

Original Research Article

Socioeconomic factors affecting trastuzumab usage in patients with breast cancer in a resource constrained setting in North India

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ABSTRACT

Background: Trastuzumab is now the standard of care in patients with Her-2 positive breast cancer. Despite its availability, high cost of treatment of trastuzumab makes it out of reach for many patients. This study analyses access to trastuzumab and identified potential barriers to its use in a large tertiary care hospital in northern India.

Methods: This is a cross-sectional study of all the Her-2 positive breast cancer patients diagnosed and treated in our institute in 2018. These patients were investigated to look into various socio-economic factors for acceptance or non-acceptance of trastuzumab by using a predesigned questionnaire. Chi square test or Fishers exact test was applied.

Results: Out of 310 diagnosed cases of carcinoma breast 52 (16%) patients were Her-2 positive. The majority of the trastuzumab recipients belonged to upper/middle socioeconomic status as compared to the non-recipient group (75% vs. 34.4%, $P=0.004$). Most of the receiver were well-educated (75% vs. 28.2%, $P=0.0009$) and belonged to the high-income strata (55% vs. 37.5%, $P=0.22$). It was found that the treatment of maximum (84.6%) Her-2 positive patients were met by out-of-pocket expenditure (OOPE) and 71.9% of the patients cited financial issues as the main cause of not taking the drug.

Conclusions: The patient's socioeconomic class and their education level significantly influenced the usage of the drug. Improving patient education as well as the implementation of the government health scheme can improve the availability and usage of this drug.

Keywords: India, Socioeconomic, Trastuzumab

INTRODUCTION

Breast cancer (BC) is the most frequent malignancy in women worldwide. Its incidence continues to soar in low- and middle-income countries.¹ Based on the cancer registry data, BC is the most prevalent cancer among women in Indian cities.² Though BC related mortality is showing a declining trend in developed countries, the survival rates of the patients with BC residing in developing countries continues to remain low. This paradox may be attributed to the paucity of health care

facilities and financial constraints to accessing the newer cancer therapies.^{3,4}

Trastuzumab is currently the standard of care in patients with Her-2 (Human epidermal growth factor receptor-2) positive BC. It is a recombinant humanized monoclonal antibody against Her-2 receptor and is approved for both non-metastatic (either in the neoadjuvant or adjuvant setting) and metastatic Her-2 positive BC.⁵ Considering the plethora of data supporting the role of trastuzumab in Her-2 positive BC, the World Health Organization

(WHO) added trastuzumab to its Model List of Essential Medicines in 2015.⁶ However, the high cost of trastuzumab remains a significant barrier for its widespread use in the majority of the countries in the world.⁷ Similarly, the trastuzumab use varies vastly across the centres in India, depending upon the financial constraints and availability of the drugs. The majority of the patients with BC, in India, are not covered by health insurance, an overwhelming 80% of the medical expenses are met by out-of-pocket expenditure (OOPE) by the patients.⁸ Many patients are forced to borrow money for the treatment and a significant number are ultimately pushed below the threshold of poverty line every year. Not unsurprisingly, high treatment cost remains a significant deterrent for the widespread use of trastuzumab in patients with BC in India.

The present study aimed to identify the potential barriers to the use of trastuzumab in patients with Her-2 positive breast cancer patients attending a tertiary care teaching hospital in a sub-Himalayan region of the resource constrained state of Northern India.

METHODS

The present cross-sectional study included patients with Her-2 positive BC who are treated in a tertiary care teaching hospital from January 1st to December 31st, 2018. The Institutional Ethical Committee for Human Research approved the study. All the study participants had a histopathologically proven and Her-2 positive invasive BC. ASCO (American Society of Clinical Oncology) guidelines, 2007 were used for Her-2 scoring - score 0 and score one was labelled as negative, score two as equivocal, and score three was considered as positive.⁹ All tumors with an equivocal Her-2 score of two were confirmed by FISH test before initiation of treatment.

