



CHANGING TRENDS IN EPIDEMIOLOGY, DIAGNOSIS, AND MANAGEMENT OF BREAST CANCER IN NORTH-WEST INDIA OVER A DECADE

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ABSTRACT

Context: The current decade has witnessed a drastic change in cancer epidemiology with breast cancer dethroning cervical cancer as the most common cancer among women in India.

Aims: The present study has been carried out to gauge & evaluate the change in spectrum in socio-demographic profile and management of breast cancer over a decade.

Methods and Material: The data of breast cancer patients for last ten years were recorded retrospectively at SMS Medical College, Jaipur; with respect to baseline patient, tumor, and treatment characteristics; and change in spectrum among them was analyzed.

Results: Over a period of ten years, significant decline was observed in post menopausal status (versus pre menopausal, $P = 0.011$), hormone receptor positivity (versus negativity, $P = 0.034$), advanced stage at presentation (versus early stage, $P = 0.020$); whereas significant increase was observed in breast conservative surgery (versus mastectomy, $P < 0.001$), neoadjuvant chemotherapy (versus no NACT, $P < 0.001$), taxane based chemotherapy (versus CMF/CAF/CEF regimens, $P < 0.001$), and radiotherapy with advanced technology (linear accelerator versus cobalt teletherapy, $P = 0.007$). Although there was increasing trend of younger age at presentation, use of newer imaging modalities like mammography & bone scan, more Her2/neu positivity, and use of targeted therapy; the trend was not statistically significant.

Conclusions: Most of the patients now present with young age before attaining menopause with hormone receptor negativity and Her2/neu positivity in early stage. There has been increased use of neoadjuvant chemotherapy followed by breast conservative surgery. Use of methotrexate is now obsolete and taxanes have become core chemotherapy. Patients now prefer advanced radiation technology over conventional one, and compliance to all form of treatment has improved.

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INTRODUCTION

Breast cancer is the most common cancer in females, both worldwide and in India. Cervical cancer has ruled as the most common cancer in females in India for the last four decades until recently when it has been stepped down by breast cancer. Even in rural parts, it is facing a strong competition with breast cancer to retain the top most position. As per the latest Globocan 2012 reports; the incidence, 5-year prevalence and mortality of breast cancer in World and India is 25.1% & 27%, 36.3% & 35.3%, and 14.2% & 21.5% respectively [1-2]. Cancer data from Rajasthan is limited, with only a few studies available highlighting this issue. Sharma *et al.* did a retrospective analysis of approximately 200,000 histopathological and cytological reports for the years 1990, 1991, 1996, 1999, 2001 and 2004; a total of 21,868 cancers were recorded in the six sample years [3]. There were 59.11% (12,926) males and 40.89% (8942) females,

with the male to female ratio being 1.45:1. Organ wise, breast (20.44%), cervix (14.99%), ovary (4.35%), brain (3.80%), esophagus (3.67%), uterus (3.01%) and rectum (2.80%) are common sites for malignancies in females. Recently, Sharma *et al.* have described the spectrum of malignant neoplasm in Jaipur region by retrospectively studying the proportion and site wise distribution of malignancy cases reported at five major hospitals and pathology centres during 2004-2008 [4]. Approximately 200,000 histopathology and cytology reports were analyzed and 34,486 new cancer cases were identified. There were 58.58% (20202) males and 41.42% (14284) females, with the male to female ratio being 1.41:1. Again, Breast (25.6%) was the most common site for malignancy in females followed by Cervix (10.26%), Ovary (5.4%), Brain (3.68%), Esophagus (3.4%), Lung (3.01%) and Gall Bladder (2.35%).

The last decade has witnessed drastic changes in the epidemiology and management of breast cancer. Sea changes have occurred in all aspects of management of breast cancer, like surgery, chemotherapy (CT), targeted therapy, and radiotherapy (RT). Ten years earlier, most of

