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CLINICO-EPIDEMIOLOGICAL PROFILE AND TREATMENT OUTCOME OF BREAST CARCINOMA - A RETROSPECTIVE STUDY FROM A TERTIARY CANCER CENTRE OF NORTH-EAST INDIA.

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ABSTRACT **Objective:** This study was undertaken to know the clinico-epidemiological profile and outcome of breast carcinoma in North-East Indian population. **Methods:** A retrospective analysis was performed on medical records of patients with breast carcinoma, diagnosed, treated and followed up in the Department of Medical Oncology, Dr. B. Borooah Cancer Institute during January 2020 to December 2021. **Results:** A total of 1500 patients were evaluated with median age of 47.6 years. Out of 1197 histopathologically proven patients with breast carcinoma, 29.5% patients presented in early stage, 44% presented in locally advanced stage and 25.9% presented with de-novo metastasis. Among all 36.7% were hormone receptor (HR) positive while 18.9% patients were HER2-enriched, 27% were triple negative and 17% patients expressed both HR and HER2. Doxorubicin-cyclophosphamide followed by Taxane was the most common regimen used in curative intent. Pathological CR rate was 27.5%. Early recurrence was high in TNBC and HER2-enriched subgroup. Among the patients presented with de-novo metastasis liver was the most common organ involved in HER2-enriched group while it was bone in other subtypes. The most common chemotherapy regimen used in palliative intent was taxane +/- trastuzumab, followed by 5-flourouracil-epirubicin-cyclophposphamide. The survival rate at 6-months, 1-year, 2-years and 3-years are 92%, 82%, 87.9%, 41.5% respectively for TNBC subset; 92%, 79.6%, 64.8%, 36.7% respectively for HER2-enriched; 93%, 86.4%, 79.48%, 55.4% respectively for HR positive subgroup; and 93.9%, 85.2%, 78.2%, 48.7% respectively for those expressing both HR and HER2. **Conclusion:** Advanced stage of presentation is the most important factor associated with poor survival amongst the patients with breast cancer. Although several novel therapeutic agents have shown promising results in clinical trials, many patients from developing countries like India are not able to avail the benefit from these therapeutic agents due to high cost, resulting poor outcome in HER2-enriched and TNBC subtypes.

KEYWORDS : Breast carcinoma, TNBC, HR+, HER2+ve, survival

INTRODUCTION

According to the GLOBOCAN 2020 report, breast cancer with estimated 2.3 million new cases (11.7%) is the most common cancer of world. [1] Among women, breast cancer accounts for 1 in 4 cancer cases and for 1 in 6 cancer deaths, ranking first for incidence in the vast majority of countries (159 of 185 countries) and for mortality in 110 countries. However, in India Breast cancer incidence is 14% in both sex groups. [1]

Globally, breast cancer was responsible for 684,996 deaths [95% UI, 675,493–694,633] at an age-adjusted rate of 13.6/100,000.[2] Although incidence rates were the highest in developed regions, the countries in Asia and Africa shared 63% of total deaths in 2020.[3]

Kulkarni et al in their systematic review and meta-analysis of 34 studies showed that breast cancer is the most common cancer in India, with the highest numbers of new cancer incidence per year (14%) and with a high incidence-to-mortality ratio (approximately 50%) .[4] In India, the incidence has increased significantly, almost by 50%, between 1965 and 1985.[5] Current trends point out that a higher proportion of the disease is occurring at a younger age in Indian women, as compared to the West.[6]

Management of breast cancer is multidisciplinary and has come a long way. It includes a loco-regional approach (targeting only the tumour with the help of surgery and radiation therapy) and a systemic therapy. The systemic therapy includes endocrine therapy for hormone receptor-positive disease, chemotherapy, anti-HER2 therapy for HER2 positive disease, bone stabilising agents, polymerase inhibitors for BRCA (breast cancer gene) mutation carriers and, recently, immunotherapy.[7]

Despite the greater effectiveness of initial diagnostics or the rapid development of pharmacotherapy in recent years, breast cancer is the first cause of death from malignant tumors in women in the world. The survival rate of patients with breast cancer is poor in India as compared to Western countries due to earlier age at onset, late stage of disease at presentation, delayed initiation of definitive management and inadequate/fragmented treatment.[8]

This study has been undertaken to know the epidemiological profile and treatment outcome of breast cancer in North East India. This study will help to generate more data on breast cancer for future reference.