A predesigned questionnaire was used to evaluate the various reasons for the non-usage of trastuzumab when indicated. The trained research staff administered the questionnaire after interviewing the eligible patients who had consented to participate in the study. All relevant clinical variables like age, stage, treatment details, receptor status (ER/PR/Her-2) were recorded. The questionnaire also looked into various factors for acceptance or non-acceptance of trastuzumab, like socio-economic status, funding of treatment, health insurance and education status.

Patients were categorised into upper, middle and lower socioeconomic status by using an appropriate scale based upon modified Kuppaswamy socioeconomic scale.¹⁰⁻¹¹ This scale takes into account three parameters-the occupation, the education status and the monthly income of the family-head to determine the socioeconomic status of the patients.¹⁰ According to this scale, socioeconomic status is divided into the upper, upper-middle, lower-middle, upper lower and lower. Upper, upper-middle and

lower-middle were clubbed together into a single group designated as called "upper/middle class", similarly, patients with upper lower and lower class were considered as "lower class" for the study. They were also divided into high and low-income groups according to their monthly income with a cut-off of INR 30,000. Those patients having education qualifications above the high school level were considered as "well-educated".

Statistical analysis

Data were entered in a Microsoft Excel spreadsheet. Two authors screened the data to confirm their completeness and accuracy. The categorical variables were represented as frequency and proportion. The continuous variables were described as mean±standard deviation for parametric data and median with the inter-quartile range for non-parametric data. The proportions were compared using Chi-square test or Fishers exact test as applicable. SPSS IBM® (Statistical Package for Social Scientists) version 23 was used for statistical analysis.

RESULTS

During the study period, 310 diagnosed cases of BC were registered. Out of them, 52 (16.7%) patients who were Her-2 positive and had received treatment, were included in the study. The baseline characteristics of the patients are shown in Table 1.

Majority of patients belonged to below 60 years of age group (41/52, 78.8%) and most of them were married homemaker. Stage III was the most common (26/52, 50 %) stage observed, whereas hormone status positive was seen among 63.5 % (33/52) of the patients. There were 51.9% (27/52) of patients who underwent surgery whereas radiation was received by 36.5% (19/52) of patients.

There were equal numbers of patients in the upper/middle as well as the lower socio-economic group. The group categorised as the high-income has 44.2% (23/52) of cases, while 55.8% (29/52) were in the low-income group. There were 46.2% (24/52) of patients who were "well-educated", and 53.8% (28/52) qualified below High school. On analysing the occupation profile of the head of the family of patients, most of them were "unskilled worker" (19/52, 36.5%) followed by professional (12/52, 23%) and skilled worker (11/52, 21.2%).

Among all the 52 Her-2 positive breast cancer patients, only 20 (38.5%) patients received trastuzumab. About 75% (15/20) of the recipient belonged to the upper/middle socioeconomic class and were well educated. Incomes of 55% (11/20) receivers were high, whereas 45% (9/20) receivers belonged to the low-income group.

Trastuzumab non-recipients were 32 (61.5%). Majority of them belonged to lower socioeconomic (21/32, 65.6%)

and low-income group (20/32, 62.5%). There were 71.8% (23/32) of the non-recipients who had education qualification of high school and below.

Table 1: Demographic, clinicopathological and treatment characteristics of study subjects (n=52).