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the patients used to present with advanced stage due to lack of mass screening programmes and awareness; so mastectomy was performed more often than Breast Conservative Surgery (BCS). However, this trend has changed over decade; with recent increased use of mammography and neoadjuvant therapies, the number of BCS has increased, although still lacking behind mastectomy. The chemotherapeutic agents and regimens have also changed, with methotrexate becoming obsolete and use of paclitaxel being increased; earlier used CAF (Cyclophosphamide, Doxorubicin, 5 fluorouracil) regimen has now almost been replaced by AC (Doxorubicin, Cyclophosphamide) followed by T (Paclitaxel) regimen. Now, more tissues are processed for Her2/neu receptor status; that has resulted in increased use of Trastuzumab. As far as radiotherapy is concerned, shift has occurred from conventional RT over telecobalt machine to 3 Dimensional Conformal RT (3DCRT) over linear accelerator machine; in case of left sided breast cancer, there has been increased use of Intensity Modulated RT (IMRT). Apart from technique, changes has also occurred in fractionation schedule, with hypofractionation becoming more and more popular in both BCS and mastectomy patients compared with conventional fractionation of 50 Gy in 25 fractions. Increased use of bone scan and Positron Emission Tomography (PET) has led to increased diagnosis of metastasis in various sites. Increased detection of bone metastasis in turn has led to increase use of bisphosphonates. In the Western world, even two steps ahead, a number of genomic tests based on BRCA 1 and 2, are being implemented; however this has not yet come to floor in our country. Although the use of Ki-67 indexing has been increased following the St. Gallen's consensus guidelines; the routine use of serum markers like Ca 15.3 and Ca 27.29 has not yet become reality.

Keeping all these things in mind, the present study was carried out to find out the changing trends in breast cancer in various aspects at our center, as our institute is a tertiary care referral hospital, that caters patients not only from the entire state of Rajasthan; but also from the neighbouring states of Delhi-NCR, Haryana, Punjab, Uttar Pradesh, Madhya Pradesh, and Gujarat. Recently, for the last two consecutive years, our institute has been designated as the institute with highest number of out-patients in the nation, leaving behind All India Institute of Medical Sciences, New-Delhi.

SUBJECTS AND METHODS

The present study is retrospective in nature, wherein data of female breast cancer patients who presented at SMS Medical College, Jaipur; for the last ten years were collected and analyzed for change in trends in epidemiology, diagnosis, and management of breast cancer. A total of 1,432 patients took radiotherapy from 2007 to 2016 at our centre. Data were analyzed for various clinic-pathological characteristics like age, menstrual history, histopathology, estrogen receptor (ER) & progesterone receptor (PR) status, Her2/neu status, tumor stage, type of surgery, details of chemotherapy, type of radiotherapy, radiotherapy technique, development of metastases, etc. For statistical analysis, all data were prepared and processed on Microsoft Excel 2007 using XLSTAT software version

2017 for windows (Addinsoft, New York, USA). Chi-square was used for all categorical data. *P*-value reports were two tailed and an alpha level of 0.05 was used to assess statistical significance.

RESULTS

The various baseline patient, tumor, and treatment parameters of the entire cohort are shown in Table 1. The mean age of entire cohort was 50.18 (range, 21-82 years). The most common histopathology was infiltrating ductal carcinoma (89.2%). AJCC III was the most common stage (52.6%). Hormone receptor negativity was more common (54.4%) than positivity. The most common surgery performed was modified radical mastectomy (MRM). Adjuvant only chemotherapy (ACT) was prescribed more commonly than neoadjuvant chemotherapy (NACT) followed by ACT. The most common chemotherapeutic regimen prescribed was AC→T (doxorubicin and cyclophosphamide for 3/4 cycles, followed by paclitaxel for 3/4 cycles). About three-fourth of patients took radiotherapy with curative intent and two-third received radiotherapy over cobalt teletherapy machine. Conventional fractionation of 50 Gy in 25 fractions has been the most common schedule of radiation. The most common site of metastasis was bone (38.4%) followed by brain (32.8%).

The last decade has witnessed sea changes in various parameters. The trend of all the parameters enlisted in Table 1 over ten years has been shown in Table 2 and Figure 1. Although the mean age of patients remained almost the same, the proportion of younger patients has increased over the decade. Significant increase was noted in proportion of pre-menopausal patients ($P = 0.011$) compared to post-menopausal status. Increased use of mammography has led to increased diagnosis of patients in early stage, whereas increased use of bone scan in locally advanced breast cancer (LABC) patients has led to upstaging of such patients to stage IV ($P = 0.021$). The proportion of patients with either ER or PR positivity has declined over the decade compared to both ER and PR negativity ($P = 0.003$). There has been increased use of fluorescent in-situ hybridization test for Her2/neu 2+ tissues, which has led to increase in Her2/neu positivity, although not significant. Although the absolute number of patients undergoing Breast Conservative Surgery (BCS) still lags behind MRM, its percentage has significantly increased ($P < 0.001$). Similarly, although ACT was prescribed more often than NACT followed by ACT, the percentage of later has increased significantly ($P < 0.001$). Also, the chemotherapeutic regimens have changed drastically, with methotrexate becoming almost obsolete; and the use of AC→T increased significantly ($P < 0.001$). The proportion of patients receiving targeted therapy for Her2/neu has also increased over time. Now, more and more patients are opting for conformal radiotherapy over linear accelerator compared to conventional radiotherapy over telecobalt machine ($P = 0.007$). Although increased diagnoses of metastases has led to increased use of radiotherapy with palliative intent, but the trend is just at the border to be labelled as significant ($P = 0.051$). There has been increasing use of hypofractionated radiotherapy, but again the trend is not statistically significant.

