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Trends in Epidemiology and Management of Breast Cancer in Women Under 46 Years: Institutional Experience from a Tertiary Cancer Centre in Eastern India

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ABSTRACT

Background: Breast cancer in younger women is a growing burden both in developed and Asian subcontinent. Despite studies showing varying results about the impact of age on treatment outcome and suboptimal survival, very few robust Indian studies have thrown light on this biologically different entity.
Methods: Histologically / cytologically confirmed cases of non-sarcomatous, female ductal breast carcinoma patients of age group less than and equal to 45 years of all stages attending radiotherapy department of R.G Kar Medical College between January 2016-December 2018 were included in the study. Relevant information was obtained from patient`s files/case records. Database was locked on 31st March 2021.The baseline demographic profile, cancer subsites along with treatment provided were analysed using SPSS version 16 (IBM Inc, Armonk, New York, U.S.). Descriptive data are provided.
Results: Total 272 patients were eligible for the study as per the inclusion criteria with median age of 39 years (22-45 years). Majority were urban married Hindu females. Majority were locally advanced and node positive high grade disease as per AJCC 7th staging system. Modified radical mastectomy was significantly higher than breast conservation surgery as the surgical modality (76 vs. 8.9%). 31.2%, 54.5% patients received neoadjuvant and adjuvant chemotherapy respectively.61% patients received curative intent radiotherapy either in conventional or hypofractionated schedule. Myelosuppression and oral mucositis were the major treatment related adverse events. Overall median PFS was 48 months.
Conclusion: Breast cancer in younger age group is distinct in terms of disease biology. Effective screening and diagnostics modalities with focus on mass awareness amongst patients and health care workers are the cornerstone of improving outcome and survival.

Key Words: breast cancer, young females, retrospective single institutional study

INTRODUCTION

Invasive breast cancer in females is a growing health concern both in developed and developing countries across the world in terms of incidence and mortality. According to Globocan 2020 statistics around 2.2 million new cases of breast cancer have been diagnosed worldwide in 2020 making it the commonest malignancy in females ahead of lung and cervical malignancies with an estimated cancer death rate of 6.9% amongst all cancers [1]. Breast cancer is the leading cause (26.3%) of total cancer burden in Indian females with significant mortality rate [2]. Classically more common in postmenopausal women, there has been an age shift globally affecting a significant

proportion of women in their 30s and 40s. According to SEER approximately 5.6% of all invasive breast cancers occur in adolescents and young adults in US with some Asian countries even showing a higher propensity of young age group predilection compared to the western world due to multifactorial etiologies [3]. Studies from the central and northern part of our country have shown about 8% incidence of breast cancer in women below 35 years of age which is bit higher in comparison to the developed countries [4]. However very few studies are available from eastern India which has looked at the epidemiological trends and variations of young adult women with breast cancer which demands more research on this alarming entity.

Higher grade tumours, less ER expression, Her 2 overexpression, advanced stage of presentation, higher node positive disease has shown that breast cancer in earlier age of onset is certainly biologically aggressive and difficult to tackle [5]. Over the decades there has been a long debate whether age as an independent prognostic factor with studies showing varying results across the globe. Pregnancy, lactation, fertility issues, lack of awareness have always been the additional crucial variables in the management that have puzzled the clinicians more in compared to postmenopausal elderly cohort [6]. Malvia et al. in their recent study showed that 5% of breast cancer cases in India have inherited familial factors and approximately 2.9% of early onset breast cancer patients in India were found to have BRCA1/2 mutations [7]. Role of alcohol intake and obesity as risk factors in young adults are also less clear in contrast to the post-menopausal group that makes it a unique biological entity [8]. Data of breast cancer among young population especially from eastern part of India is lacking and our retrospective study is an attempt to identify the demographic profile, treatment and survival parameters in this population.

METHODS

Epidemiological data, treatment particulars and survival analysis were done for histologically/cytologically confirmed cases of non-sarcomatous, female ductal breast carcinoma patients of age group less than and equal to 45 years of all stages attending radiotherapy department of R.G Kar Medical College between January 2016-December 2018 in retrospective manner. Relevant information obtained from patient`s files/case records. Database was locked on 31st March 2021. Chi-square test for categorical variables and t test for non-categorical variables were used for comparisons. SPSS version 21(IBM Inc. Armonk, New York, USA) used for statistical derivation [10]. CTCAE v 4.03 scale was used for toxicity analysis [11]. For Calculating PFS (progression free survival) Kaplan-Maier survival plot was used [12]. PFS was defined as the time from date of diagnosis to tumour progression (local/regional/systemic). Median follow up time was calculated using reverse Kaplan Meier analysis. P value less than or equal to 0.05 was considered to be significant.

