

# A Prospective Study on Drug Prescription Pattern of Chemotherapeutic Agents in Breast Cancer Patients in a Tertiary Care Hospital

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## ABSTRACT

**Background:** Breast cancer is a multi-factorial disease, comprises a group of heterogeneous and complex diseases that evolves due to uncontrolled cellular growth, differentiation and the loss of normal programmed cell death. The present study was explicitly aimed to assess the prescription pattern of chemotherapeutic agents in breast cancer patients in a tertiary care hospital. **Materials and Methods:** The demographic details and required relevant treatment chart information of patients who met the inclusive standards have been entered into specially designed proforma for the evaluation of prescription pattern against standard NCCN guidelines. The study was conducted in December 2020 to May 2021 at medical oncology department, SVIMS, SPMC (W), Tirupati, and Andhra Pradesh. **Results:** A total of 75 patients were included in this study. The most prescribed combinational regimen had been found to be Adriamycin, Cyclophosphamide and Taxanes (ACT), which were utilised in 29.33% of patients. Trastuzumab was the most prescribed monotherapeutic agent in 10.6% Patients. Apart from Ondansetron, Dexamethasone and Ranitidine which were considered nearly in all the patients, Promethazine and PEG filgrastim have been set up in 53.3% and 44%. Neoadjuvant chemotherapy in 13 patients, adjuvant chemotherapy in 30 patients and chemotherapy alone in 32 Patients were established. **Conclusion:** The drugs prescribed had been determined to be rational and acknowledged to preclude the development of ailment keeping the compliance with respective NCCN guidelines. Smaller pattern length might be a restricting thing ceasing the in-intensity analysis.

**Keywords:** Breast cancer, Drug prescription pattern, Neoadjuvant chemotherapy drugs, Adjuvant chemotherapy drugs.

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## INTRODUCTION

Cancer is a collection of illnesses that is life threatening and correlated with loss of cohesiveness and orderliness of regular tissue.<sup>1</sup> Globally cancer is the second leading cause of death and is chargeable for approximately 10 million deaths consistent within the year and about 1 in 6 deaths is due to cancer.<sup>2</sup> It is one of the common causes of deaths in India and has profound social and financial consequences, often leading to family impoverishment and societal inequity. In 2018, globally 18.1 million instances and 9.6 million deaths of cancer had been recorded those figures had been predicted to almost double by 2040 with the greatest increase in low middle income countries.<sup>3</sup> Breast cancer is the

second greatest cause of death among women worldwide. In India 1, 62,458 new instances and 87,090 deaths had been pronounced as of 2018 statistics. Survival charge declines with higher stages of breast cancer and 50% of Indian women are afflicted by level three and four of breast cancer. Post cancer survival for women with breast cancer turn into stated 60% for Indian women, in comparison to 80% within the U.S.<sup>4</sup>

Drug utilization has been described by the WHO as the marketing, distribution, prescription and use of drugs in society with unique emphasis on ensuing medical and social consequences. Drug Utilization Studies (DUS) could be beneficial to apprehend the drug exposure patterns and make contribution to national health policies which are designed to promote the safe and effective medicines.<sup>5,6</sup> Prescription monitoring study is an evolving discipline which clearly compares the found styles of drug use with present day suggestions and guidelines. The call for Primary Progressive Multiple Sclerosis (PPMS) is enhancing



