

## A Multicentric non-interventional observational study to determine treatment patterns and response of drugs in various stages of breast cancer along with epidemiology

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### ABSTRACT

Cancer is a life-threatening disease which causes to lose cohesiveness and orderliness of normal tissue. These malignant cells can spread to any other organ through blood flow or lymphatic flow and develop malignancy over there; this phenomenon is called metastasis. The aim is to focus on treatment pattern and response of drugs in various stages of breast cancer along with epidemiology. It is a non-interventional multicentric observational study. Female patients confirmed with Breast cancer are included in the study. All the relevant data were collected on a patient demographic form after obtaining informed consent from individual patients. In our study, the mean age of presentation in breast cancer patients was 41.35 years. Further it was found that 40.5% (n = 81) majority-female patients with Breast cancer are from Guntur District and 21.5% (n= 43). The majority of women with Breast cancer have hormone receptor expression of ER+/PR+HER2- was found to be 33% (n= 50). In the study on analyzing comorbidities of the study population, it was noted that 28.5% of women were affected with Diabetes mellitus. In our study, it was found that most of the patients with Breast cancer have been most often prescribed with Adriamycin 27.86%. From these observations, we conclude that late menarche may be one of the etiological causes of breast cancer in women, Invasive carcinoma in situ is the most commonly reported breast cancer in the study. Patients have been diagnosed with breast cancer at their stage 3 of progression, which may be the reason for making it mandatory for more than 50% of patients to undergo 6 to 8 cycles of chemotherapy.



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### INTRODUCTION

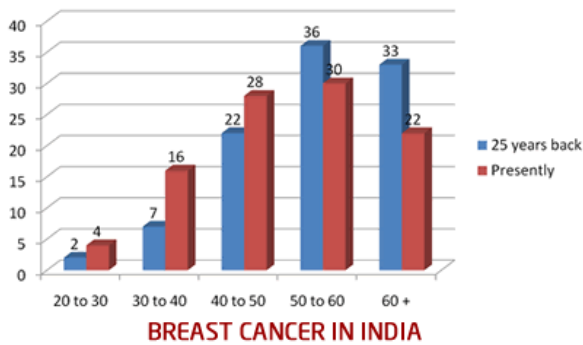
Cancer is a life-threatening disease which causes to lose cohesiveness and orderliness of normal tissue. Apoptosis or programmed cell death in normal tissues is replaced by uncontrolled cell growth in cancer cells. The cells which grow uncontrollably are called malignant cells, and the phenomenon of converting a normal cell to malignant cell is called "malignancy." These malignant cells can spread to any other organ through blood flow or lymphatic flow and develop malignancy over there; this phenomenon is called metastasis. Malignant cells can

also invade the surrounding tissue [1].

## MATERIALS AND METHODS

### Epidemiology of breast cancer

The two variables mainly associated with the occurrence of Breast cancer, are gender and age. Although the incidence of breast cancer increased globally over the last several decades, the most significant increase has been in Asian countries. The disease is sporadic before the age of 20 seldom occurs below 30 years of age, and its incidence rates rise to the age of 50 years [2]. Figure 1



**Figure 1: Epimediology of breast cancer women in india**

### Types of breast cancer

1. Ductal carcinoma in situ (DCIS)
2. Invasive ductal carcinoma (IDC)
3. Metastatic Breast cancer (MBC)
4. Triple-negative breast cancer (TNBC)
5. Inflammatory Breast cancer (IBC)

### Staging of breast cancer

The AJCC has designated staging by TNM classification. This system takes into account [3]:

1. The tumour size and spread (T)
2. Whether cancer has spread to lymph nodes (N)
3. Whether it has spread to distant organs (M) for metastasis [4].

### Stages of breast cancer Figure 2

#### Stage 0

Non- invasive breast cancer has spread to breast tissues.

#### Stage I

≤ 2cm and has not spread to lymph nodes. Cancers are likely to one part of the body, and it is likely to be removed if small enough.

#### Stage II

Cancers are locally advanced. Stage II cancer can be treated by chemotherapy, radiation or surgery. [5]

#### Stage II A

≤ 2 cm and has not spread to lymph nodes or 2- 5 cm and has spread to 1- 3 lymph nodes.

#### Stage II B

2 – 5 cm and has spread to lymph nodes or ≥ 5 cm and has spread to more than 1-3 lymph nodes.

#### Stage III

Cancers are generally locally advanced whether any cancer is designated as stage II or stage III can depend on the specific type of cancer, for example in Hodgkin's disease, stage II signifies affected lymph nodes on only one side of the diaphragm whereas stage III depicts affected above and below diaphragm [6].