RESULTS

Total 272 patients were eligible for the study as per the inclusion criteria with median age of 39 years (22-45 years). The median follow up was 24 months for entire study population using reverse Kaplan Meier survival technique. Majority of the population were married urban females with good performance status and without significant family history as shown in table no 1.

Majority of the patients (50.9%) presented with stage 3 disease as per AJCC 7th staging system with 17.1% of the patients being upfront metastatic (bone mets most common). Nodal positivity rate was comparable across 3 years and was about 4 times than node negative disease as depicted in table no 2.

Table: 1 Demographic parameters of the study population

Parameters		Year						P VALUE
		2016 (N=77)		2017 (N=91)		2018 (N=104)		
		Count	Column N %	Count	Column N %	Count	Column N %	
Age in years	*Mean*	38.48		37.68		38.08		0.593
	Median	40.00		39.00		39.00		
	S.D	5.330		5.140		4.737		
	Minimum	22		27		25		
	Maximum	45		45		45		
Menarche in years	*Mean*	13.45		13.68		13.77		0.387
	Median	13.00		14.00		14.00		
	S.D	1.518		1.673		1.429		
	Minimum	10		10		11		
	Maximum	17		17		17		
ECOG Performance Status	*1*	53	68.8%	60	65.9%	64	61.5%	0.594
	2	15	19.5%	24	26.4%	24	23.1%	
	3	8	10.4%	6	6.6%	12	11.5%	
	4	1	1.3%	1	1.1%	4	3.8%	
Residence	*Urban*	40	51.9%	45	49.5%	59	56.7%	0.584
	Rural	37	48.1%	46	50.5%	45	43.3%	
Martial_status	*Married*	71	92.2%	85	93.4%	94	90.4%	0.738
	Unmarried	6	7.8%	6	6.6%	10	9.6%	
Parity	*Multipara*	62	80.5%	75	82.4%	79	76.0%	0.517
	Nulliparous	15	19.5%	16	17.6%	25	24.0%	
OCP	*Yes*	28	36.4%	33	36.3%	39	37.5%	0.981
	No	49	63.6%	58	63.7%	65	62.5%	
Family history	*0*	77	100.0%	88	96.7%	101	97.1%	0.292
	1	0	0.0%	3	3.3%	3	2.9%	
Second Malignancy	*0*	77	100.0%	91	100.0%	104	100.0%	NA

Table 2. TNM characteristics of the study population

TNM PARAMETERS		Year						P VALUE
		2016		2017		2018		
		Count	Column N %	Count	Column N %	Count	Column N %	
T	T1	4	5.2%	8	8.8%	4	3.8%	0.880
	T2	29	37.7%	36	39.6%	36	34.6%	
	T3	24	31.2%	22	24.2%	37	35.6%	
	T4B	10	13.0%	13	14.3%	15	14.4%	
	T4C	9	11.7%	10	11.0%	11	10.6%	
	T4D	1	1.3%	2	2.2%	1	1.0%	
N	N0	15	19.5%	20	22.0%	23	22.1%	0.994
	N1	29	37.7%	31	34.1%	38	36.5%	
	N2	17	22.1%	22	24.2%	21	20.2%	
	N3	16	20.8%	18	19.8%	22	21.2%	
M	M1	12	15.6%	15	16.5%	20	19.2%	0.790
	MO	65	84.4%	76	83.5%	84	80.8%	
TNM stage*	1A	2	2.6%	4	4.4%	2	1.9%	0.996
	2A	8	10.4%	11	12.1%	11	10.6%	
	2B	14	18.2%	17	18.7%	18	17.3%	
	3A	18	23.4%	19	20.9%	20	19.2%	
	3B	10	13.0%	13	14.3%	14	13.5%	
	3C	13	16.9%	12	13.2%	19	18.3%	
	4	12	15.6%	15	16.5%	20	19.2%	

**AJCC TNM STAGING 7th edition was used for group staging.*

32%, 30% and 25% cases were the proportion of triple negative disease from 2016-18 respectively with 40% presenting with grade 3 disease as per Bloom-Richardson grading system(table no 3). Her 2 positivity rate showed a rising trend as years progressed with more patients proceeding to costlier tests like FISH for Her-2-neu score 2 in IHC.