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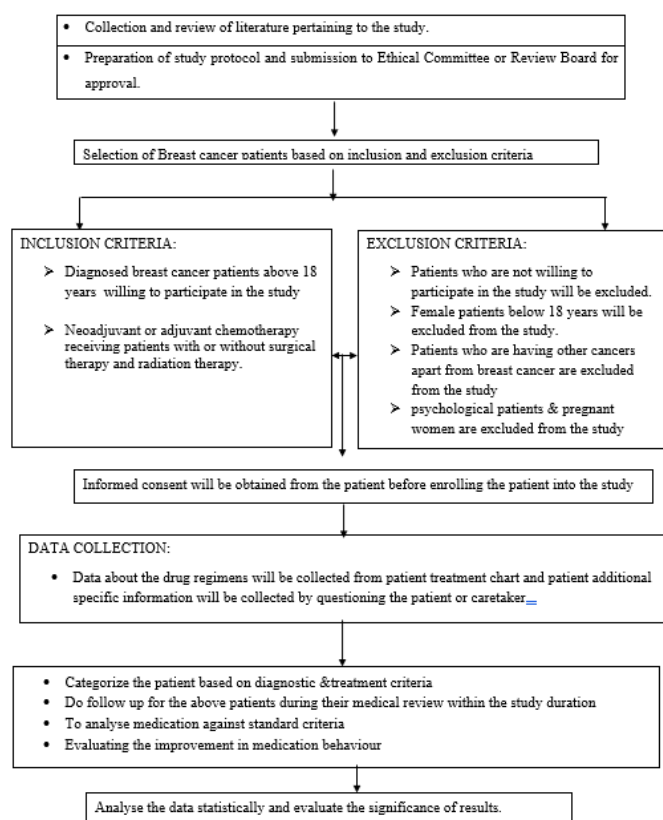
because of increasing concern towards the adverse effects caused by the drugs available in the market.<sup>7</sup>

The prescription pattern of anticancer drugs has been evolved significantly in current years due to better understanding of underlying pathophysiology of Carcinomas in addition to establishment of the newer drugs.

The objective of this study is to analyse the type of therapy, obtain statistics about number of patients exposed to a particular drug or a particular class of drugs, provide pattern of drug consumption and to analyse the most common chemotherapeutic agents and supportive care medicines prescribed. Hence, the present study was aimed to analyse the prescription pattern of chemotherapeutic agents in breast cancer patients in a tertiary care hospital, Tirupati.

## MATERIALS AND METHODS

The study was observational prospective and non-interventional study conducted at Department of Medical Oncology, Sri Venkateswara Institute of Medical Sciences (SVIMS), Sri Padmavathi Medical College (SPMCW), Tirupati, and Andhra Pradesh. (Ref No: AS/11/IEC/SVIMS/2017; No. 1103) Overall 75 patients receiving chemotherapy have been covered into the study according to the inclusion and exclusion criteria. Sample size was calculated by using Cohen's *d* statistical tool. This study at become performed at some stage in 6 months from December 2020 to May 2021 prospectively. The inclusion standards consist



of recognized breast cancers patients above 18 years, neoadjuvant/ adjuvant chemotherapy acquired patients without or with surgical therapy or radiation therapy. The exclusion standards consist of patients who aren't inclined to take part in this study, patients under 18 years and sufferers who're having different cancers other than breast cancers were excluded.

Before initiation of the study the approval from ethical committee was acquired. An established patient demographic form was used to acquire the affected person info like age, sex, weight, family history, past medical history, and history beyond clinical records, social records etc. Data about the drug regimens was amassed from patient treatment chart and additional unique information was collected with the aid of questioning the patient or caretaker (By using Patient data collection form and Informed consent form).

The accrued records become to begin with entered into the Microsoft excel work sheet (Microsoft Corporation, Redmond WA) and the evaluation was performed. The data on continuous variables had been summarized on descriptive statistics using mean and standard deviation. Categorical data had been expressed in numbers and percentages. All the entries had been double checked for any feasible errors. The acquired outcomes had been offered in tabular and graphical paperwork with the aid of Microsoft word and excel.

## RESULTS

### Frequency of age distribution

It became found that out of 75 patients most of the breast cancer cases have been found among age group 41-50 ( $n=30$ ) 40% followed by 51-60 ( $n=22$ ) 29.33%, 61-70 ( $n=11$ ) 14.6%, 30-40 ( $n=10$ ) 13.33% and 71-75 ( $n=2$ ) 2.6%. Mean age became 50.2 and Standard deviation  $\pm 10.11$  (Table 1).

### Percentage of type of breast cancer in patients and frequency of type of therapy

Among 75 patients 39 patients have been identified as right breast cancer patients and 36 patients have been identified as left breast cancer patients.