#### STAGE III-A

≤ 5 cm and spread to lymph nodes forming or ≥ 5 cm and spread to 4-9 lymph nodes without forming lumps [7].

#### Stage IIIB

Any size and spread to the 4-9 lymph nodes and skin or chest wall with swelling.

#### Stage III C

Any size and has spread to 10 or more lymph nodes or more

#### Stage IV

Cancers spread to other organs or throughout the body (lymph nodes, lungs, bone, liver, brain [8, 9]. Figure 3

### Treatment oatterns of breast cancer

Treatment depends on the stage of cancer.

#### Surgery

Surgery is generally the first line of attack against breast cancer. This section explains the different types of breast cancer surgery. Patient and doctor will determine the kind of surgery that's most appropriate for you based on the stage of cancer and the "personality" of cancer [10].

Lumpectomy knew as breast-conserving surgery which is mainly the removal of only the tumour and a small amount of surrounding tissue [11].

Mastectomy is the removal of all breast tissues. Mastectomy is refined and less intrusive than it used



to be because in most cases, the muscles under the breast are no longer removed.

Lymph node removal or axillary lymph node dissection takes place during Lumpectomy and Mastectomy when biopsy shows that breast cancer has spread outside the milk duct. Some people qualify for the less-invasive sentinel lymph node dissection.

Breast reconstruction is the rebuilding of the breast after Mastectomy and sometimes lumpectomy. Reconstruction can also take place at the time of cancer-removing surgery, or months to years later [12].

Prophylactic Mastectomy is the preventive removal of the breast to lower risk of breast cancer in high-risk people.

Prophylactic ovary removal is a preventive surgery which lowers the amount of estrogen in the body, making it harder for estrogen to stimulate & develop into breast cancer.

Cryotherapy also called cryosurgery, uses extreme cold to freeze and kill cancer cells. As of now, cryotherapy is an experimental treatment for breast cancer [13].

### **Chemotherapy**

Chemotherapy treatment weakens and finally destroy cancer cells in the body, including cells at the original cancer site and any cancer cells which spreads to other parts of the body. Chemotherapy often denotes as just "chemo," is a systemic therapy, which means it affects the whole body by going through the bloodstream [14].

### **Hormonal therapy**

Hormonal therapy medicines treat hormone-receptor-positive breast cancers in two ways:

1. By lowering the amount of the hormone estrogen in the body
2. By blocking the action of estrogen on breast cancer cells

### **Targeted therapy**

Targeted cancer therapies are treatments that target specific characteristics of cancer cells, such as a protein that allows the cancer cells to grow rapidly or abnormally. Some targeted therapies are antibodies that work like the antibodies made naturally by our immune systems. These types of targeted therapies are sometimes called targeted immune therapies [15].

### **Immunotherapy**

Cancer immunotherapy medicines work by helping your immune system work harder or more efficiently to fight cancer cells. Immunotherapy uses substances — either made naturally by your body or human-made in a lab — to boost the immune system to:

1. Stop or slow cancer cell growth.
2. Stop cancer cells from spreading to other parts of the body.
3. Be better at killing cancer cells.

### **Radiation therapy**

Radiation therapy — also called radiotherapy — is a highly targeted and highly effective way to destroy cancer cells in the breast that may stick around after surgery.

#### **Radiation therapy is used in several situations**

After breast-conserving surgery (BCS) to help lower the chance will come back in the same breast or nearby lymph nodes.

After a mastectomy mostly if the cancer was more extensive than 5 cm (about 2 inches) if cancer is found in many lymph nodes or certain surgical margins have cancer such as the skin or muscle

If cancer has spread to other parts of the body such as the bones or brain

#### **Timings of radiotherapy**

Radiotherapy should be between 3 – 4 weeks following any adjuvant chemotherapy, although planning may commence before this [16].

#### **Radiotherapy in patients with ductal carcinoma INSITU (DCIS)**

The need for radiotherapy in patients with DCIS can be guided by the use of the Van Nuys Prognostic Index (NPI) score. The need for informed decisions made at multi-disciplinary meetings is vital. A tumour bed boost should be considered [16]Table 1

#### **Aims and objectives**

The aim is to focus on treatment pattern and response of drugs in various stages of breast cancer along with epidemiology.

#### **Primary objection**

To study different treatment patterns and response of drugs in stages of breast cancer.

To give a brief overview of ER/PR and HER2 positive and ER/PR HER2 negative type of breast cancer.