Characteristics	Number (%)
Age (in years)	
Mean age	46
≥60	11 (21.2)
<60	41 (78.8)
Occupation	
Employed	3 (5.8)
Housewife	49 (94.2)
Marital status	
Married	49 (94.2)
Widow	2 (3.8)
Divorced	1 (2)
Occupation of head of family	
Professional	12 (23)
Arithmetic skill worker	3(5.8)
Skilled worker	11(21.2)
Semi-skilled worker	7 (13.5)
Unskilled worker	19 (36.5)
Education status of head of family	
Intermediate and above	24(46.2)
High school and below	28 (53.8)
Monthly income	
High income (>30,000 INR)	23 (44.2)
Low income (≤30,000 INR)	29 (55.8)
Socioeconomic status	
Upper, upper middle, lower middle	26 (50)
Upper lower, lower	26 (50)
Stage of breast cancer	
I	3 (5.8)
II	9 (17.3)
III	26 (50)
IV	14 (26.9)
Hormone receptor status (ER/PR)	
Positive	33 (63.5)
Negative	19 (36.5)
Other related variables	
Metastasis	14 (32.7)
Surgery	27 (51.9)
Radiotherapy	19 (36.5)
Adjuvant endocrine therapy	33 (63.5)
Reasons for not receiving Trastuzumab	
Financial	23 (71.9)
Not informed	9 (28)

On comparing socioeconomic status, income and education status of trastuzumab recipients with non-recipients (Table 2), it was found that a majority of trastuzumab recipients belonged to upper/middle socioeconomic status as compared to the non-recipient

group (15/20,75% vs. 11/32,34.4%, $P=0.004$). There was a significant difference in the education status of the trastuzumab receiving group when compared to the non-receiver group. Most of the trastuzumab recipient patients were well-educated (15/20, 75% vs. 9/32, 28.2%, $p=0.0009$). The patients belonging to the high-income strata were more commonly in the receiver group as compared to the non-receiver group (11/20, 55% vs. 12/32, 37.5%, $p=0.22$).

Table 2: Association between trastuzumab received group with sociodemographic factors.

Parameters	Received (n=20)	Not received (n=32)	Total (n=52)	P value
Education				
Intermediate & above	15(75%)	9(28.2%)	24(46.2%)	0.0009
High school & below	5(25%)	23(71.8%)	28(53.8%)	
Income				
High	11 (55%)	12 (37.5%)	23 (44.2%)	0.216
Low	9 (45%)	20(62.5%)	29(55.8%)	
Socioeconomic Class				
Upper/middle	15 (75%)	11 (34.4%)	26 (50%)	0.004
Lower	5 (25%)	21 (65.6%)	26 (50%)	
Treatment Support				
OOPE expenditure	16(80%)	28(87.5%)	44(84.6%)	0.694
Govt. support	4(20%)	4 (12.5%)	8 (15.4%)	

The flow chart shows the source of financial support among Her-2 positive patients (Figure 1). 80% of trastuzumab users took the drug by OOPE. Among 32 trastuzumab non-recipient patients, 28 (87.5%) were self-financing their overall treatment and had no support like government aid or insurance.

Inter-group comparison for various factors like education and socioeconomic status, OOPE, government support, high and low income, upper/middle and lower class group among the recipient and non-recipient of the drug was also made. The majority of patients (84.6%,44/52) who could afford the trastuzumab by OOPE were well-educated (13/16,81.3% vs.8/28, 28.6%, $P=0.0014$) (Table 3).

A similar analysis in the high-income group also revealed that, the trastuzumab recipient group was predominantly of high education status (10/11, 90% vs. 5/12, 41.7%, $P=0.027$). Concerning the socioeconomic status, the majority of trastuzumab recipients affording by OOPE belonged to upper/ middle socioeconomic class (14/16, 87.5% vs. 10/28, 37.5%, $P=0.014$) (Table 4). An analysis of various causes of non-acceptance of trastuzumab highlighted that 71.9% (23/32) of patients reported financial issues as the leading cause of not taking trastuzumab, the remaining (9/32, 28.1%) patients

informed that the treating physician did not offer them this drug.

