Out-of-pocket payment and financial risk protection for breast cancer treatment: a prospective study from India

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Summary

Background Available data on cost of cancer treatment, out-of-pocket payment and reimbursement are limited in India. We estimated the treatment costs, out-of-pocket payment, and reimbursement in a cohort of breast cancer patients who sought treatment at a publicly funded tertiary cancer care hospital in India.

Methods A prospective longitudinal study was conducted from June 2019 to March 2022 at Tata Memorial Centre (TMC), Mumbai. Data on expenditure during each visit of treatment was collected by a team of trained medical social workers. The primary outcome variables were total cost (TC) of treatment, out-of-pocket payment (OOP), and reimbursement. TC included cost incurred by breast cancer patients during treatment at TMC. OOP was defined as the total cost incurred at TMC less of reimbursement. Reimbursement was any form of financial assistance (cashless or repayment), including social health insurance, private health insurance, employee health schemes, and assistance from charitable trusts, received by the patients for breast cancer treatment.

Findings Of the 500 patients included in the study, 45 discontinued treatment (due to financial or other reasons) and 26 died during treatment. The mean TC of breast cancer treatment was ₹258,095/US$3531 (95% CI: 238,225, 277,934). Direct medical cost (MC) accounted for 56.3% of the TC. Systemic therapy costs (₹50,869/US$696) were higher than radiotherapy (₹33,483/US$458) and surgery costs (₹25,075/US$343). About 74.4% patients availed some form of financial assistance at TMC; 8% patients received full reimbursement. The mean OOP for breast cancer treatment was ₹186,461/US$2551 (95% CI: 167,666, 205,257), accounting for 72.2% of the TC. Social health insurance (SHI) had a reasonable coverage (33.1%), followed by charitable trusts (29.6%), employee health insurance (5.1%), private health insurance (4.4%) and 25.6% had no reimbursement. But SHI covered only 40.1% of the TC of treatment compared to private health insurance that covered as much as 57.1% of it. Both TC and OOP were higher for patients who were younger, belonged to rural areas, had a comorbidity, were diagnosed at an advanced stage, and were from outside Maharashtra.

Interpretation In India, the cost and OOP for breast cancer treatment are high and reimbursement for the treatment flows from multiple sources. Though many of the patients receive some form of reimbursement, it is insufficient to prevent high OOP. Hence both wider insurance coverage as well as higher cap of the insurance packages in the health insurance schemes is suggested. Allowing for the automatic inclusion of cancer treatment in SHI can mitigate the financial burden of cancer patients in India.

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Keywords: Breast cancer; Oncology; Health policy; Health economics; Cancer costs; OOP; Health care expenditure; Health insurance; Reimbursement

Research in context

Evidence before this study

Estimates of the economic burden of cancer treatment in India are primarily drawn from cross-sectional health surveys conducted by the National Sample Survey. Various small-scale studies have provided estimates of cost of treatment, out-of-pocket payment (OOP), and insurance coverage for specific cancer sites. Evidence from these studies suggests that OOP for cancer treatment is large due to the long duration of treatment, the high cost of treatment and low insurance coverage. Based on data from the latest round of NSS, 2017–2018, the OOP for any cancer treatment was estimated at ₹85,595 (USD 1171) for hospitalization.[1] Jain and Mukherjee (2016)[2] estimated that the major mode of financing for breast cancer treatment was OOP (91%), with only 9% of the patients covered by any health insurance.

Added value of this study

Our study followed a longitudinal approach to collect data on cost of treatment of breast cancer. In our sample, 86.0% patients were treated as subsidized patients (general or non-chargeable) and 14.0% were treated as non-subsidized patients (private). Our estimated total cost (TC) of treatment at TMC was ₹258,095/USD 3531 (95% CI: 238,255, 277,934) and the mean out-of-pocket payment (OOP) was ₹186,461/USD 2551 (95% CI: 167,666, 205,257). The TC and OOP for subsidized patients were ₹210,246/USD 2876 (95% CI: 195,308, 225,183) and ₹149,315/USD 2043 (95% CI: 135,179, 163,451), respectively. For non-subsidized patients, the TC was ₹552,368/USD 7556 (95% CI: 478,449, 626,287) and the OOP was ₹414,910/USD 5676 (95% CI: 331,623, 498,197). Systemic therapy was found to be the largest contributor to the direct medical cost of treatment, while accommodation and travel were the two major non-medical costs for patients. Reimbursement from state funded healthcare payments (insurance and welfare schemes) was to the tune of 40.1% of TC, while that from private and employee health insurance was to the tune of 58.5% and 57.1%, respectively. We observed marked variations in OOP and reimbursements across different socio-demographic and economic subgroups in the study cohort. Reimbursement at current level was insufficient to protect the breast cancer patients from financial hardship.

Implications of all the available evidence

To our knowledge, this study is the first to longitudinally capture costs incurred by patients undergoing breast cancer treatment in India. The knowledge of different treatment modalities and of the economic burden of treatment, especially in the changing landscape of treatment, is necessary to guide healthcare spending such that it benefits the underserved optimally. There is certainly a need to increase the reimbursement limits within the purview of state sponsored health insurance and to increase awareness of different insurance schemes among patients. Reduction of OOP for cancer patients can increase their financial protection and achieve the health-related sustainable development goals (SDGs).