**Table 1: Calculation of the VNPI score**

Score	1	2	3
<b>Size (mm)</b>	<15	16- 40	≥ 41
<b>Margin width (mm)</b>	≥ 10	1 – 9	< 1
<b>Pathologic classification</b>	Non-high grade without Necrosis	Non-high grade with Necrosis	High grade with or without Necrosis
<b>Age (Years)</b>	.>60	40 – 60	< 40

List and discuss the surgical treatment options of breast cancer.

To describe the rationale for adjuvant chemotherapy, radiation therapy, hormonal therapy, immunotherapy, breast reconstruction [17].

### Secondary objective

To give a synopsis on the epidemiology of breast cancer in various areas.

To make a statistical analysis of Exposure of breast cancer in pre & post menstrual women along with epidemiology.

## METHODOLOGY

### Study design

1) This is a non- interventional multicentric observational study conducting approximately 200 female patients confirmed with Breast cancer.

2) No study medication will be prescribed or administered as a part of the study procedure.

3) Patients who have been treated as per Investigator routine, clinical practice will be screened in study.

4) Patients who have been treated as per Investigator routine clinical practice will be enrolled in the study.

For eligible patient's baseline data will be collected, i.e., demographic details, age, district, past medical and surgical history, mammogram, Laboratory test, and concomitant medication [18].

### Study site

A Prospective and Retrospective Observational study was conducted in the oncology department in Tertiary care hospital in Guntur region.

### Study population

The study was carried out in all Pre and postmenopausal women diagnosed with breast cancer attending the oncology department in tertiary care hospital.

### Study duration

The study was carried out for six months from August 2019 to January 2020, and data was collected in a pre-designed data collection form.

**Sample size:** Total number of subjects: 200

### Inclusion criteria

1. Pre- and postmenopausal women who are diagnosed with breast cancer and women undergoing various treatments in breast cancer
2. Patients who have provided written informed consent form
3. Laboratory test
4. Mammogram (BIRADS)

### Exclusion criteria

1. Pregnant women.
2. Lactation women
3. Patients with mental illness

### Study procedure

#### Prospective and retrospective observational study

##### Step 1

A prospective and retrospective observational study was conducted in the oncology department in a tertiary care hospital.

##### Step 2

Study procedure was explained, and data were collected with patient approval.

##### Step 3

Patient data were collected in a pre-designed data collection form.

##### Step 4

The data include patient demographics, past medical & medication history, newly occurred/reoccurred case.

**Step 5**

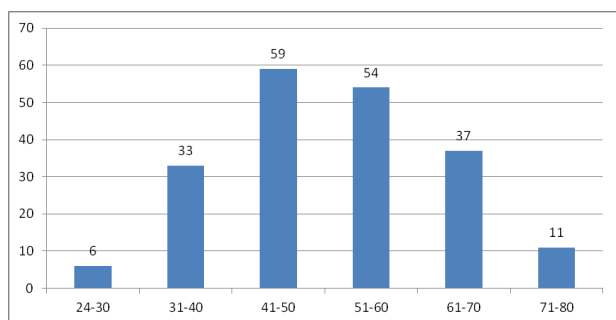
The treatment patterns given in different stages will be assessed, and also the epidemiological studies of breast cancer will be analyzed.

**Step 6**

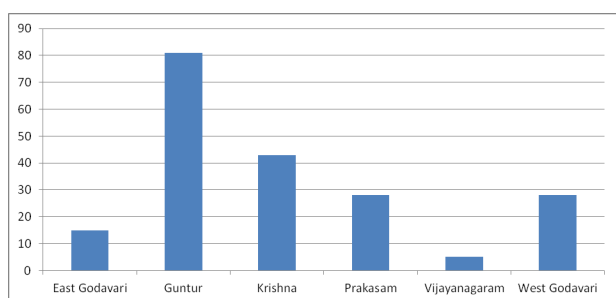
Percentage of drugs prescribed in different stages cancer was calculated. The data was statistically analyzed using simple student-t-test, and P-value was analyzed.

**RESULTS AND OBSERVATIONS**

In our study, the mean age of presentation in breast cancer patients was 41.35 years. Majority of the patients (n= 200) were in the age group of 41- 50 years. In the present study, the incidence of breast cancer patients was low among patients over the age of 24 - 30 years. Figure 4 .