Table 1 Baseline parameters of entire cohort of breast cancer patients

Parameters	Number (%) (n=1,432)
Age (years)	< 40 475 (33.2)
	> 40 957 (66.8)
Menstrual status	Mean (range) 50.18 (21 to 82)
	Premenopausal 559 (39)
	Postmenopausal 873 (61)
Histopathology	Ductal 1278 (89.2)
	Lobular 113 (7.9)
	Medullary 29 (2.1)
	Papillary 7 (0.5)
AJCC stage	Tubular 5 (0.3)
	I 102 (7.1)
	II 305 (21.3)
	III 753 (52.6)
Hormone receptor status	IV 272 (19)
	Either ER &/or PR + 428 (29.9)
	Both ER & PR - 779 (54.4)
Surgery	Unknown 225 (15.7)
	No Surgery 168 (11.7)
	Simple mastectomy 346 (24.2)
Chemotherapy	BCS 206(14.4)
	MRM 712 (49.7)
	Data not available 148 (10.3)
Chemotherapeutic regimen (n=1,284)	NACT→Adjuvant chemotherapy 396 (27.7)
	Adjuvant chemotherapy only 888 (62)
	CMF 114 (8.9)
Radiotherapy	CAF 352 (27.4)
	CEF 184 (14.3)
	AC→T 602 (46.9)
Radiotherapy technique	Trastuzumab 32 (2.5)
	Radical 1098 (76.7)
Dose fractionation (n=1,098)	Palliative 334(23.3)
	Cobalt teletherapy 969 (67.7)
Site of metastases (n=469)	Linear accelerator 463 (32.3)
	50 Gy/25 fractions 994 (90.5)
	42.7 Gy/16 fractions 104 (9.5)
	Brain 154 (32.8)
	Bone 180 (38.4)
	Liver 48 (10.2)
	Lung 69 (14.7)
	Other 18 (3.9)

+: positive, -: negative, AC→T: Doxorubicin-Cyclophosphamide→Taxane, AJCC: American Joint Committee on Cancer, BCS: Breast Conservative Surgery, CAF: Cyclophosphamide-Doxorubicin-5 fluorouracil, CEF: Cyclophosphamide-Epirubicin-5 fluorouracil, CMF: Cyclophosphamide-Methotrexate-5 fluorouracil, ER: Estrogen Receptor, MRM: Modified Radical Mastectomy, NACT: Neoadjuvant chemotherapy, PR: Progesterone Receptor

DISCUSSION

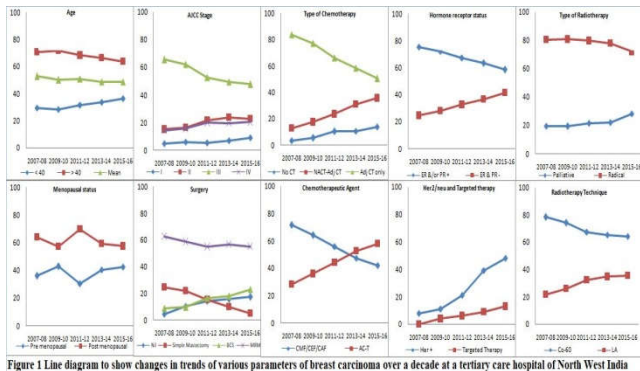
For more than half of the century, cervical cancer has ruled as the most common cancer among Indian women, breast cancer has now become dethroned it to grab the top most position. Kim, Yoo, & Goodman have shown that Asian countries now account for 40% of breast cancer cases diagnosed worldwide [5]. Breast cancer mortality has also increased among Asian women, in contrast to decreased mortality in Northern America, Western Europe, and Oceania. Agarwal *et al.* conducted a multi-national collaborative study to retrospectively compare the demographic, clinical, pathological and outcome data in breast cancer patients in India, Malaysia and Hong Kong [6]. Pathology of breast cancers in young Asian women and the clinical picture are different from those of average patients managed elsewhere in the world. They concluded that although rising, the incidence of breast cancer is lower in developing Asian countries compared with developed countries in Asia and the rest of the world, yet the cause-specific mortality is significantly higher. Patients are about one decade younger in developing countries, yet present with locally advanced stage, carrying poorer prognosis.