In this take a look at out of 75 patients monotherapy became installed in 13 patients (17.33%) and 62 patients acquired combination therapy (82.66%).

Most prescribed monotherapeutic agents like trastuzumab become commonly installed in 8 patients (50%) accompanied through capecitabine  $n=4$  (30.76%) and paclitaxel  $n=1$  (7.69%) (Table 2).

### Most Prescribed Combinational regimens

From Table 3, look at ACT ( $n=22$ ) 35.48% turned into usually prescribed combinational regimen accompanied through TCH

(n=20) 32.25%, AC (n=14) 22.58%, DCT (n=2) 3.22%, TH (n=1) 1.6%, DT (n=1) 1.6%, and DC (n=1) 1.6%.

### Menopausal Status among the patients and Frequency of IHC Status

Out of 75 patients 40 had been premenopausal (53.3%) and 35 were post-menopausal (48.66%) (Figure 1).

In this study, out of 75 patients 37 patients were identified as HER2 (+) (49.33%) accompanied by TNBC 17 patients (22.66%), HR + 12 patients (16%), TPBC 8 patients (10.66%) and PR+ 1 patient (1.33%).

### Supportive Care Medications and Type of treatment

The supportive care medications like promethazine changed into prescribed for 40 patients (53.33%) and PEG filgrastim changed into prescribed for 33 patients (44%) however ondansetron, dexamethasone and ranitidine were taken into consideration in nearly all of the Patients.

Type of treatment includes- the modern-day study disseminates that amongst 75 patients 32 obtained chemotherapy alone (42.66%), 30 obtained Adjuvant Chemotherapy (ACT 40%), and 13 patients obtained NACT (17%) (Table 4).

### Type of Surgical Procedures performed

Among 75 patients' surgical incision become accomplished in 34 patients. MRM become accomplished in 29 patients (85%) BCS is accomplished in 2 patients (6%), MRM+ALND in 1 patient

(3%), simple mastectomy in 1 patient (3%) and WLE+ALND in 1 patient (3%) (Table 5).

### Neo adjuvant chemotherapy (Table 6)

For 13 patients NACT become considered, amongst which 7 patients obtained ACT (53.84%) 4 patients obtained A+C (30.76%) and 2 patients obtained TCH regimen (15.38%).

### Adjuvant Chemotherapy and Chemotherapy

Chemotherapy by myself become prescribed for 32 patients amongst which 11 obtained TCH (34.37%), 11 patients obtained ACT (34.37%), 6 patients obtained AC (18.75%), 2 patients obtained DCT (6.25%), 1 affected person obtained DT (3.12%), 1 affected person obtained Capecitabine (3.12%) (Table 7).

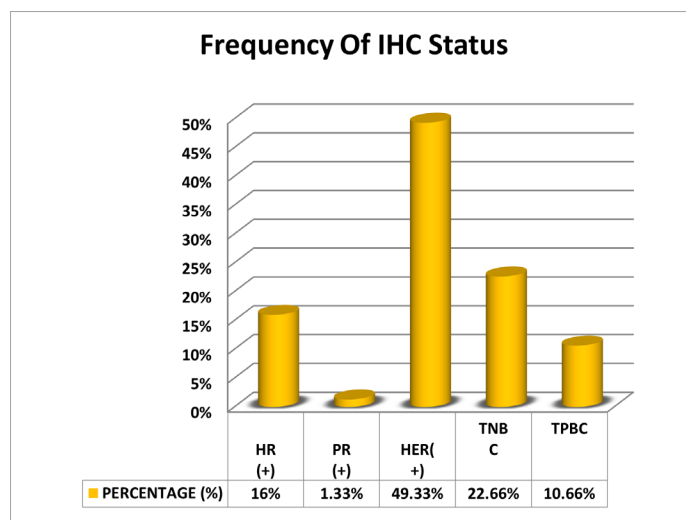


Figure 1: Frequency of the Immunohistochemistry status in breast cancer patients

Table 1: Frequency of the age distribution in our study sample size.