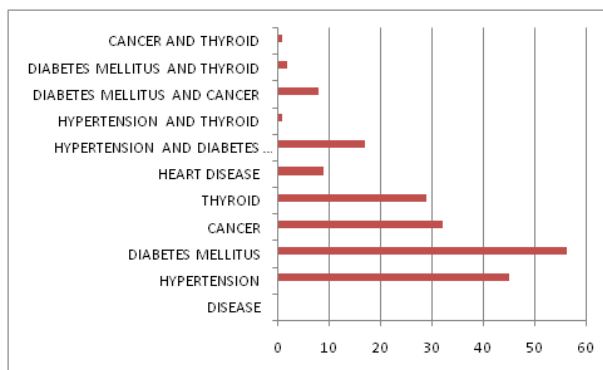
**Figure 4: Age distribution among women with breast cancer**



**Figure 5: Distribution of district**

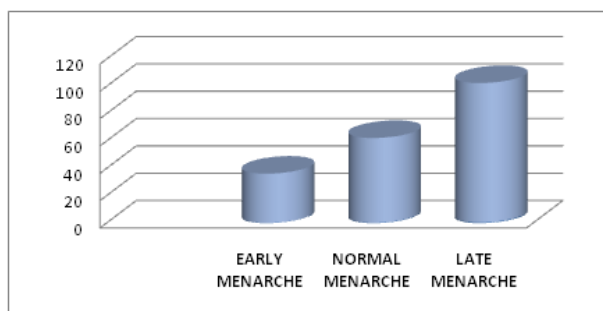
In our study 40.5% (n = 81) female patients with Breast cancer are from Guntur District was 21.5% (n= 43) are from Krishna District, 14% (n=28) from Prakasam , 1.4% (n= 28) from West Godavari , 7.5% (n= 15) from East Godavari , 2.5% (n= 5) from Vijayanagaram. Figure 5

In the study on analyzing comorbidities of the study population, it was noted that 28.5% women were effected with Diabetes mellitus, 22.5% with Hypertension, 16% women with cancer other than breast cancer, 14.5% women with thyroid, 8.5% women are effected with both Hypertension and



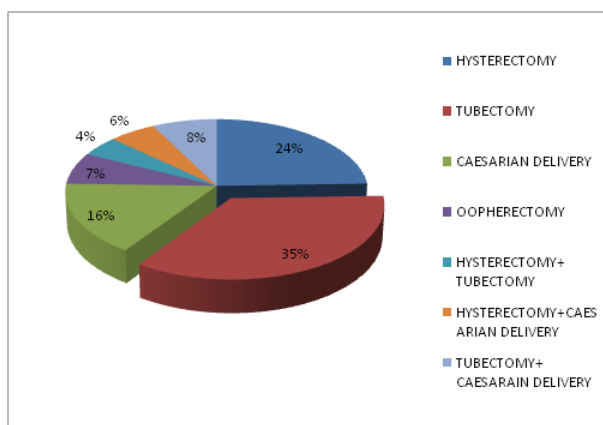
**Figure 6: Showing the comorbid conditions in patients**

Diabetes Mellitus, 4.5% women with Heart disease, 4% women are effected with both Diabetes Mellitus and Cancer, 1% women effected with both Diabetes Mellitus and Thyroid. Figure 6.



**Figure 7: Distribution of age of menarche**

In the study it was found that 51% (n= 102) women with Breast cancer have Late menarche, 31% (n= 62) women have Normal Menarche, and 18% (n=36) women have Early Menarche. Figure 7.



**Figure 8: Distribution of past surgeries underwent by women with breast cancer**

Breast cancer was found to be more common in Postmenopausal women 37% (n=74) than Per-Menopausal women 63% (n= 126). Figures 8 and 9. Most of the patients had stage 3 Breast Cancer