MATERIAL AND METHODS

A retrospective observational descriptive single institutional study was done to study the clinico-epidemiological pattern and treatment outcome in patients with breast carcinoma in North-East Indian population. Patients ≥18 years of age, histopathologically proven case of breast carcinoma, registered, treated and followed up at Dr. B. Borooah Cancer Institute from January 2020 to December 2021 were included in this study.

Data Collection and Follow Up

Data were collected retrospectively from hospital-based cancer registries, individual medical case notes, electronic patient records and pathology reports, including age, gender, performance status, history of any medical risk factors, symptom burden, stage and distant metastatic sites.

A detailed retrospective chart review was performed to document staging, treatment history, follow-up, and survival outcome. Details of the treatment received i.e. date and time of surgery, chemotherapy (CT)/ radiotherapy (RT)/hormone therapy, time of 1st recurrence or progression and the type of treatment noted. For the patients who were treated with curative intent, pathological complete response (pCR) rate was used to assess response to neoadjuvant treatment. Standard criteria were used to assess radiological response to treatment as complete response (CR), partial response (PR), progressive disease (PD) and no response (NR) for the patients treated with palliative intent.

Survival status was determined from the date of registration for each patient at BBCI. The overall survival (OS) was defined as the time from the date of registration to the date of death or date of last follow-up. Those patients whose data was not available in the records were

contacted over phone. For the patients where survival information was not obtained, the interval between the date of diagnosis and the date of last follow up was used to calculate survival duration. Those patients who received at least 3 chemotherapy cycles were taken up for survival analysis. The recurrence free survival (RFS) was calculated for the patients treated with curative intent and it was determined from the date of surgery to the date of 1st diagnosis of recurrence. Progression free survival (PFS) was assessed from the date of completion of 1st line chemotherapy to the 1st progression or deterioration of the disease in the patients treated with palliative intent.

Statistical Analysis

Descriptive statistics was used to describe the numbers and percentages, bar and pie charts were used for graphical representation of the descriptive statistics. Patient and demographic features were summarized using median/centiles, means and standard deviations. Kaplan Meier analysis was used for survival analysis and log rank test was used to see the survival difference among groups. Overall survival (OS) was considered as the length of time from either the date of diagnosis to the date of last follow-up or death. Patients who had no follow-up visit for over 1 year and could not be reached by telephonic communication were considered as lost to follow-up.

RESULTS

A total of 1500 patients were analysed in our study. Among them 1197 were histo-pathologically proven breast cancer patients. The most common age group affected was 40-50 years with the median age of 47.6 years (Figure 1). Only 11 patients were male, rest all are female. The TNM AJCC 8th edition guidelines were used for staging. The details regarding the stage were found in 731 patients, out of which 216 patients presented in early stage, 325 patients presented in locally advanced stage and 190 patients presented with de-novo metastasis as shown in Table 1. The details about the receptor status were found in 844 patients. The distribution of the subtypes based on receptor status is as follows: HR+ve /HER-ve 36.7%, HR+ve/HER2+ve 17%, TNBC 27.2% and HER2-enriched 18.9 % respectively (Table 2). Overall, 53.7 % patients were HR+ve and 35.9% patients were HER 2+ve.

Table 1: Details of stage

Stage	n=731	%
Early	216	29.5
LABC	325	44.4
De-novo metastasis	190	25.9

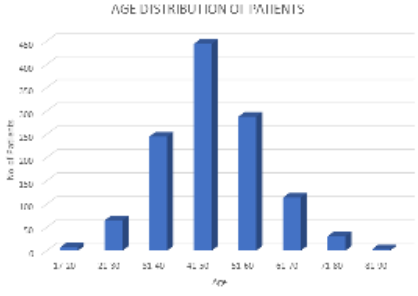

Figure 1: Age distribution

Table 2: Details of receptor status

N= 844	HR positive		TNBC	HER2-enriched	Receptor status not known	HR positive (overall)	HER2+ve (overall)
	HER2-ve	HER2+ve					
Early	85	33	60	26	12	-	-
LABC	103	55	92	61	14	-	-
De-novo metastatic	49	36	41	47	17	-	-
Details of stage not known	73	20	37	26	-	-	-
Total	310	144	230	160	-	-	-
Percentage	36.7 %	17%	27.2%	18.9%		53.7%	35.9 %

The details about the pathological subtype were found in 656 patients. The distribution of the pathological subtype is shown in Table 3. Majority of the patients (93%) diagnosed with infiltrating ductal carcinoma (IDC) while only 1.9% diagnosed as infiltrating lobular carcinoma (ILC). Among the with patients IDC 350/614 (57%) had grade II and 262/614 (42.6%) patients had grade III carcinoma.