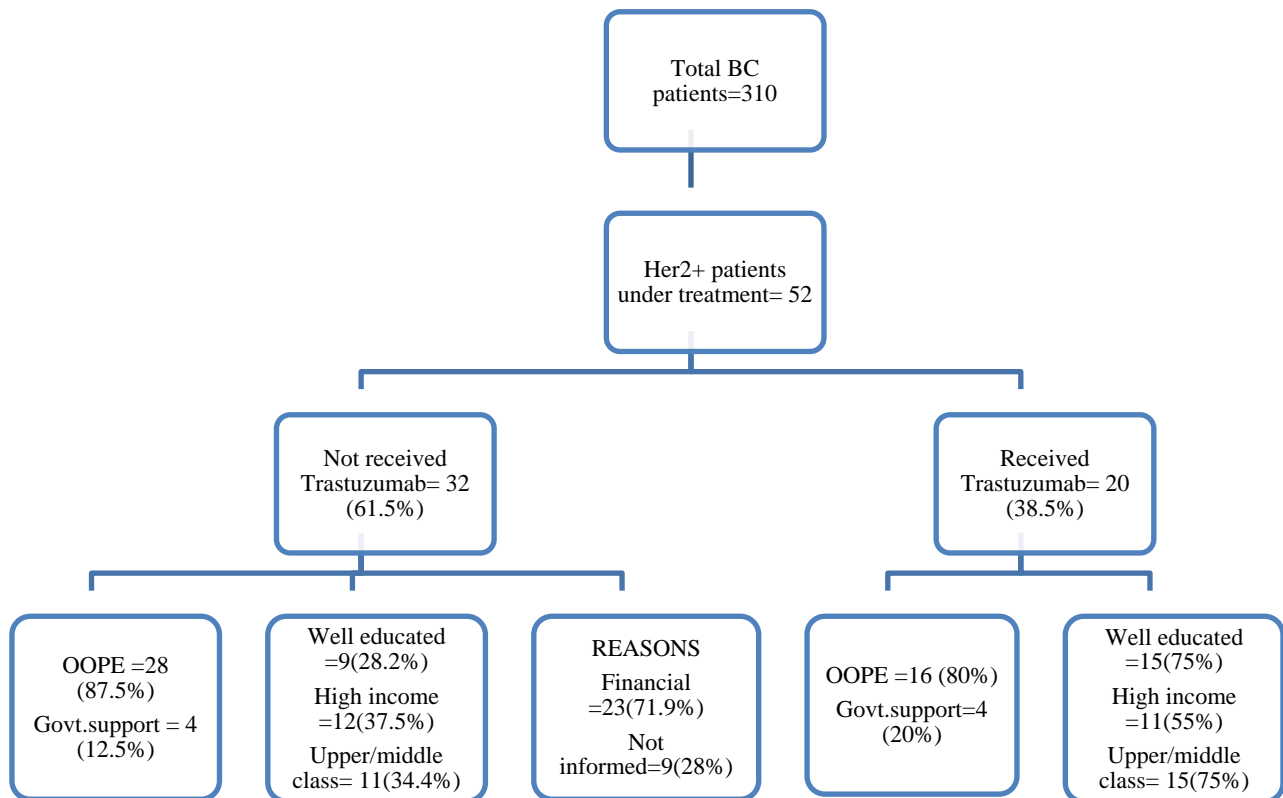


Figure 1: Use of trastuzumab among Her-2 positive patients, source of financial support for the same and reasons for non-usage of the drug.

Table 3: Association of education status of trastuzumab received group with OOPE expenditure, government support, income and socioeconomic status.