As for treatment a total of 85 patients (31.2%) received neo-adjuvant chemotherapy, median number of cycles was 4(3-6) with TAC (Docetaxel, Doxorubicin, Cyclophosphamide) being the most common regimen used followed by FEC (5 FU, Epirubicin, Cyclophospha-mide). An average of 54.5% patients received adjuvant chemotherapy with TAC being the most common regimen used. Modified radical mastectomy was by far the commonest surgical approach in comparison to breast conservation surgery in our study

population (76 vs. 8.9%). 61% of the total population received curative intent radiation therapy with conventional fractionation (50 Gy /25 fractions) being the most used fractionation schedule (33.3%). 17.2% patients received palliative chemotherapy for metastatic disease. 8.4% of total study population received palliative radiotherapy for bone metastasis with 76.9% of all bone mets patients receiving oral or intravenous bisphosphonates (oral Ibandronate / i.v Zoledronic acid)(table 4). 41.% and 7.7% were treated with Tamoxifen and aromatase inhibitor respectively for hormone positive disease. 33 % of patients of all Her 2 positive disease received desired dose of Trastuzumab as per protocol(table 5).

Table 3. Tumour characteristics

Parameters		Year						P value
		2016		2017		2018		
		Count	Column N %	Count	Column N %	Count	Column N %	
ER	NEG	33	42.9%	43	47.3%	45	43.3%	0.808
	POS	44	57.1%	48	52.7%	59	56.7%	
PR	NEG	47	61.0%	54	59.3%	61	58.7%	0.948
	POS	30	39.0%	37	40.7%	43	41.3%	
HER 2 neu	EQUI	1	1.3%	4	4.4%	3	2.9%	0.415
	NEG	60	77.9%	64	70.3%	69	66.3%	
	POS	16	20.8%	23	25.3%	32	30.8%	
Grade	1	12	15.6%	14	15.4%	16	15.4%	0.995
	2	34	44.2%	42	46.2%	45	43.3%	
	3	31	40.3%	35	38.5%	43	41.3%	
Margin	0**	5	6.5%	6	6.6%	8	7.7%	0.973
	NEG	52	67.5%	62	68.1%	73	70.2%	
	POS	20	26.0%	23	25.3%	23	22.1%	
LVSI	NEG	45	58.4%	47	51.6%	59	56.7%	0.644
	POS	32	41.6%	44	48.4%	45	43.3%	
Site	Left	43	55.8%	50	54.9%	57	54.8%	0.989
	Right	34	44.2%	41	45.1%	47	45.2%	
Quadrant	Upper Outer	45	58.4%	43	47.3%	51	49.0%	0.236
	Lower Outer	14	18.2%	25	27.5%	26	25.0%	
	Lower Inner	9	11.7%	12	13.2%	12	11.5%	
	Upper Inner	4	5.2%	11	12.1%	10	9.6%	
	Central / NAC	5	6.5%	0	0.0%	5	4.8%	

***Only biopsy was done from primary lesion*
**Ki-67 was done in only 30% of patients and was >14% in 80% of these individuals. Because of paucity of data, Ki-67 was omitted during analysis.*

Table 4. Adjuvant chemotherapy in non-metastatic patients

ACT DRUGS	Year						P VALUE
	2016		2017		2018		
	Count	Column N %	Count	Column N %	Count	Column N %	
No adjuvant	30	46.2%	34	44.7%	38	45.2%	0.972
AC	2	3.1%	2	2.6%	4	4.8%	
AC,T	3	4.6%	4	5.3%	2	2.4%	
FAC	3	4.6%	4	5.3%	2	2.4%	
FAC,T	1	1.5%	1	1.3%	2	2.4%	
FEC	2	3.1%	1	1.3%	3	3.6%	
FEC,T	2	3.1%	1	1.3%	1	1.2%	
GEM,DOCE	0	.0%	1	1.3%	1	1.2%	
T	8	12.3%	15	19.7%	10	11.9%	
TAC	14	21.5%	13	17.1%	21	25.0%	