Table 3: Pathological subtype

Pathological types	Grade of tumour	n=656	%
IDC	I	2	93
	II	350	
	III	262	
Mucinous	II	9	1.6
	III	2	
Metaplastic		11	1.6
Solid papillary		6	0.9
Lobular		13	1.9
Medullary		1	0.01

Out of 1197 patients 534 patients were treated with curative intent and 190 patients were treated with palliative intent. A large no of patients (401/1197; 33%) defaulted during initial work up and 72/1197 patients received initial treatment in different health care facility and came to BBCI for subsequent treatment or follow up, so these patients were excluded from the final analysis. Among the patients who received treatment at BBCI, 72.9% patients received minimum no. of 3 chemotherapy cycles. A total no. of 272/534 patients received neoadjuvant chemotherapy and 211/534 patients received adjuvant chemotherapy. The most common chemotherapy regimen received in neoadjuvant and adjuvant setting is doxorubicin-cyclophosphamide followed by taxane +/- trastuzumab (4AC-4T+/-H). The details of surgery were found in 400 patients. Modified radical mastectomy (MRM) was done in 73% patients while breast conservative surgery (BCS) was done in 26.2% patients as shown in Table 4.

Table 4: Details of surgery

	n=400	%
MRM	292	73
BCS	105	26.2
Toilet mastectomy	3	0.75

Among the patients who received neoadjuvant chemotherapy pathological complete response (pCR) was assessed in those patients who had undergone surgery (218/272) and observed rate was 27.5% (60/218). The distribution of the subtypes of the patients attaining pCR is shown in Table 5.

Table 5: The pathological CR rates of different subtypes

Subtypes	n=218	%
HR+ve/HER2-ve	14/71	19.7
HR+ve/HER2+ve	11/31	35.4
TNBC	21/51	41
HER2-enriched	14/31	45

After a median follow up of 42 months, out of 534 patients who were treated with curative intent, total 81 patients had disease recurrence. Nine patients presented with only local recurrence while 16 patients presented with local along with distant metastasis and 56 patients presented with distant metastasis only. The most common distant organ involved was bone (27/81), followed by lung (24/81) and liver (16/81) as shown in Table 6.

Table 6: Details of sites involved in recurrence

Site	n=81	%
Local/chest wall alone	9	11.1
Local with distant recurrence	16	19.7
Lung	24	29.6
Liver	16	19.7
Brain	9	11,1
Bone	27	33.3
SCLN	7	8.6
Axillary lymph node	10	12.3
Mediastinal lymph node	11	13.5
Abdominal lymph node	9	11
Pleural effusion	13	16
Pericardial effusion	2	2.4
Ascites	2	2.4

The recurrence free survival rate at 6-month, 1-year, 2-years and 3-years are 90.63%, 84.38%, 65.63% and 31.25% respectively for the HER2-enriched; 91.13%, 77.42%, 65.32% and 33.06% respectively for the TNBC; 94.62%, 84.62%, 76.15% and 36.15% respectively for

the HR+ve subtype; and 98.46%, 98.46%, 83.08% and 29.23% respectively for patients with both HR+/HER2+ve (p=0.04) as shown in Table 7 and Figure 2.

Table 7: Recurrence free survival rate of the patients treated with curative intent

Time	HR+ve/HER2-ve	HR+ve/HER2+ve	HER2-enriched	TNBC	p=0.04
6 month	94.62	98.46	90.63	91.13	
1-year	84.62	98.46	84.38	77.42	
2-years	76.15	83.08	65.63	65.32	
3-years	36.15	29.23	31.25	33.06	

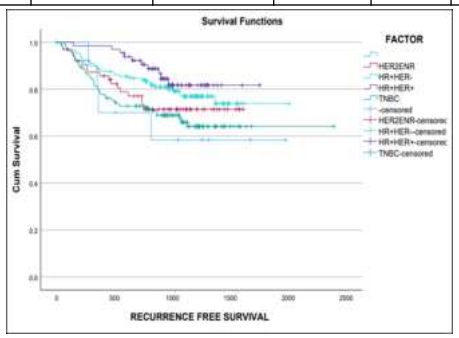

Figure 2: Recurrence free survival of the patients treated with curative intent

Patients presented with de novo metastasis-

Out of total 731 patients, 190 presented with de-novo metastasis. The distribution of different organs involved during initial presentation is shown in Table 8.