| Sl. No | Age (Year) | No. of Patients | Percentage (%) |
|--------|------------|-----------------|----------------|
| 1.     | 30 – 40    | 10              | 13.33          |
| 2.     | 41 – 50    | 30              | 40             |
| 3.     | 51 – 60    | 22              | 29.33          |
| 4.     | 61 – 70    | 11              | 14.66          |
| 5.     | 71 – 75    | 02              | 2.6            |

Table 2: Percentage of type of breast cancer in patients and frequency of type of therapy.

| Sl. No | Breast Cancer       | No. of Patients | Percentage (%) |
|--------|---------------------|-----------------|----------------|
| 1.     | Right Breast Cancer | 39              | 52             |
| 2.     | Left Breast Cancer  | 36              | 48             |
| Sl. No | Treatment           | No of Patients  | Percentage (%) |
| 1.     | Monotherapy         | 13              | 17.33          |
| 2.     | Combination Therapy | 62              | 82.66          |

**Table 3: Most prescribed combinational regimens among breast cancer patients.**

| Sl. No | Drug   | No. of people | Percentage |
|--------|--|---------------|------------|
| 1      | Adriamycin+Cyclophosphamide+Paclitaxel (ACT)     | 22            | 35.48      |
| 2      | Docetaxel+Carboplatin+Trastuzumab (TCH)          | 20            | 32.25      |
| 3      | Adriamycin+Cyclophosphamide (AC)                 | 14            | 22.58      |
| 4      | Docetaxel + Cyclophosphamide + Trastuzumab (DCT) | 2             | 3.22       |
| 5      | Paclitaxel + Trastuzumab (TH)                    | 1             | 1.61       |
| 6      | Trastuzumab + Cyclophosphamide (TC)              | 1             | 1.61       |
| 7      | Docetaxel + Trastuzumab (DT)                     | 1             | 1.61       |
| 8      | Docetaxel + Cyclophosphamide (DC)                | 1             | 1.61       |

**Table 4: Supportive Care Medication.**

| Sl. No | Drug           | People | Percentage |
|--------|----------------|--------|------------|
| 1.     | Promethazine   | 40     | 53.33      |
| 2.     | PEG Filgrastim | 33     | 44         |

**Table 5: Type of Surgical Procedures performed.**

| Sl. No | Surgical procedure   | No. of Patients | Percentage |
|--------|--|-----------------|------------|
| 1.     | Modified Radical Mastectomy (MRM)                                | 29              | 38.66%     |
| 2.     | Breast Conserving Therapy(BCS)                                   | 2               | 2.66%      |
| 3.     | MRM + Axillary Lymph Node Dissection (ALND)                      | 1               | 1.33%      |
| 4.     | Single Mastectomy  | 1               | 1.33%      |
| 5.     | Wide Local Excision (WLE)+ Axillary Lymph Node Dissection (ALND) | 1               | 1.33%      |

### Distribution of drugs among various stages of breast cancer

Most recognized patients have been in stage IIIB and stage II A; Among the 75 patients stage III patients were exposed to maximum of the anticancer drug (Table 8).

### DISCUSSION

Prescription pattern studies are predominant tool in different healthcare systems however they are usually restrained to certain drug or certain class of drugs or specific stage of breast cancer. DUS should be encouraged for diseases like breast cancer as the patients are exposed to high volume of drugs which are expensive and are subjected to significantly serious ADR'S if used irrationally.

In our study it turned into found that most of the cases were recorded in age group between 41-50 years ( $n=30$ ) and Invasive ductal carcinoma of 45.3% turned out to be the most common type of breast cancer accompanied by infiltrating Ductal carcinoma with 38.66%. The most of the cancers were reported

to be in stage III (38%) and stage II (36%). Most predominantly prescribed medications were combinational regimens accounting for about 82.66% which incorporates AC-T 29.3%, TCH 26.66%, AC 18.66%, and rest 7.9% enlists of TH, DCT, TH, DT and DC. Monotherapy drugs were of about 17.33% which covers trastuzumab of 10.6%, capecitabine 5.3% and paclitaxel of 1.3%.