Parameters	Received	Not received	Total	P-Value
OOPE EXPENDITURE Group(n=44)				
Intermediate & above	13/16 (81.3%)	8/28 (28.6%)	21(47.7%)	0.0014
High school	3/16 (18.8%)	20/28 (71.4%)	23 (52.2%)	
GOVERNMENT SUPPORT GROUP (n=8)				
Intermediate & above	2/4 (50%)	1/4 (25%)	3(37.5%)	1
High school	2/4 (50%)	3/4 (75%)	5(62.5%)	
HIGH INCOME GROUP (n=23)				
Intermediate & above	10/11(90%)	5/12 (41.7%)	15 (65.2%)	0.0272
High school	1/11(10%)	7/12 (58.3%)	8 (34.8%)	
LOW INCOME GROUP(n=29)				
Intermediate & above	5/9 (55.6%)	4/20 (20%)	9 (31%)	0.088
High school	4/9 (44.4%)	16 /20 (80%)	20 (69%)	
UPPER/ MIDDLE CLASS GROUP (n=26)				
Intermediate & above	14/15 (93.3%)	7/11 (63.6%)	21 (80.8%)	0.1279
High school	1/15 (6.7%)	4/11 (36.4%)	5 (96.2%)	
LOWER CLASS GROUP (n=26)				
Intermediate & above	1/5 (20%)	2/21(9.5%)	3 (11.5%)	0.4885
High school	4/5(80%)	19/21(90.5%)	23 (88.5%)	

Table 4: Association of socioeconomic status of trastuzumab received group with OOPE expenditure, government support, income and education level.

Parameters	Received	Not received	Total	P-value
OOPE EXPENDITURE GROUP(n=44)				
Upper/middle class	14/16 (87.5%)	10/28 (35.7%)	24(54.5%)	0.014
Lower class	2/16 (12.5%)	18/28 (64.3%)	20 (45.5%)	
GOVERNMENTT SUPPORT GROUP (n=8)				
Upper/middle class	1/4 (25%)	1/4 (25%)	2(25%)	1
Lower class	3/4 (75%)	3/4 (75%)	6(75%)	
HIGH INCOME GROUP (n=23)				
Upper/middle class	10/11(90%)	6/12 (50%)	16 (69.6%)	0.0686
Lower class	1/11(10%)	6/12 (50%)	7 (30.4%)	
LOW INCOME GROUP(n=29)				
Upper/middle class	5/9 (55.6%)	5/20 (25%)	10(34.5%)	0.2047
Lower class	4/9 (44.4%)	15 /20 (75%)	19 (65.5%)	
INTERMEDIATE & ABOVE EDUCATION GROUP (n=24)				
Upper/middle class	14/15 (93.3%)	7/9 (77.8%)	21 (87.5%)	0.5331
Lower class	1/15 (6.7%)	2/9 (22.2%)	3 (12.5%)	
HIGH SCHOOL & BELOW EDUCATION GROUP (n=28)				
Upper/middle class	1/5 (20%)	4/23(17.4%)	5 (17.9%)	1
Lower class	4/5(80%)	19/23(82.6%)	23 (82.1%)	

DISCUSSION

There is an increased incidence of BC globally over the last several decades, with the highest increase observed in Asian countries like India, especially in premenopausal women.¹²⁻¹⁴ The advent of trastuzumab has changed the management of patients with BC worldwide. Although it was approved in adjuvant setting ten years back, it is still not affordable for most of the Indian patients.¹⁵ This single-centre study illustrates various socioeconomic factors and barriers limiting accessibility to trastuzumab in patients with Her-2 positive BC from resource constrained geography in Northern India.

In our study, a majority (78.8%) of patients with BC are below 60 years of age, contrary to the western population, where BC is primarily observed in women older than 60 years.¹⁶⁻¹⁷ Various studies showed that the incidence of Her-2 positivity in Indian population is between 26% and 50%.¹⁸⁻²⁰ The incidence in our study is 16.8% which is almost similar to other studies from India.² The exact prevalence of Her-2 positive BC is still unknown because a significant proportion of tumours with equivocal Her-2 results (on immunohistochemistry) are not subjected to FISH for confirmation due to financial constraints.