Table 8: Details of organ of involvement in de-novo metastasis

Site of involvement	n=190	Percentage
Liver	50	26.3
Lung	51	26.8
Bone	92	48.4
Brain	8	4.2
Axillary lymphadenopathy	30	15.7
Mediastinal lymphadenopathy	7	3.6
Supraclavicular lymphadenopathy	6	3.1
Abdominal lymphadenopathy	7	3.6
Ascites	2	1.05
Pleural effusion	16	8.4
Pericardial effusion	2	1.05
Spleen	2	1.05
Ovary	2	1.05
Adrenal	2	1.05

The distribution of distant site of involvement according to the molecular subtype is shown in Table 9. Overall, bone (48.4%) was the most common distant site of involvement, whereas liver and lungs are the common sites in HER2-enriched subtype. A few patients presented with metastasis to adrenal, spleen and ovary.

Table 9: Organ of involvement according to the receptor status

Molecular subtype	n=190	Most common distant site of involvement		
HR+ve/HER2-ve	49	Bone (35/49)	Liver (8/49)	Lung (6/49)
HR+ve/HER2+ve	35	Bone (16/35)	Lung (10/47)	Liver (10/47)
TNBC	41	Bone (14/41)	Lung (9/41)	Liver (6/41)
HER2-enriched	47	Liver (20/47)	Lung (20/47)	Bone (19/47)

The most common chemotherapy regimen used in palliative intent was taxane+/-trastuzumab followed by fluorouracil-epirubicin-cyclophosphamide (FEC). Total 115 patients out of 190, received 1st-line palliative chemotherapy and 46 patients out of 115 received 2nd-line chemotherapy while 10/46 patients received 3rd-line palliative chemotherapy. The most common chemotherapy regimen used in 2nd-line was lapatinib plus capecitabine (22/46). Among 115 patients receiving 1st-line palliative chemotherapy, details regarding response to chemotherapy was found in 74 patients. As shown in Table 10, the best response observed was partial response (PR) which was seen in 35 patients (n=35/74), followed by sTable disease (SD) in 24 (n=24/74) patients. The overall response rate (ORR) was found to be 52.7%.

Table 10: Response to chemotherapy in palliative setting

Response	n=74	%
CR	4	5.4
PR	35	47.2
SD	24	32.4
PD	11	14.8

The patients who received at least 3 cycles of chemotherapy were taken for survival analysis. After a median follow up period of 42 months it was observed that the survival rates at 6-months, 1-year, 2-years and 3-years were 97.5%, 93%, 88.5% and 62.6% respectively for the early-stage disease; 92.5%, 83.6%, 74.8% and 46.1% respectively for the locally advanced disease; and 85.8%, 68.7%, 46.8% and 21.2% respectively for the metastatic disease (as shown in Table 11 and Figure 3). The survival rates at 6-months,1-year, 2-years and 3-years are 92%, 82%, 87.9% and 41.5% respectively for TNBC; 92 %, 79.6%, 64.8% and 36.7% respectively for HER2-enriched group; 93%, 86.4%, 79.4.8% and 55.4% respectively for HR+ve subgroup, 93.9%, 85.2%, 78.2% and 48.7% respectively for HR+ve/HER2+ve subgroup (p=<0.001) (shown in Table 12 and Figure 4).

Table 11: The stage wise distribution of survival rates for all the patients

Time	Early stage	LABC	Metastatic	p =<0.001
6-months	97.5	92.5	85.8	
1-year	93	83.6	68.7	
2-years	88.5	74.8	46.8	
3-years	62.6	46.1	21.2	

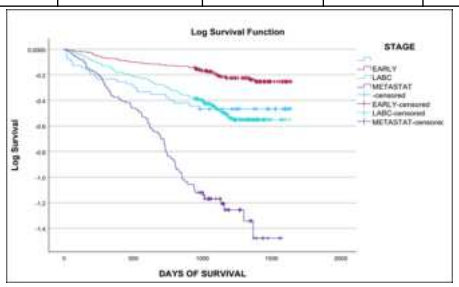

Figure 3: Overall survival of the patients according to the clinical stage

Table 12: The distribution of the survival rates of the patients according to the receptor status