This cutting edge research suits with the study carried out in 2020 via way means of avinash khadela in 201 patients which represented that most common types of breast cancers were infiltrating ductal Carcinoma (46.3%), ductal Invasive carcinoma (35.8%), metastatic cancer (9.0%); and cyclophosphamide (92%) turned into fantastically prescribed drug followed by donorubicin, dexamethasone 61.2%, ondansetron 50.8%, pantoprazole (25.4%) and peg filgrastim (16.9%) as normally prescribed supportive care medications.<sup>8</sup>

Similar study became carried out in 2017 by Anjan adhikari in 28 patients which arrived at the realisation that 75 patients were post-menopausal women and invasive ductal cancer was the most common breast cancer. Most of the drugs were from

**Table 6: Neo adjuvant chemotherapy drugs in breast cancer patients .**

| Sl. No | Neo adjuvant chemotherapy                       | No. of patients | Percentage% |
|--------|---|-----------------|-------------|
| 1      | Adriamycin + Cyclophosphamide (A+C)             | 4               | 30.76%      |
| 2      | Docetaxel +Carboplatin + Trastuzumab (TCH)      | 2               | 15.38%      |
| 3      | Adriamycin + Cyclophosphamide+ paclitaxel (ACT) | 7               | 53.84%      |

**Table 7: Adjuvant chemotherapy drugs in breast cancer patients.**

| Sl. No | ACT   | No. of Patients | Percentage% |
|--------|---|-----------------|-------------|
| 1.     | Trastuzumab                                   | 8               | 26.66%      |
| 2.     | Docetaxel+Carboplatin+Trastuzumab (TCH)       | 7               | 23.33%      |
| 3.     | Adriamycin+ Cyclophosphamide (AC)             | 4               | 13.33%      |
| 4.     | Adriamycin+Cyclophosphamide+ paclitaxel (ACT) | 4               | 13.33%      |
| 5.     | Capecitabine                                  | 3               | 10%         |
| 6.     | Docetaxel+Cyclophosphamide (DC)               | 2               | 6.66%       |
| 7.     | Paclitaxel + Trastuzumab (TH)                 | 1               | 3.33%       |
| 8.     | Paclitaxel                                    | 1               | 3.33%       |

**Table 8: Distribution of chemotherapeutic drugs prescribed for various stages of breast cancer patients.**

| Stage | No. of patients | Chemotherapy prescribed  |
|-------|-----------------|--|
| I     | 7               | Adriamycin + Cyclophosphamide (AC-2);<br>Docetaxel + Carboplatin + Trastuzumab (TCH- 2);<br>Trastuzumab -2; Paclitaxel + Trastuzumab (TH-1).   |
| IIA   | 15              | Adriamycin + Cyclophosphamide (AC -4);<br>Adriamycin+Cyclophosphamide+ paclitaxel (ACT - 4);<br>Docetaxel +Carboplatin + Trastuzumab (TCH - 5); Trastuzumab - 5.   |
| IIB   | 12              | Docetaxel +Carboplatin + Trastuzumab (TCH - 4);<br>Adriamycin + Cyclophosphamide (AC - 2);<br>Adriamycin+Cyclophosphamide+ paclitaxel (ACT - 3);<br>Trastuzumab - 1; Capecitabine - 1.   |
| IIIA  | 12              | Adriamycin + Cyclophosphamide (AC - 3);<br>Adriamycin+Cyclophosphamide+ paclitaxel (ACT- 5);<br>Trastuzumab - 2; Capecitabine - 1.   |
| IIIB  | 17              | Adriamycin + Cyclophosphamide (AC - 2)<br>Adriamycin+Cyclophosphamide+ paclitaxel (ACT - 9);<br>Docetaxel +Carboplatin + Trastuzumab TCH - 5; Capecitabine - 1   |
| IV    | 12              | Adriamycin + Cyclophosphamide (AC- 1);<br>Docetaxel +Carboplatin + Trastuzumab (TCH- 4);<br>Trastuzumab -1; Docetaxel + Trastuzumab (DT -1); Paclitaxel - 1;<br>Docetaxel + Cyclophosphamide + Trastuzumab (DCT -2);<br>Adriamycin+Cyclophosphamide+ Paclitaxel (ACT - 1);<br>Docetaxel + Cyclophosphamide (DC - 1). |