The present study represents a cohort of female breast cancer patients who were treated with radiotherapy at one of the largest tertiary care centre of India. A number of striking changes has been observed in all aspects of breast cancer over a decade (2007-2016)- epidemiology, diagnosis (radiology, and pathology), and management (surgery, chemotherapy, and radiotherapy). In fact, some of the findings were shocking, turning the table upside-down.

Table 2 Change in trends in various parameters over a decade in breast cancer patients

Parameters	2007/08	2009/10	2011/12	2013/14	2015/16	P- value
Age (years)						
< 40	41 (29.5)	47 (28.3)	86 (31.7)	134 (33.8)	167 (36.4)	0.064
> 40	98 (70.5)	119 (71.7)	185 (68.3)	263 (66.2)	292 (63.6)	
Mean	52.67	50.09	50.74	48.55	48.85	
Menopausal status						
Pre	50 (35.9)	71 (42.8)	82 (30.3)	161 (40.6)	195 (42.5)	0.011
Post	89 (64.1)	95 (57.2)	189 (69.7)	236 (59.4)	264 (57.5)	
AJCC Stage						
I	7 (5)	10 (6)	15 (5.5)	28 (7.1)	42 (9.2)	0.021
II	21 (15.1)	27 (16.3)	59 (21.8)	94 (23.7)	104 (22.7)	
III	91 (65.5)	103 (62.1)	143 (52.8)	197 (49.6)	219 (47.7)	
IV	20 (14.4)	26 (15.6)	54 (19.9)	78 (19.6)	94 (20.4)	
Hormone receptor status						
Either ER &/or PR +	83 (59.7)	98 (59)	151 (55.7)	213 (53.7)	234 (51)	0.003
Both ER & PR -	27 (19.4)	38 (22.9)	73 (27)	124 (31.2)	166 (36.2)	
Unknown	29 (20.9)	30 (18.1)	47 (17.3)	60 (15.1)	59 (12.8)	
Surgery						
None	6 (4.3)	17 (10.2)	38 (14)	62 (15.6)	79 (17.2)	< 0.001
Simple Mastectomy	34 (24.5)	36 (21.7)	41 (15.1)	39 (9.8)	23 (5)	
BCS	12 (8.6)	16 (9.6)	44 (16.2)	72 (18.1)	105 (22.9)	
MRM	87 (62.6)	97 (58.5)	148 (54.7)	224 (56.5)	252 (54.9)	
Chemotherapy						
None	5 (3.6)	9 (5.4)	28 (10.3)	42 (10.6)	64 (13.9)	< 0.001
NACT→Adjuvant	18 (12.9)	29 (17.5)	64 (23.6)	123 (31)	163 (35.6)	
Adjuvant only	116 (83.5)	128 (77.1)	179 (66.1)	232 (58.4)	232 (50.5)	
Chemotherapeutic agents						
CMF/CEF/CAF	96 (71.6)	98 (62.4)	132 (54.3)	164 (46.2)	160 (40.5)	< 0.001
AC→T	38 (28.4)	55 (35)	105 (43.2)	182 (51.3)	222 (56.2)	
Trastuzumab	0	4 (2.6)	6 (2.5)	9 (2.5)	13 (3.3)	
Adjuvant Radiotherapy						
Palliative	27 (19.4)	32 (19.3)	58 (21.4)	88 (22.2)	129 (28.1)	0.051
Radical	112 (80.6)	134 (80.7)	213 (79.6)	309 (77.8)	330 (71.9)	
Radiotherapy Technique						
Cobalt teletherapy	109 (78.4)	123 (74.1)	183 (67.5)	259 (65.2)	295 (64.3)	0.007
Linear accelerator	30 (21.6)	43 (25.9)	88 (32.5)	138 (34.8)	164 (35.7)	