Introduction

The incidence and prevalence of breast cancer has been increasing worldwide. Globally, breast cancer is the leading type of cancer, accounting for 2.3 million of the 19 million new cancer cases.[3] In low- and middle-income countries (LMICs), a majority of breast cancer patients are in the reproductive age group, are diagnosed at an advanced stage, and experience high mortality.[4–6] Economic hardship due to breast cancer treatment is high as treatment is expensive in middle-income countries, including India, and the cost of treatment has been increasing over time.[7–9] Households often borrow or sell assets to meet the high out-of-pocket payment (OOP) for cancer treatment.[10] In many LMICs, the financial protection mechanism systematically excludes cancer treatment from its ambit, leading to financial catastrophe.[11]

Breast cancer treatment involves long-term care. The treatment begins with identification of symptoms and evaluation for diagnosis, followed by an appropriate treatment and follow-up visits to monitor the disease status regularly.[12] Multimodal treatment that includes surgery, radiation therapy, and systemic therapies is needed as the treatment spreads over a year. Breast cancer treatment adversely affects the economic condition of the households as they often resort to borrowing from social networks, taking loans at high interest rates, selling assets, pawning jewellery, and other such measures. In addition, the patients and their accompanying person suffer from loss of daily wages and exhaustion of paid leaves.[13,14] The nature and degree of cost of and OOP for breast cancer treatment vary across countries. Chemotherapy is the largest contributor to the total cost in stage V of the disease and the lowest contributor at the initial stage.[15] Most of the OOP is made towards medication, transportation, and physician visits.[16] Evidences suggest that place of residence, patient age, stage

at diagnosis, use of multiple therapies, type of institutional facility (public vs. private), and extent of insurance coverage are the primary drivers of treatment cost.[15,17–19]

In India in 2020, breast cancer accounted for 14% of the total cancer cases diagnosed and 22% of the disease adjusted life years (DALY) related to cancer.[20,21] The prevalence of breast cancer has been increasing in the country. Delivery of complex cancer care requires specialist cancer centers, 95% of which are located in urban India, while 68.8% of the Indian population lives in rural areas.[22] The concentration of cancer care centers in the northern and eastern regions of India is low, often leading to patients travelling long distances for treatment.[9,23] In addition to this, the cancer statistics are limited to screening, prevalence, and incidence of cancer. The cancer registry provides number of cases, new cases, and deaths by type of cancer, broad age groups, and sex. With limited geographical coverage; 15% of the population in urban areas and 1% in rural areas implying larger urban representation.[24,25] Population-based national-level surveys like the National Sample Survey (NSS) are cross-sectional and provide very limited information on cancer.[26] Another national-level survey, the National Family Health Survey (NFHS), collected data on the screening prevalence of only breast, cervical, and oral cancer in its last two rounds (NFHS-4 and 5).[27,28]

Studies on the economic burden of breast cancer in India are few and based on small-scale and unrepresentative data. A household-based study from the state of Punjab showed that medicines and hospitalization accounted for over 60% of the total cost of breast cancer treatment.[2] The NSS data does not segregate cost of or OOP for treatment by type and stage of cancer; rather it only provides inpatient and outpatient expenditure for any cancer treatment by household. In 2018, the mean OOP for hospitalisation for any cancer treatment in India was estimated at ₹85,595. The mean OOP for treatment was lower in public (₹38,859) hospitals compared to private hospitals (₹115,771)[1]; the estimates were similar to those of earlier studies.[29,30] As the breast cancer treatment is multimodal and multifaceted, the estimates derived from cross-sectional studies underestimate the cost of treatment and OOP owing to recall bias in self-reported data. In this paper, we estimated of the cost of treatment of and OOP for breast cancer from a prospective longitudinal study carried out at a publicly funded tertiary cancer care center in India.

Methods

Study design and setting

We conducted a prospective study in a cohort of patients with breast cancer who were registered at Tata Memorial Centre (TMC), Mumbai. Patients who were partially/fully investigated outside TMC were eligible for the study; however, patients who had begun any part of cancer directed treatment outside the centre were not included. The study was reviewed and approved by the Institutional Ethics Committee of TMC. Patient accrual was initiated after the registration of the patients in the Clinical Trials Registry-India (CTRI/2019/07/020142). All patients were newly diagnosed, histologically confirmed cases of breast cancer that were treatment naïve. Recurrent cases were excluded. Consecutive patients seeking treatment at TMC were screened from the outpatient department. The patients were enrolled from June 2019 to August 2021 after written informed consent and followed up till March 2022. The study was a joint collaborative study between TMC and the International Institute for Population Sciences (IIPS), Mumbai. The study site, design, and setting have been elaborated in Supplementary Texts S1 and S2. Details of the study design and sample design, including inclusion and exclusion criteria, can be found elsewhere.[31]