Antimetabolite class followed by anthracycline derivatives.<sup>9</sup> But in our study, it became to be found that post-menopausal women were about 46.6% which is lesser in comparison to premenopausal women of 53.3%, and alkylating agents (cyclophosphamide) were mostly prescribed in combination with anthracycline Derivatives (Adriamycin) followed by Taxans (paclitaxel or docetaxel). The most notably used supportive care agents in this study were found to be 5HT<sub>3</sub> antagonists (ondansetron), corticosteroids (dexamethasone) and H<sub>2</sub> receptor antagonists (ranitidine) which were prescribed in almost all the patients further to which promethazine of 53.33% and PEG filgrastim of 44% have been mounted prior to Chemotherapy to lessen the ADRs of chemotherapy.

In this take a look at its miles located that surgical procedures have been Performed in 34 Patients regard less of their age however maximum of them are achieved among age group of 40-50 ( $n=13$ ). MRM alone which includes elimination of whole breast, nipple areola complex and axillary lymph nodes, Sparing pectoralis major turned into achieved in 29 patients, it is chosen to lessen the nearby reoccurrence that's better in BCS for stage II and stage I, it is nonetheless a choice for stage 3a regionally superior breast cancer. Lumpectomy which is right preference for stage 1 BC turned into achieved in 2 patients. It is thought that breast cancer prevalence is 5-10% higher in left breast; however, it turned into located that 39 patients have been recognized with right breast cancer and 36 have been left breast cancer recognized Patients.

The treatment alternatives of the Breast Cancer depend on the age, stage, importantly IHC status. Receptor status performs essential position in identifying the kind of therapy, in this study it is recognized that 49.3% Patients have been HER positive, 22.7% TNBC, 16% HR positive (Both ER and PR) patients, TPBC 10.7% followed by 1.3% PR positive. HR Positive (ER/PR) Breast Cancers shows good desirable reaction to chemotherapy however TNBC is taken into consideration as aggressive because it has better risk of reoccurrence. Trastuzumab, a tyrosine kinase receptor inhibitor that's a targeted drug is taken into consideration ideal for the Patients having HER Positive breast cancer. Around 10.6% of trastuzumab is prescribed as monotherapy in this study accompanied by capecitabine of 5.3%.

The overall study translates that Adriamycin and cyclophosphamide have been prescribed for all the tiers of breast cancer. Most of the Breast Cancer patients were pre-menopausal that is contradictory to the recognised reality that post-menopausal women have better chance of acquiring breast cancer. Smaller pattern length might be a restricting thing ceasing the in-intensity analysis.

## CONCLUSION

This cutting-edge study states that the occurrence of breast cancer was higher in premenopausal women among the age group of 41-50. Combination regimens had been taken into consideration for majority of population which incorporates alkylating agents (cyclophosphamide) as maximum prescribed in combination with anthracycline Derivatives (Adriamycin) accompanied through paclitaxel or docetaxel. Majority of the chemo regimens have been acquired through level 3b breast cancer patients who had been approximately 23% and on average of 3 anticancer drugs had been prescribed for each patient. Trastuzumab was the most prescribed monotherapeutic agent that's majorly taken into consideration for patients requiring adjuvant therapy relying on HER status accompanied through capecitabine. The drugs prescribed had been determined to be rational and acknowledged to preclude the development of ailment keeping the compliance with respective NCCN guidelines.

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## CONFLICT OF INTEREST

The authors declare that there is no conflict of interest.

