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Pharmacoepidemiological Perspective of Carcinoma Breast in a Tertiary Health Care Set Up of Central India: A Retrospective, Cross-Sectional, Surveillance Study.

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ABSTRACT

Carcinoma Breast is a tumor that starts from cells of the breast tissue, either in cells that line the ducts that carry milk to the nipples (ductal carcinoma) and/or in cells that line the lobules, which are glands involved in milk production (lobular carcinoma).In 2004, Carcinoma Breast caused 519,000 deaths worldwide (7% of cancer deaths); almost 1% of all death. The first noticeable symptom of breast cancer is typically a lump that feels different from the rest of the breast tissue. More than 80% of breast cancer cases are discovered when the woman feels a lump. The primary risk factors that have been identified are sex, age, lack of childbearing or breastfeeding and higher hormone levels. The risk factors for them are ageing(>60 yrs),family history ,inherited gene mutations, Klinefelter's syndrome, alcohol, liver disease like cirrhosis, obesity, estrogen treatment as used in prostatic carcinomas, testicular conditions like undescended testis, mumps, orchiectomy and long term exposures to higher temperature and radiation. Therefore, the present study was conceived, designed and carried out as the pioneer study of this arena to explore the pharmacoepidemological domain of carcinoma breast in Acharya Vinoba Bhave Rural Hospital- a tertiary health care setting of central India.

Keywords: Pharmacoepidemological, Carcinoma Breast, Central India, Retrospective, Cross-Sectional, Surveillance study.

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INTRODUCTION

Carcinoma Breast is a tumor that starts from cells of the breast tissue, either in cells that line the ducts that carry milk to the nipples (ductal carcinoma) and/or in cells that line the lobules, which are glands involved in milk production (lobular carcinoma) [1]. Worldwide, Carcinoma Breast comprises 10.4% of all cancer incidences among women, making it the second most common type of non-skin cancer (after lung cancer) and the fifth most common cause of cancer death [2].

In 2004, Carcinoma Breast caused 519,000 deaths worldwide (7% of cancer deaths); almost 1% of all death [3].

In India cancer prevalence is estimated around 2.5 million, with over 0.8 million new cases and 0.5 million deaths occurring each year [4]. According to National Cancer Registries and Regional Cancer Centers, it is the commonest cancer amongst women in Delhi, Mumbai, Ahmedabad, Kolkata and Trivandrum[5,6,7].Moreover, data from national and regional cancer centers from 1984 to 2002 also show that there is an increase in the incidence of breast cancer and found to be gradually overtaking cancer of the cervix. The major burden of Carcinoma breast is due to its early onset, whereas it is mostly a postmenopausal disease in western population. Carcinoma Breast has been the most extensively studied human tumor site not only from clinicoepidemological, Experimental and molecular angle but also from a psychological point of view because breast is an emotional symbol of women's pride and personality, including sexuality and motherhood ,any threat to breast is to shake the very core of her mind and feminine orientation[8]

The first noticeable symptom of breast cancer is typically a lump that feels different from the rest of the breast tissue. More than 80% of breast cancer cases are discovered when the woman feels a lump [9].

By the time a breast lump is noticeable, it has probably been growing for years.

The primary risk factors that have been identified are sex, age, lack of childbearing or breastfeeding and higher hormone levels [10].

Carcinoma Breast has been reported in males also, although they tend to have poorer outcomes due to delays in diagnosis [5].

The risk factors for them are ageing(>60 yrs),family history ,inherited gene mutations, Klinefelter's syndrome, alcohol, liver disease like cirrhosis, obesity, estrogen treatment as used in prostatic carcinomas, testicular conditions like undescended testis, mumps, orchiectomy and long term exposures to higher temperature and radiation[11]. Current treatment modalities available are Surgery(Modified Radical Mastectomy, Lumpectomy), Chemotherapy (Cyclophosphamide, Adriamycin, Metotrexate, Paclitaxel, 5-Flurouracil), Hormonal blocking agents (Tamoxifen, Anastrazole) and Radiation. Women can reduce their risk by maintaining a

healthy weight, drinking less alcohol, being physically active and breastfeeding their children [12]. Therefore, the present study was conceived, designed and carried out as the pioneer study of this arena to explore the pharmacoepidemological domain of carcinoma breast in Acharya Vinoba Bhave Rural Hospital- a tertiary health care setting of central India.

