanced-stage disease, with luminal B and HER2-enriched molecular subtypes being the most common. Trastuzumab was the most frequently prescribed drug in both neoadjuvant and adjuvant settings. A high proportion of patients experienced side effects, primarily nausea, vomiting, and alopecia, emphasizing the need for effective supportive care measures. The results of this study can guide efforts to improve the quality of care for breast cancer patients and inform the development of targeted interventions to enhance treatment outcomes and patient well-being.

Compliance with ethical standards

Conflict of interest statement

The authors declare that there are no known competing financial interests or personal relationships that could have influenced the work reported in this paper.

Statement of ethical approval

Ethical approval was obtained from SVIMS SPMC (W) before initiation of the study

Statement of informed consent

Informed consent was obtained from all individual participants included in the study

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