Doxorubicin, C – Cyclophosphamide, T / Doce – Docetaxel, F – 5Fluorouracil , E – Epirubicin, Gem - Gemcitabine

Table 5. Hormonal therapy & targeted therapy

Treatment			Year						P value
			2016		2017		2018		
			Count	Column N %	Count	Column N %	Count	Column N %	
Hormone Therapy	Anastrazole		0	.0%	0	.0%	1	1.0%	0.312
	Letrozole		2	2.6%	2	2.2%	2	1.9%	
	NO hormone therapy		49	63.6%	48	52.7%	51	49.0%	
	Tamoxifen (TMX)		24	31.2%	40	44.0%	50	48.1%	
	TMX, Anastrazole		2	2.6%	1	1.1%	0	.0%	
HER 2 neu positive	TRASTUZUMAB	Yes	6	37.5%	8	34.8%	8	25.0%	0.604
		No	10	62.5%	15	65.2%	24	75.0%	

Table 6. Adverse events during treatment

Different parameters.		Year						P value
		2016		2017		2018		
		Count	Column N %	Count	Column N %	Count	Column N %	
Skin_all_grades**	No	67	87.0%	79	86.8%	84	80.8%	0.396
	Yes	10	13.0%	12	13.2%	20	19.2%	
Skin_G3**	No	75	97.4%	86	94.5%	102	98.1%	0.349
	Yes	2	2.6%	5	5.5%	2	1.9%	
Lymphedema**	No	62	80.5%	75	82.4%	81	77.9%	0.728
	Yes	15	19.5%	16	17.6%	23	22.1%	
Mucositis_all_grades	No	55	71.4%	63	69.2%	75	72.1%	0.901
	Yes	22	28.6%	28	30.8%	29	27.9%	
Mucositis_G3	No	70	90.9%	81	89.0%	94	90.4%	0.911
	Yes	7	9.1%	10	11.0%	10	9.6%	
Anemia_all_grades	No	51	66.2%	58	63.7%	71	68.3%	0.800
	Yes	26	33.8%	33	36.3%	33	31.7%	
Anemia_G3	No	69	89.6%	82	90.1%	93	89.4%	0.987
	Yes	8	10.4%	9	9.9%	11	10.6%	
Neutropenia_all_ grades	No	50	64.9%	59	64.8%	69	66.3%	0.970
	Yes	27	35.1%	32	35.2%	35	33.7%	
Neutropenia_G3	No	52	67.5%	62	68.1%	73	70.2%	0.919
	Yes	25	32.5%	29	31.9%	31	29.8%	
Thrombocytopenia_all_grades	No	66	85.7%	78	85.7%	90	86.5%	0.982
	Yes	11	14.3%	13	14.3%	14	13.5%	
Thrombocytopenia_G3	No	63	81.8%	74	81.3%	83	79.8%	0.936
	Yes	14	18.2%	17	18.7%	21	20.2%	
Myalgia_all_grades	No	48	62.3%	58	63.7%	68	65.4%	0.913
	Yes	29	37.7%	33	36.3%	36	34.6%	
Myalgia_G3	No	65	84.4%	82	90.1%	90	86.5%	0.533
	Yes	12	15.6%	9	9.9%	14	13.5%	

***Skin and Lymphedema – radiation induced adverse event. The parameters were due to chemotherapy induced.*

Table 7a. Case Processing Summary for Progression Free Survival analysis.

Year	Total N	N of Events	Censored	
			N	Percent
2016	77	19	58	75.3%
2017	91	25	66	72.5%
2018	104	25	79	76.0%
Overall	272	69	203	74.6%

Table 7b. Means and Medians for Survival Time

Year	Mean[a]				Median			
	Estimate	Std. Error	95% Confidence Interval		Estimate	Std. Error	95% Confidence Interval	
			Lower Bound	Upper Bound			Lower Bound	Upper Bound
2016	46.754	2.656	41.549	51.959	57.000	6.537	44.188	69.812
2017	39.740	1.656	36.495	42.985	46.000	1.512	43.037	48.963
2018	29.499	1.185	27.175	31.822	36.000	4.183	27.802	44.198
Overall	42.931	1.583	39.829	46.034	48.000	2.763	42.584	53.416

a. Estimation is limited to the largest survival time if it is censored.