Time	HR+ve/HER2-ve	HR+ve/HER2+ve	HER2-enriched	TNBC	p= 0.003
6-months	93.01	93.91	92.19	92.13	
1-year	86.46	85.22	79.6	82.02	
2-years	79.48	78.26	64.8	67.98	
3-years	55.46	48.7	36.7	41.57	

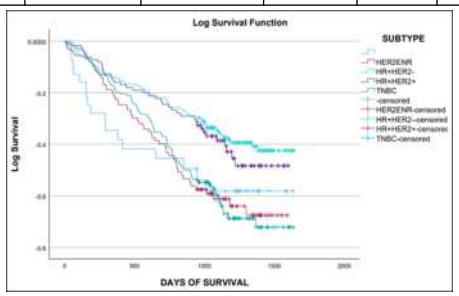

Figure 4: overall survival of the patients according to the receptor status

Progression free survival (PFS) was assessed for the patients presented with de novo metastasis. The median PFS (mPFS) was 21.3 months for all the patients (Table 14). The mPFS was 14.5 months for TNBC, 14.7 months for HER2-enriched, 27.1 months for HR+ve/HER2-ve and 18.1 months for HR+ve/HER2+ve subgroups, respectively (p=0.003) (as shown in Table 14). The progression free survival rate at 6-months,1-year, 2-years and 3-years according to the receptor status has been shown in Table 13. (shown in Figure 5).

Table 13: Progression free survival of the patients presented with de novo metastasis

n =190	HR+ve/HER2-ve	HR+ve/HER2+ve	HER2-enriched	TNBC
6-months	80.49	90.32	80.95	76.47
1-year	51.22	70.97	57.14	50
2-years	34.15	35.48	27.19	20.5
3-years	9.76	6.45	11.9	14.7

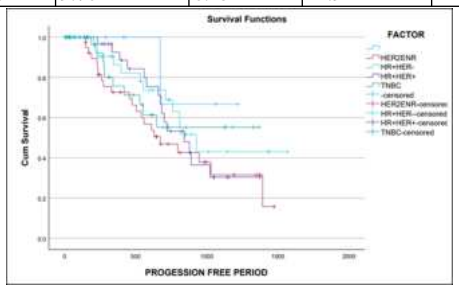

Figure 5: Progression free survival of the patients presented with de-novo metastasis

Table 14: Median progression free survival according to the receptor status

n=190	m PFS		95% confidence interval		Standard error	p=0.34
	Days	Months	Lower boundary	Upper boundary		
HER2-enriched	442	14.7	89.3	794.6	179.9	
HR+ve/HER2-ve	813	27.1	569.0	1056.9	124.4	
HR+ve/HER2+ve	544	18.1	392.05	695.9	77.5	
TNBC	437	14.5	-	-	-	
Overall	640	21.3	488.2	791.7	77.4	

The median overall survival (mOS) of the patients presented with de novo metastasis was 35.4 months. The mOS was 38.3 months for HR+ve/HER2-ve subgroup, 34.7 months for HER2-enriched, 26.2 months for TNBC and 38.5 months for HR+ve/HER2+ve subgroup respectively (p=0.8) (as shown in Table 15 and Figure 6).

Table 15: Overall survival of the patients presented with de-novo metastasis:

n=190	mOS		95% confidence interval		Standard error	p=0.8
	Days	months	Lower boundary	Upper boundary		
HER2-enriched	1042	34.7	991.803	1091.96	25.611	
HR+ve/HER2-ve	1151	38.3	710.818	1590.723	224.465	
HR+ve/HER2+ve	1157	38.5	1001.113	1312.429	79.417	
TNBC	788	26.2	365.006	1210.535	215.696	
Overall	1062	35.4	950.096	1173.446	56.977	