MATERIALS AND METHODS:

A monocentric retrospective surveillance study was conducted at Acharya Vinoba Bhave Rural Hospital, Sawangi(Meghe),Wardha.243 case sheets of patients admitted from 1st January 2009 to 15th April 2012 in Surgery I.P.D were collected. The synopsis of the study protocol was submitted to the Institutional Ethics Committee of Datta Meghe Institute of Medical Sciences, Wardha.

The study was approved on 30/09/2010, vide ref.no.DMIMS (DU)/IEC/201011/75.

RESULTS

1) **Prevalence** (shown in **Table – 1**)

TABLE-1: Prevalence of Carcinoma Breast

Sr. No.	Year	No of Patients admitted in Surgery	No. of Carcinoma breast Patients	Prevalence
01	2009*	39	16.05	16.05
02	2010	69	28.40	28.40
03	2011	111	45.68	45.68
04	2012**	24	9.88	9.88
	Total	243	100.0	100.0

January to December 2009*, **January to April 2012

Figure No 1: PREVALENCE OF CARCINOMA BREAST
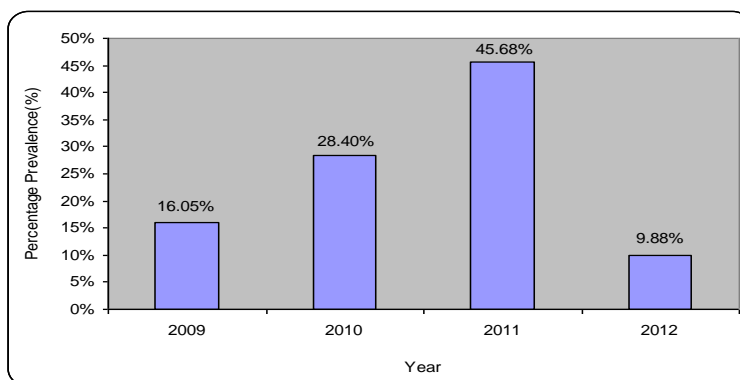
**Prevalence**- **45.68%** in the year 2011.(**Fig-1**)

2) **Age distribution** (**Table – 2**)

Most patients were between the ages of 41-60 years (**48.56%**), followed by 21-40 years (37.86%) and 61-80 years (11.52%). No patients were found in the age group below 10 years and above 80 years of age.

TABLE-2: AGE DISTRIBUTION OF PATIENTS

Sr. No	Age (yrs)	No. of patients	Percentage (%)
1	1-20	5	2.06
2	21-40	92	37.86
3	41-60	118	48.56
4	61-80	28	11.52
	Total	243	100.0

Figure No-2: AGE DISTRIBUTION OF PATIENTS
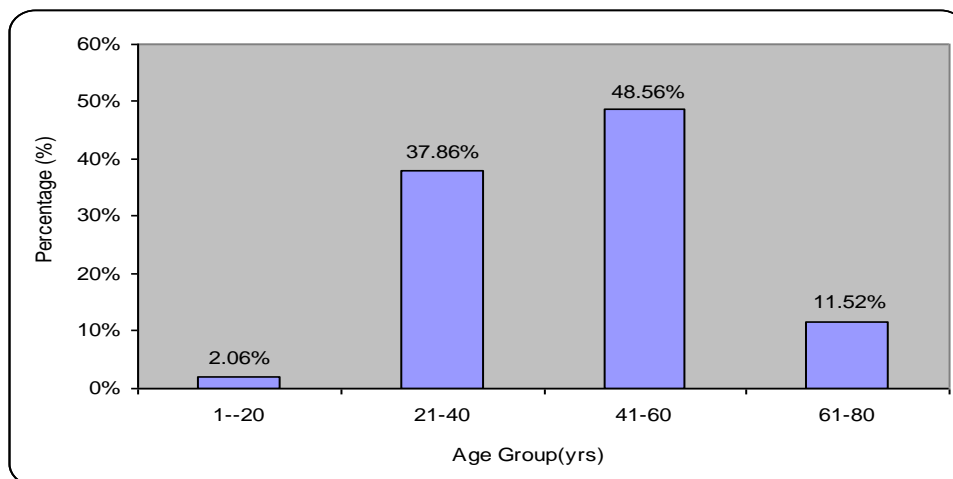
3) **Drug pattern**

The drugs were classified according to Anatomical Therapeutic Chemical (ATC) classification system.