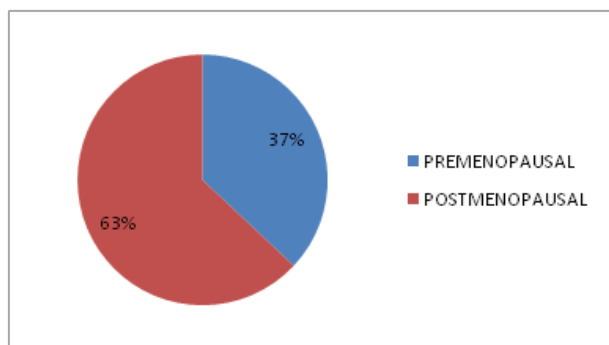


Figure 9: Distribution of menopausal status

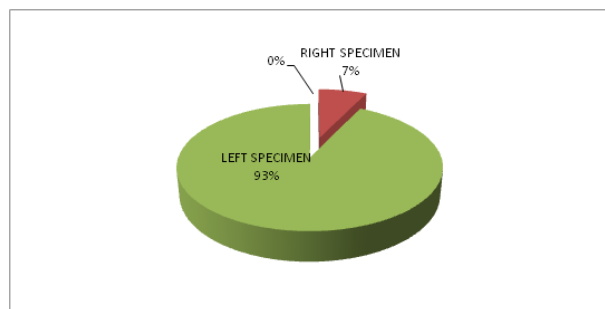


Figure 12: Distribution of specimen in breast cancer patients

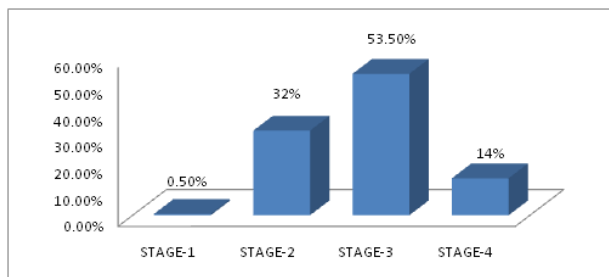


Figure 10: Distribution of stages wise distribution of breast cancer

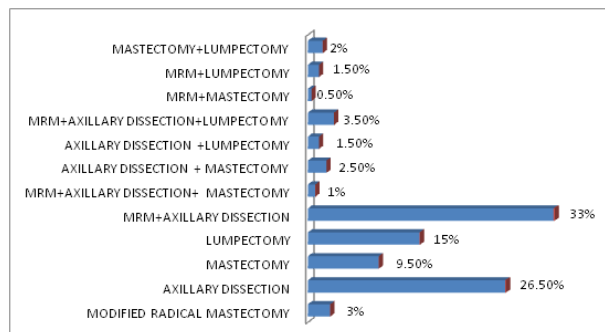


Figure 13: Distribution of surgeries among women with breast cancer

54.5%, 31.5% presented with Stage 2 Breast cancer, 13.5% presented with Stage 4 and 0.5 % with Stage 1 Figure 10

tomy, 9.50% with Mastectomy, 3.50% with MRM +axillary dissection +lumpectomy, 2.50% with axillary dissection+ Mastectomy, 2% with mastectomy+ lumpectomy, 1.50% with MRM+ Lumpectomy. Figure 13 .

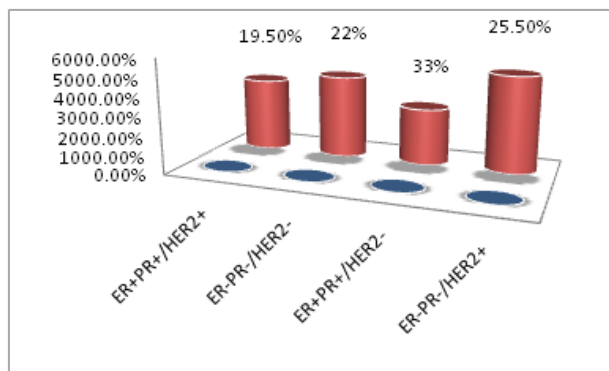


Figure 11: Showing the expression of hormones

In the study, the women with Breast cancer have hormone receptor expression of ER+/PR+/HER2+ was found to be in 19.50% (n=39), ER-/PR-/HER2- was found to be 22% (n= 44), ER+/PR+/HER2- was found to be 33% (n= 50), ER-/PR-/HER2+ was found to be 25.50% ( n= 51) Figure 11.

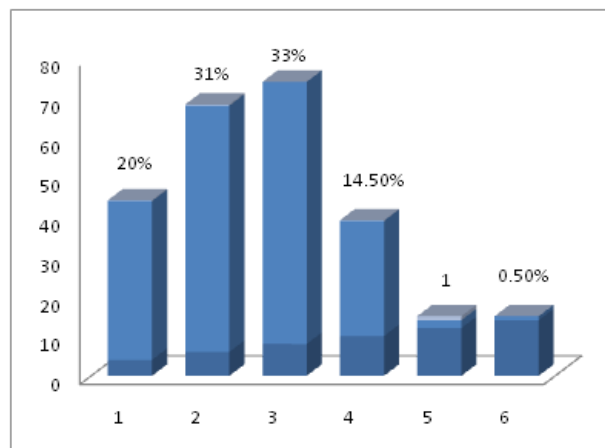


Figure 14: Number of chemocycles given to breast cancer patients

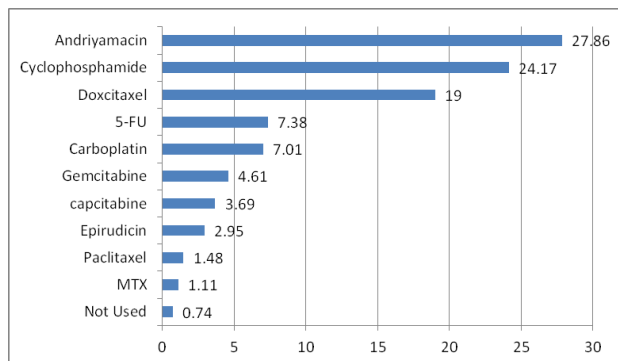
Most of the women had breast cancer in the left breast 93% when compared to that of the right-side breast 7.5%. Figure 12