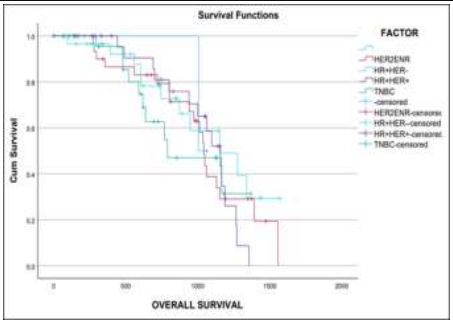

Figure 6: Overall survival of the patients presented with de novo metastasis

DISCUSSION

Breast cancer is one of the most common cancers and a major health problem in the world. It has now surpassed lung cancer as the leading cause of global cancer incidence in 2020, with an estimated 2.3 million new cases, representing 11.7% of all cancer cases. [9] As per the Globocan data 2020, in India, breast cancer accounted for 13.5% (178361) of all cancer cases and 10.6% (90408) of all deaths with a cumulative risk of 2.81. [4] Breast cancer is a rising health problem and the most common cancer in female in India.

The median age at diagnosis in this study is 47.6 years with the most common age group affected 40-50 years. It is comparable to the other epidemiological studies done in BHU and SGPGI Lucknow.[10] Female constituted 99% of the patients.

In this study 53.7% patients were HR+ve, among which 17% were HER2+ve. TNBC accounted for 27% patients and 18% patients were HER2-enriched. Overall 35% patients were HER2+ve. Similar results were also seen in the study done by Viral P et al. [14] Higher percentage of TNBC was found in our study as compared to the western population and it is comparable to the study done by Thakur et al. [11]

Majority of the patients (44.5%) presented with LABC while 29.5% patients presented in early stage and 25.9% patients presented with de novo metastasis. This is comparable to the findings of a survival study on breast cancer done under national cancer registry program.[12] A cohort of 3,473 patients from SGPGIMS demonstrated an 11% incidence of Stage IV disease at presentation, and although this did decrease over time from 1990 when the incidence of Stage IV disease was 20%, this is significantly higher than the 6% incidence observed in the US [13]. The group at BHU reported a 35% incidence of Stage IV breast ca at initial presentation [10]. The most common distant site of involvement was bone (48%) followed by liver (26.3%) and lung (26.8%). Similar findings were observed in the previous studies done by Almashri et al [15]. Liver was the most common distant site involved in HER2-enriched subtype (42.5%) while bone was the most common site in the other subtypes.

In our study 93% patients were diagnosed with infiltrating ductal carcinoma (IDC) while only 1.9 % diagnosed as infiltrating lobular carcinoma (ILC). Among the patients presented with IDC, 57% had grade II and 42.6% patients had grade III cancers.

The most common chemotherapy regimen received in neoadjuvant and adjuvant setting is 4AC-4T +/- trastuzumab. The pCR was achieved in 27.5% patients. The highest pCR rate was observed in HER2-enriched subgroup (45%) followed by TNBC (41%) subgroup. After a median follow up period of 42 months it was observed that recurrence rate is high in the TNBC and the HER2-enriched subtype. The most common site of involvement in recurrence setting was bone (33.3%) followed by lung (29.6%). Early recurrence was more commonly seen in TNBC and HER2-enriched subgroups, while, the late recurrences are seen in HR+ve/HER2+ve subgroup of patients.

The most common systemic therapy regimen used in palliative setting was taxane based (T/TH/TCH) followed by FEC. Lapatinib and capecitabine was the most common regimen used in 2nd line (47%) followed by taxane. The overall response rate to palliative chemotherapy was 52.7% and the best response seen was PR (in 47.2%).

The overall survival is better in the early-stage disease as compared to the advanced stage disease. While analyzing the survival data according to the receptor status, it was observed that molecular subtype has got strong impact on survival outcome. The survival of those with HER2-enriched and TNBC is poor compared to the other subgroups. The survival outcome of HER2-enriched subgroup was found to be worst in our population which may be due to high cost of HER2 targeted therapy leading to poor access to these novel agents.

CONCLUSION

Advanced stage of presentation with metastasis to distant organ is the most important factor associated with poor survival amongst the patients with breast cancer. Delay in diagnosis and lack of adherence to the treatment is a major cause of poor outcome in our population. Hence, measures to increase the public awareness as well as mass screening to detect more patients in early stage should be undertaken. Although several novel therapeutic agents like immunotherapy, pertuzumab, ado-trastuzumab emtansine, trastuzumab deruxtecan etc. have shown promising results in clinical trials, due to the high cost, many patients from developing countries like India are not being able to avail the benefit from these therapeutic agents. So, research to generate quality controlled biosimilar may be encouraged so that people from lower socio-economic status and developing countries may get benefitted.

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