Antineoplastic agents (Table – 3)

Most commonly used was 5-Flurouracil**(62%)** followed by Cyclophosphamide**(59%).**

TABLE-3: ANTINEOPLASTIC AGENTS

Sr. No	Name	Dosage Form	ROA	FOA	No.of patients	%	ATC code
1	Cyclophosphamide	Inj	IV	Stat	144	59.26	L01AA01
2	5 FU	Inj	IV	Stat	151	62.14	L01BC02
3	Adriamycin	Inj	IV	Stat	84	34.57	L01BC03
4	Methotrexate	Inj	IV	Stat	52	21.40	L01BA01
5	Paclitaxel	Inj	IV	Stat	22	9.05	L01CD01
6	Cisplatin	Inj	IV	Stat	2	0.82	L01XA01
7	Doxorubicin	Inj	IV	Stat	2	0.82	L01DB01

Figure No-3: ANTINEOPLASTIC AGENTS
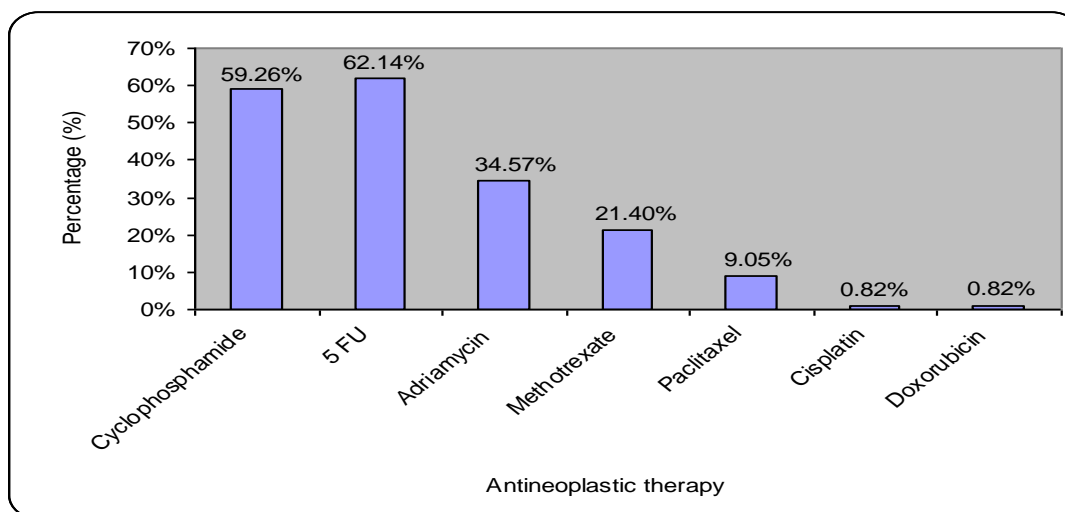
TABLE-4: ANTIMICROBIAL AGENTS

Sr. No	Name	PN	Dosage Form	ROA	FOA	No.of patients	%	ATC code
1	Ceftriaxone	C.Tax	Inj	IV	BD	6	2.47	J01DD54
2	Metronidazole	Metrogyl	Inj	IV	BD	2	0.82	J01XD01
3	Clavullinic Acid	Calvum	Tab	Oral	BD	6	2.47	J01RA01
4	Ciprofloxacin + Tinidazole	Ciplox TZ	Tab	Oral	BD	3	1.23	J01MA02
5	Amikacin	Amikin	Tab	Oral	BD	6	2.47	J01GB06
6	Amoxicillin + Sulphamethazole	Augmentin	Tab	Oral	BD	2	0.82	J01EE01
7	Gentamycin	Genta	Inj	IV	BD	3	1.23	J01GB03
8	Cefexime	Nufixim CV	Tab	Oral	BD	9	3.70	J01DD12
9	Ceftriaxone + Sulbactum	Odicef S	Inj	IV	BD	24	9.88	J01DD54
10	Ofloxacin	Oflox	Inj	IV	BD	1	0.41	J01MA01
11	Tobramycin	Tobraneg	Inj	IV	BD	6	2.47	J01GB01