In our study it was found that most of the women with Breast cancer receive eight chemo cycles 33%, then six chemo cycles 31%, and 10 and 12 chemo cycles respectively include 14.50% & 20%. Figure 14

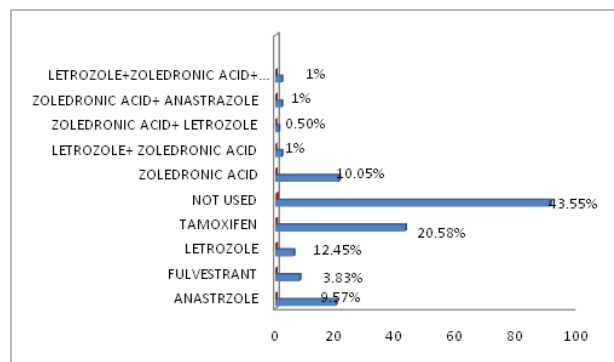
Most of the women with breast cancer had undergone with Modified Radical Mastectomy + Axillary dissection 33% in this group, 26.50% with axillary dissection, 15% underwent with lumpec-

In our study it was found that most of the patients with Breast cancer have been most often prescribed with Adriamycin 27.86%, then cyclophos-

phamide 24.17%, Docetaxel 19%, then with 5 Fluorouracil 7.38%, Carboplatin 7.01%, Gemcitabine 4.61%, Ciptacibine 3.69%, Epirubicine 2.95%, Paclitaxel 1.48%, Methotrexate 1.11%, and finally not used Drugs 0.74%.Figure 15

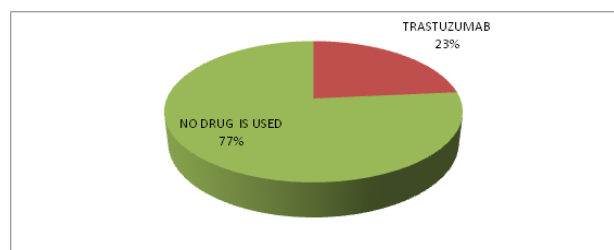


**Figure 15: Distribution of usage of cytotoxic drugs given to patients**



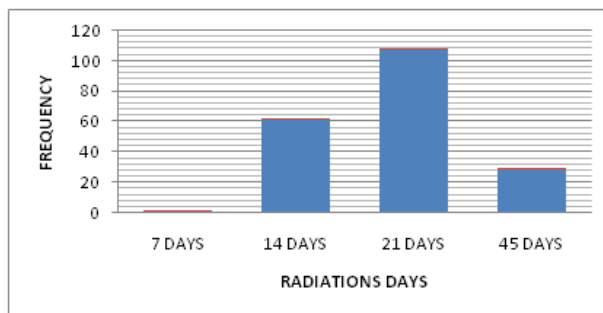
**Figure 16: Distribution of hormonal drugs given to patients**

In our study, it was found that some of the patients are treated with hormonal drugs; some of them are prescribed with Tamoxifen 20.58%, Letrozole 12.45%, Zoledronic Acid 10.05%. Indeed, the maximum number of the women have not been using any Hormonal drugs 43.55%. Anastrozole 9.57%, Fulvestrant 3.83% and also some of them are prescribed with combination of Letrozole+ Zoledronic acid+ Anastrozole 1%, Zoledronic acid + Anastrozole 1%, Zoledronic acid+ Letrozole 0.5%.Figure 16



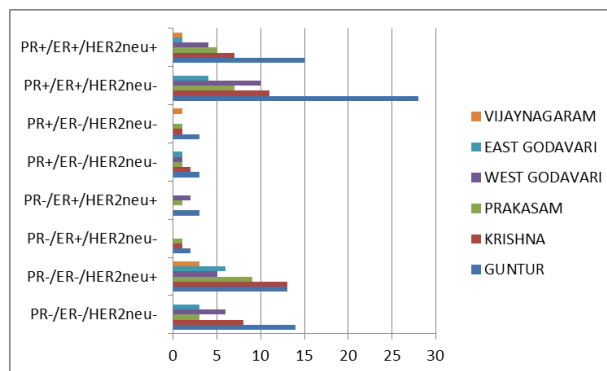
**Figure 17: Distribution of targeted drug given to women with breast cancer**