+: positive, -: negative, AC→T: Doxorubicin-Cyclophosphamide→Taxane, AJCC: American Joint Committee on Cancer, BCS: Breast Conservative Surgery, CAF: Cyclophosphamide-Doxorubicin-5 fluorouracil, CEF: Cyclophosphamide-Epirubicin-5 fluorouracil, CMF: Cyclophosphamide-Methotrexate-5 fluorouracil, ER: Estrogen Receptor, MRM: Modified Radical Mastectomy, NACT: Neoadjuvant chemotherapy, PR: Progesterone Receptor



In the present study, a shift has been noted from older age to young age, post-menopausal to pre-menopausal status, and advanced stage to early stage at the time of diagnosis. Increasing trend has been noted in BCS compared to MRM, NACT→ACT compared to ACT alone, AC→T compared to CMF/CAF/CEF, Palliative radiotherapy, conformal radiotherapy, and hypofractionation. Shankar *et al.* compared various factors among breast cancer patients from 1997-98 to 2005-06 and concluded that more aggressive patterns of disease have become more common with early age ($P = 0.04$), pre-menopausal status ($P < 0.01$) and receptor negative tumours ($P < 0.01$) at presentation [7]. There was a significant increase in patients receiving neo-adjuvant chemotherapy ($P < 0.01$) and palliative treatment ($P < 0.01$). Chauhan *et al.* retrospectively analyzed the data of 112 breast cancer patients in a tertiary care hospital situated in coastal Karnataka in South India [8].

Mean age of the subjects was 45 years (range 23 -70). Age distribution showed two peaks at 35-39 years and 50-54 years. 61.5% patients had pre-menopausal status. Takalkar *et al.* reviewed records of 260 pathologically diagnosed patients of breast cancer managed at a tertiary care hospital in Marathwada region of Western India from years 2009 to 2015, and reported the mean age of presentation to be 52.6 years, with average age of menarche of 11.3 and menopause of 52.6 years [9]. The majority of patients were from urban regions and were postmenopausal (64.3%). Main clinical feature of presentation was lump in breast. Most common stage was stage II and most common histopathology was infiltrating ductal carcinoma. Saxena *et al.* analyzed data of 569 breast cancer patients during the years 1989-2003 [10]. Mean age of the patient at presentation was 47.8 years (range, 13-82 years). IDC was the commonest histology (88.2%), followed by ILC (3.7%). Stage IIIB (35.2%) was the commonest stage.

Similar trends have been reported from other Asian countries as well. Afsharfard *et al.* have retrospectively studied 714 Iranian breast cancer patients in four chronologic phases from 1994-2009, and found more aggressive disease for younger age groups, earlier peak incidence age and high rate of advanced breast cancer in 2009 compared to 1999 [11]. Overall, most of cases (33.2%) were in 41-50 age group; infiltrative ductal carcinoma (87.1%) was the most common histology, and MRM (48.8%) was the most common method of breast surgery. The most common stage was IIIA (27%). They

observed a significant decreasing trend in the mean lymph node count ($P < 0.05$) and blood vessel invasion ($P = 0.02$) from younger to older age groups. Tumor size decreased significantly during the period ($P < 0.05$). Memon *et al.* have studied breast cancer data in Pakistan and has concluded that Pakistan is the second country after Israel in Asia to have highest proportional cases of breast cancer [12]. A painless lump was the most frequent clinical presentation noted. Overall age at first child more than 20 years, physical breast trauma, lack of breast feeding, early menarche at less than 11 year of age were the most frequent risk factors. The Korean Breast Cancer Society (KBCS) has reported a nationwide breast cancer data since 1996 [13]. Min *et al.* collected data on 19,316 newly diagnosed breast cancer patients in the year 2013 from 99 hospitals by using nationwide questionnaire survey. The incidence rate of female breast cancer was 76.2 cases per 100,000 women. The median age at diagnosis was 50 years, and the proportions of postmenopausal women accounted for more than half of total patients. The proportion of early breast cancer increased consistently. Breast-conserving surgery was performed in more cases than total mastectomy in the year.

To conclude, most of the female breast cancer patients now present with young age before attaining menopause with hormone receptor negativity and Her2/neu positivity in early stage. There has been increased use of neoadjuvant chemotherapy followed by breast conservative surgery. Use of methotrexate is now obsolete and taxanes have become core chemotherapy. Patients now prefer advanced radiation technology over conventional one, and compliance to all form of treatment has improved. The dynamic trends in socio-demographic profile and management of breast cancer are likely to be the result of the increased breast cancer awareness, increased use of mammography and bone scan, increased skill in surgical aspects, development of newer chemotherapeutic agents and targeted therapies, and availability and accessibility to advanced radiotherapy technology.

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