Figure No-4: ANTIMICROBIAL AGENTS
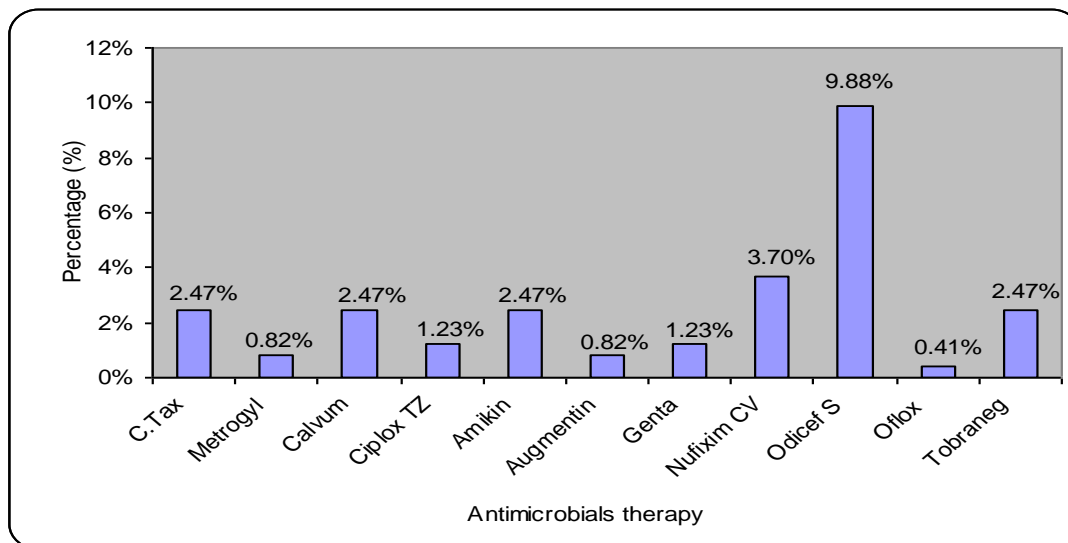
Antimicrobial Agents(Table – 4)

Ceftriaxone-Sulbactum combination(**9%**) and Cefexime (**3%**;) were the common antibiotics used in Carcinoma Breast patients.

Vitamin Supplement(Table – 5)

Vitamin B complex was used in (**22%)** while Iron (**7%**) was prescribed along with 5-Flurouracil therapy.

TABLE-5: VITAMIN SUPPLEMENT

Sr. No	Name	PN	Dosage Form	ROA	FOA	No.of patients	%	ATC code
1	B.Complex	Becolin	Oral	Tab	BD	55	22.63	A11EB
2	Vitamins	Neurobion forte	Oral	Tab	BD	8	3.29	A11DB
3	Iron	Ferrium	Oral	Tab	OD	19	7.82	B03AA02
4	Vitamin C	Limcee	Oral	Tab	OD	6	2.47	A11GA01

Figure No-5 VITAMIN SUPPLEMENT
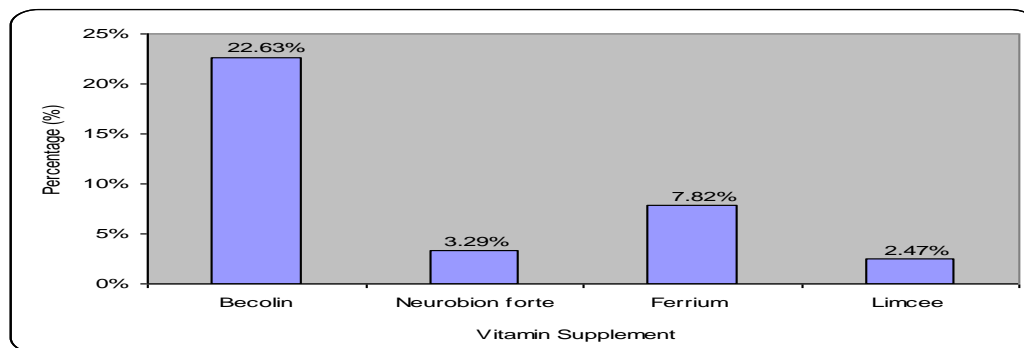
DISCUSSIONS

In our study prevalence of Carcinoma Breast is highest i.e. 45.68% in the year 2011 with the mean age of patients was 46.1 $\pm$ 15. Most patients were between the age group of 41-60 years (48.56%).5-Flurouracil was used in 62.14% of patients.

Vitamin B complex was used in 22% while Iron (7%) was prescribed along with 5-Flurouracil therapy. Ceftriaxone-Sulbactum combination(9%) and Cefexime (3%;) were the common antibiotics used in Carcinoma Breast patients.

CONCLUSIONS

Carcinoma Breast is widely diffused in all over the world, but its epidemiological and clinical perspective varies from one population to other. A protocol composed of cyclophosphamide, methotrexate and 5-fluorouracil(CMF) was one of the early combinations with proven efficacy. Conventional systemic therapy continues to be the mainstay of treatment in majority of Carcinoma Breast patients because of its ease of administration, cost effectiveness and better patient compliance in this tertiary health care setting of Maharashtra. The society should know that Carcinoma Breast is a non- contagious skin disorder and Carcinoma Breast patients also are the part and parcel of the society.

ACKNOWLEDGEMENTS

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