Most women with breast cancer have been prescribed with Trastuzumab 23%.Figure 17



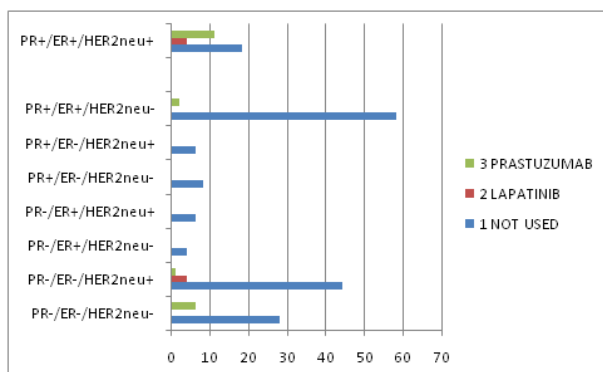
**Figure 18: Number of days radiation was given**

In our study, the majority of the patient with Breast cancer have undergone radiation of 21 days.Figure 18



**Figure 19: Comparison between hormone expression Vs district**

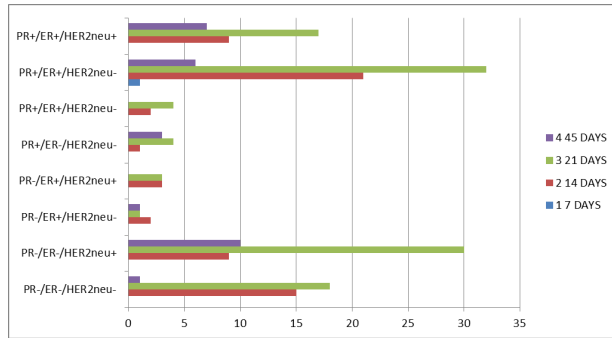
In the present study, while comparing districts Vs Hormone Expression, it was found that Guntur district has most cases of hormone expression (ER+/PR+/HER1 neu) while that of other districts in Andhra Pradesh.Figure 19



**Figure 20: Comparison between hormone expression Vs immunotherapy drug**

It was found that immunotherapy drugs are most not given in case of excessive hormone expression, whereas Lapatinib and Prastuzumab are prescribed in some casesFigure 20.





**Figure 21: Comparison between radiations Vs hormone expression**

It was found in our study that most of the patients were given to the patients for 21 days with more of hormone expression PR+/ER+/HER2neu. (Figure 21)

## DISCUSSION

The current study on a multicentric non-interventional observational study to determine treatment patterns and the response of drugs in various stages of breast cancer along with epidemiology was carried out in inpatient in the oncology department of a tertiary care hospital. A total of 200 prescriptions were analyzed based on inclusion and exclusion criteria. Out of 200 prescriptions, Age-wise distribution was analyzed and found that most of the prescriptions were in the age group of 41-50 with 59 patients (29.5%) followed by age group of 51-60 with 54 patients (27.5%). Which was similar to the study conducted by Augustine Balekuzou et.al

Categorization based on district wise was analyzed and found that most of the patients were from Guntur district with 81 patients contributing 40.5%, which was similar to study conducted by Anjan Adhikari et al. (2018).

Categorization based on family history, the study reports that a significant number of patient's family members have diabetes mellitus with 56 (28%). This study was similar to the study conducted by Kerryn W Reding.

The most common surgeries done in the patients was Tubectomy for 70 patients (35%) which could be compared to a similar study conducted by Anjan Adhikari, Dipesh et al. (2018).

Categorization based on menopausal status that 74 patients with premenopausal (37%) and 126 patients with postmenopausal (63%) which was similar to study conducted by Bahram Fariborz Farshad et al. (2016).

Reports on the age of menarche show that 102 of patients with late menarche (51%), 62 of the patients with average menarche (31%) and 36 of patients with early menarche (18%). A similar study was conducted by Anjan Adhikari et al. (2018).

The reports on the type of tumour were categorized invasive carcinoma in situ was high with 86 patients (43%) followed by triple-negative breast cancer with 59 patients (29.5%) followed by metastatic breast cancer with 22 patients (11%) which is similar to study conducted by Sanoj Panicker et al. (2017).