In our study, out of 52 Her-2 positive patients diagnosed in a year, there were only 20 (38.5%) patients who received trastuzumab. We looked at all our Her 2 positive patients for their socioeconomic status, education and income status and tried to find their relations with the usage of trastuzumab and found a significant correlation for socioeconomic and education status with the usage of trastuzumab. Most of the trastuzumab recipients belonged

to the upper/middle socioeconomic class and were well educated. The Income status was not a significant factor for drug usage, and the arbitrary cut-off values for different income groups in the study can be revised.

A subgroup analysis was further done with the education and socioeconomic status of the patients as they came out to be a significant factor associated with trastuzumab usage. We found that education plays a principal role in removing the barrier for non-acceptance of the drug as most of the patients in high income and OOPE expenditure groups who received the drug were well educated. As a result of the high cost of the drug, patients might face a more significant economic burden creating a barrier to access treatment. However, the educated family could easily comprehend the necessity of the drug and step forward with a positive response.

The annual treatment cost with trastuzumab is around INR 241963 (US\$3447).²¹ In India, with GDP per capita income of \$2044.²² and restricted resources, it limits the accessibility of the drug for most of the lower socioeconomic class. We also observed a similar trend as most of OOPE expenditure patients who received the drug belonged to upper/middle socioeconomic class.

We noticed that maximum trastuzumab recipients i.e. 80% of Her-2 positive patients underwent treatment by OOPE as also observed by Ghosh et al which reported that after excluding on-going trial patients there were 18 trastuzumab recipient and among them, majority patients (n=13) were self-financing their treatment.²

The reason cited by our study group of non-acceptance of trastuzumab was financial issues and the drug not offered to them by the treating physician. There were 71.9% of patients unable to receive trastuzumab due to high OOOPE. As reported earlier, only 76(35.8%) Her-2 positive patients received trastuzumab reflecting the financial constrain determining trastuzumab usage. The investigators concluded that the single most critical factor for not proceeding with treatment was lack of financial resources in 90% of the cases.¹⁵

Similarly in an international survey of physicians (n = 151) conducted in 2011, 27% of physicians reported at least one instance within the previous year in which adjuvant trastuzumab was recommended to a patient who ultimately did not receive it cited cost as the reason for withholding treatment.²³ Similar results have been reported from developed countries also. Kimberly et al surveyed oncologists in the United States and reported that 34% (of 137 respondents) and 42% (of 41 respondents) cited "high out-of-pocket treatment cost for the patient" as a barrier to use trastuzumab in the neoadjuvant and adjuvant settings, respectively.⁶ The most common barriers to the use of trastuzumab across the countries were related to insurance coverage, availability of the drug, treatment guidelines, patient comorbidities and cost to the patient. In a survey, nearly one-third of all physicians, with a higher percentage from Mexico, Brazil and Russia, answered "yes" to the question "are there any instances where you have not been able to treat a patient with trastuzumab or have had to delay their treatment due to reimbursement issues/unavailability of hospital fund/ patient unable to pay co-payment?".³

Our analysis of the causes of non-usage of the trastuzumab, when indicated, highlights that 28.1% of patients informed that their physician did not offered them the drug. This decision probably shows that treating oncologists get influenced by either the poor financial status of the patients or unavailability of insurance or government funding for treatment. Physicians working in low- and middle-income countries usually cite cost as a significant reason for withholding adjuvant trastuzumab compared to those practicing in high-income countries (73% vs. 7%; p <0.0001).²³

Since a majority of the Indian population is uninsured, has low annual income and resides in rural and semi-urban areas, we believe that our data reflects the real-world scenario of low usage of this useful but expensive drug in a resource-constrained setting.^{24,25}

CONCLUSION

We conclude that financial status and educational status are essential determinants for Trastuzumab usage. There is a need for incorporation of the Trastuzumab into national and state health scheme programs to make it easily accessible. Broader coverage of the population by

affordable insurance government health schemes and treatment- cost reduction strategies like the use of bio-similar, can bridge the gap between the need and use of trastuzumab for patients with Her-2 positive in developing countries.

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