## ABBREVIATIONS

**WHO:** World Health Organization; **DUS:** Drug Utilization Studies; **SVIMS:** Sri Venkateswara Institute of Medical Sciences; **SPMCW:** Sri Padmavathi Medical College for Women; **PPMS:** Primary Progressive Multiple Sclerosis; **ACT:** Adriamycin Cyclophosphamide Paclitaxel; **TCH:** Docetaxel Carboplatin Transtuzumab; **AC:** Adriamycin Cyclophosphamide; **DCT:** Docetaxel Cyclophosphamide Transtuzumab; **TH:** Paclitaxel Transtuzumab; **TC:** Transtuzumab Cyclophosphamide; **DT:** Docetaxel Transtuzumab; **DC:** Docetaxel Cyclophosphamide; **IHC:** Immunohistochemistry; **HR:** Progesterone Estrogen; **PR:** Progesterone; **HER:** Human Epidermal Growth Factor; **TNBC:** Triple Negative Breast Cancer; **TPBC:** Triple Positive Breast Cancer; **NACT:** Neo Adjuvant Chemotherapy; **ACT:** Adjuvant Chemotherapy; **MRM:** Modified Radical Mastectomy; **BCS:** Breast Conserving Therapy; **ALND:** Axillary Lymphnode Dissection; **5-HT<sub>3</sub>:** 5-Hydroxy Tryptamine 3; **H<sub>2</sub>:** Histamine 2; **NCCN:** National Comprehensive Cancer Network.

## SUMMARY

Breast cancer is a multi-factorial disease, comprises a group of heterogeneous and complex diseases that evolves due to uncontrolled cellular growth, differentiation and the loss of normal programmed cell death. The study was observational prospective and non-interventional study conducted at Department of Medical Oncology, Sri Venkateswara Institute of Medical Sciences (SVIMS), Sri Padmavathi Medical College (SPMCW), Tirupati, and Andhra Pradesh. The present study was explicitly aimed to assess the prescription pattern of chemotherapeutic agents in breast cancer patients in a tertiary care hospital. The demographic details and required relevant treatment chart information of patients who met the inclusive standards have been entered into specially designed proforma for the evaluation of prescription pattern against standard NCCN guidelines. The inclusion standards consist of recognized breast cancers patients above 18 years, neoadjuvant/adjuvant chemotherapy acquired patients without or with surgical therapy or radiation therapy. The exclusion standards consist of patients who aren't inclined to take part in this study, patients under 18 years and sufferers who're having different cancers other than breast cancers were excluded. Neoadjuvant chemotherapy in 13 patients, adjuvant chemotherapy in 30 patients and chemotherapy alone in 32 Patients were established. The objective of this study is to analyse the type of therapy, obtain statistics about number of patients exposed to a particular drug or a particular class of drugs, provide pattern of drug consumption and to analyse the most common chemotherapeutic agents and supportive care medicines prescribed. Data about the drug regimens was amassed from patient treatment chart and additional unique information was collected with the aid of questioning the patient or caretaker.

DUS should be encouraged for diseases like breast cancer as the patients are exposed to high volume of drugs which are expensive and are subjected to significantly serious ADR'S if used irrationally in 201 patients which represented that most common types of breast cancers were infiltrating ductal Carcinoma

(46.3%), ductal Invasive carcinoma (35.8%), metastatic cancer (9.0%); and cyclophosphamide (92%) turned into fantastically prescribed drug followed by daunorubicin, dexamethasone 61.2%, ondansetron 50.8%, pantoprazole (25.4%) and peg filgrastim (16.9%) as normally prescribed supportive care medications. The treatment alternatives of the Breast Cancer depend on the age, stage, importantly IHC status. Trastuzumab, a tyrosine kinase receptor inhibitor that's a targeted drug is taken into consideration ideal for the Patients having HER Positive breast cancer. The overall study translates that Adriamycin and cyclophosphamide have been prescribed for all the tiers of breast cancer.

Prescription monitoring study is an evolving discipline which clearly compares the found styles of drug use with present day suggestions and guidelines. The prescription pattern of anticancer drugs has been evolved significantly in current years due to better understanding of underlying pathophysiology of Carcinomas in addition to establishment of the newer drugs.

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