In the present study hormone receptor was categorized ER-/PR-/HER2+ was in 51 patients (25.5%) followed by EP-/PR-/HER2- receptor with 44 patients(22%) followed by ER+PR+/HER2+ receptor in 39 patients (19.5%) and ER+/PR+/HER2- with 30 patients(15%) Our study was compared with the study conducted by Ruohong Shui et al. (2019).

Categorization on stages wise distribution of breast cancer most of the patients in stage 3 with 109 patients (54.5%) which could be compared with a study conducted by Rohen White et.al (2000).

Distribution of surgeries done among women with breast cancer was analyzed 66 patients was done for MRM + axillary dissection (33%) followed by axillary dissection for 53 patients (26.5%), Lumpectomy for 30 patients, Mastectomy for 19 patients, axillary dissection + lumpectomy for seven patients, MRM for six patients, MRM+ axillary dissection + lumpectomy for five patients, Mastectomy+ Lumpectomy for four patients, Axillary dissection+ Mastectomy for three patients, MRM+ lumpectomy for one patient which was compared by Mathias Worni et.al (2015).

Distribution of specimen is categorized 15 patients are with the right (7.5%) and 185 patients with left (92.5%) which is compared with Dipesh Chakraborty et.al (2018).

The number of chemo cycles given in breast cancer was analyzed four cycles were given to 40 patients (20%), six cycles were given for 62 patients(31%),8cycles was given for 66 patients(33%), ten cycles was given for 29 patients(14.5%), 12 cycles was given for two patients(1%), 14 cycles was given for one patient (0.5%) which was compared with Jean-Marc Nabhoitz et..al (2003).

Distribution of usage of cytotoxic drugs was analyzed Adriamycin was the highest drug which was prescribed in 151 patients (27.86%), followed by cyclophosphamide in 131 patients (24.17%) which

is compared with Stephan Chan et.al (2009).

Distribution of hormonal drugs was analyzed hormonal drugs are not used in all patients 91 patients are not used any hormonal drugs (43.55%), Tamoxifen is the drugs which were used in 43 patients which were high (20.58%) which was compared with Jing XI Aabha et al. (2019).

Distribution of targeted drugs was categorized 47 patients were treated with Trastuzumab (23.5%), 153 patients were not treated with any type of drug (76.5%) which was compared with Natasha Woodward et al. (2019).

Distribution of radiation given to women with breast cancer was analyzed 108 patients was treated for 21days (54%), 62 patients were treated for 14days (31%), 29 patients were treated for 45days (14.5%), and one patient was treated for 7days (0.5%) compared with J. H Kin et al. (2019).

## CONCLUSION

It was observed from the study that more than half of the study population with breast cancer had been reported with a medical history of late menarche accounting to a percentage of 50% of over of study population women. Invasive Carcinoma Insitu was reported with first highest incidence rate among study enrolled women with 43%, Triple Negative Breast Cancer showed second highest incidence in comparison with other types of breast cancers, with an accountable percentage of 29.5%. 54.5% of women had a late diagnosis of breast cancer, which was at their Stage 3 of breast cancer. 33% of the population had to undergo eight cycles of chemotherapy, and 30% of the population had mandatory chemotherapy of 6 cycles. The most commonly used drug was ADRIAMYCIN, which was used in 27.86% of study population which included 151 patients, followed by CYCLOPHOSPHAMIDE used in 24.17% which included 131 patients and third most frequently used drug was DOCETAXEL in 19% of the study population with 103 patients.

From these observations, we conclude that late menarche may be one of the etiological causes of breast cancer in women, Invasive carcinoma insitu is the most commonly reported breast cancer in the study. Patients have been diagnosed with breast cancer at their stage 3 of progression, which may be the reason for making it mandatory for more than 50% of patients to undergo 6 to 8 cycles of chemotherapy. Coming to the patterns of drug use, Adriamycin, Cyclophosphamide and Docetaxel are the three most commonly used single drug and combinational drug therapies among the study popu-

lation. Hormonal therapy was not given in almost 40% of the study population. However, further large-populated multicentric studies are required to assess and report on the above observations for making required changes in the therapeutic approach.

Finally, we can conclude that the risk of breast cancer is alarming, especially in various states. The present study is conducted on breast cancer patients attending the tertiary care hospital in various districts to evaluate the patterns of breast carcinoma and therapeutic regimen provided to patients. This study is essential to evaluate the epidemiological profile of the disease. Awareness about screening procedures and treatment of breast cancer among common people can help reduce the mortality of the disease.

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## Conflict of Interest

The authors declare that they have no conflict of interest for this study.

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