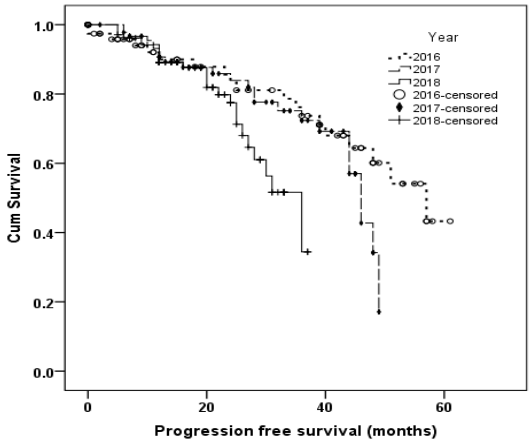

Figure 1. Progression free survival analysis comparison among patients according to year wise recruitment with Log Rank test – Chi Square 6.401, df 2, p value 0.041.

Amongst all, 31.4% and 19% patients developed grade 3 neutropenia and thrombocytopenia respectively during treatment. Around 10% of the patients developed grade 3 oral mucositis during chemotherapy/radiation. Skin toxicities, lymphedema of the arm are the different non haematological toxicities encountered during and after the treatment as detailed below in table no.6.

Total 69 patients (25.3%) experienced an event either in form of local/regional or systemic progression or death. The Progression Free Survival were 57, 46 and 36 months respectively for

patients recruited in 2016, 2017 and 2018, with significant log rank test, p value 0.041. (table 7 and figure 1). Overall median progression free survival for the study population was 48 months as shown in the KM survival plot.

DISCUSSION

Breast cancer in females has shown a clear age shift both in developed and Asian population in past few years posing a threat to younger adults. Earlier studies published from different parts of our country showed incidence of 5-8% of breast cancer cases in women <35 years age group with a mean age of diagnosis ranging from 45-50 years. Sofi N et.al in their study from central India showed approximately 49% of the cases being diagnosed under 45 years of age [9]. Thangjam et.al.in their study from Manipur showed that 31% of all breast cancer cases were diagnosed below 40 years of age which is more or less in line with our study where 30.3% of all breast cases were diagnosed in less than 45 years age group [10]. However it is somewhat lower in percentage to other available evidences may be due to more attrition of patients owing to several socioeconomic factors [11].

As similar to previous data, breast cancer in our study was commoner in urban females (52.7%) as compared to rural though not statistically significant [12]. Disease was more common in married multiparous women which may be linked to earlier age of marriage and lack of proper contraception practices (36.7% users of oral contraceptive pills).

Stage III infiltrating ductal carcinoma was the commonest presenting stage in our study which resembles earlier published studies like Das et.al [13]. Nodal positivity rate in our patients were higher than some earlier published studies based on young age breast malignancy may be due to late stage of presentation due to lack of health awareness and education [14]. Percentage of patients presenting with triple negative disease and high grade tumours was comparable with some other Indian studies published earlier [15].

There was a striking difference between modified radical mastectomy and breast conservation surgery found in our studies that was in contrast to most international and even some national studies which reflected the need for more focus on breast cancer screening to pick up early operable and large operable disease as well as to popularize the practice of doing BCS in our setting [16].

Regarding adherence to treatment regarding chemotherapy, radiation therapy, targeted therapy the findings in our study reflected the real time situation due to logistics issue and multiple factors like distance from treatment centre, poverty, lack of health knowledge amongst patients and caregivers which was in contrast with the western world data that demonstrated better compliance and survival [17].

Regarding survival data, 74.7% of patients were disease free in our study till last follow up which was more or less similar to the results found from Saudi Arabia and higher as compared to Egyptian data on young women having breast cancer [18]. However with varying patient characteristics, sample size and follow up period wide range of PFS data have been found in different studies that makes any direct comparison difficult.

We accept our study had its limitations in form of being single institutional, having low sample size, more attrition and being retrospective. However large prospective studies on this topic are needed for further knowledge and intervention.

CONCLUSION

Breast cancer in younger women is a distinct and growing entity which calls for effective screening programme and timely diagnosis along with improved health care resource and practices to optimize the outcome.

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