Data collection and follow-up

A structured data collection tool was developed to record various demographic and socio-economic characteristics of the households and patients. The process of data collection for capturing direct medical and direct non-medical costs was a continuous one from the time of registration (baseline) to treatment completion (endline/conclusion). After obtaining consent for the study, information on the socio-demographic and economic condition of the household was collected during a 40-min to 1-h long interview of the patient/relative by a trained social worker using the structured data collection tool. The cost of treatment prior to registration at TMC was also recorded. During the subsequent hospital visits up to treatment completion, only cost data was collected. Cost data collection was carried out by verifying the billing data produced by the patient/relative or the data was drawn up from the electronic hospital records. Some patients sought some specific treatment from another health center due to the long waiting period at TMC. Data on the costs incurred by the patients on such treatment were recorded during the patients' visit to TMC. As financial matters were often handled equally by the patients and their caregivers, we did not mandate the patient's interview over the relative's or vice versa (Supplementary Text S2).

Study outcome

The primary outcome variables included the total cost (TC) of treatment at TMC, out-of-pocket payment (OOP), and reimbursement. Reimbursement is an umbrella term that includes the expenses recovered by patients either in full or partially by financial assistance from sources such as social health insurance schemes, private health insurance, employee health insurance schemes, and charitable trusts. Many of the schemes provides cashless claim and in fact, treatment for cancer starts only after receiving in principle approval from the

insurer. Patients received reimbursement from single as well as from multiple sources. The TC included direct medical costs and direct non-medical costs. The direct medical costs of treatment consisted of costs incurred on registration, consultation, admission, investigation, medicine, surgery, systemic therapy, and radiotherapy, whereas direct non-medical costs included food, travel and accommodation costs. We did not include indirect costs such as loss of wage or salary to the patient and the accompanying person in the estimation of TC. Data on source(s) (public or private health insurance schemes, charitable trust funding, etc.) and amount of reimbursement was collected at the time of treatment conclusion. The OOP was defined as TC less of reimbursement.

Independent variables

The study used a broad set of socio-demographic, economic, and household variables. Patients' characteristics included standard demographic variables like age (up to 45 years, over 45 years), marital status (currently married, others), and educational level (never attended school, primary, secondary, higher secondary, higher secondary and above). Type of patient (general or non-chargeable, private), place of treatment (TMC, at least one outside TMC), comorbidity (no comorbidity, at least one comorbidity), duration of treatment (<9 months (M), 9 M–12 M, >12 M), and stage of breast cancer (early stage (I/II), advanced stage (III/IV)) were included as disease-specific variables. For household characteristics, we used religion (Hindu/Muslim/Others), caste (general, Other Backward Class (OBC), Scheduled Caste (SC) or Scheduled Trible (ST), other), location of residence (urban, rural), distance from native place to Mumbai (<500 kilometres (kms), 501–1500 kms, >1500 kms), major source of income (agriculture, labour, self-employed, service), and monthly per capita expenditure (MPCE) (poorest, poorer, middle, richer, richest). The MPCE variable did not include the expenditure on health care as used elsewhere, the reason being that cancer households spend a large amount of money on cancer treatment, which may distort the estimates of their true MPCE. A brief description of these variables is given in Supplementary Text S3.

The variables were described using frequency tables and percentages along with mean and 95% confidence interval (CI), the median, and interquartile range (IQR). Continuous outcomes (TC and OOP) were compared between groups using the non-parametric Kruskal–Wallis test.[32] We used the Generalised Linear Models (GLMs) to estimate OOP across socio-economic and disease characteristics. Using a GLM allowed the OOP estimates to handle skewness,[33] heteroskedastic errors, and non-linear responses to covariates.[34] We considered GLMs like Gaussian family with log link, gamma family with log link, gamma inverse, etc. A model fitting algorithm was used to choose the best regression model to estimate OOP for breast cancer treatment. The model with the minimum AIC (Akkaike Information Criterion) and BIC (Bayesian Information Criterion) was chosen as the best regression model (Supplementary Table S1), which happened to be the GLM model with gamma distribution and log-link. The model is given as follows:

$$ln(E(OOP_i|X_i)) = \alpha + \sum_{k=1}^{K} \beta_k X_{ik},\ OOP_i \sim Gamma$$

where the variance function of OOP is quadratic ($(E(OOP_i|X_i))^2 \propto V(OOP_i|X_i)$), X_i denotes the various socio-demographic and economic characteristics considered in the model, α is the intercept, and β_k are the K + 1 regression coefficients.

We reported the coefficients (Supplementary Table S7) and fitted an interaction model of MPCE quintile and type of insurance (Supplementary Table S8). The analysis was performed using the Stata (16.0) software.

Role of the funding source

The funder of the study had no role in study design, data collection, data analysis, data interpretation, or writing of the report. The corresponding author had full access to all the data in the study and had final responsibility for the decision to submit the report for publication.

Results

Patient characteristics

The baseline data consisted of 500 patients who were registered for treatment at TMC. Of them, 429 had successfully completed treatment and were interviewed at the end of the treatment (referred as endline). A total of 71 patients did not complete the treatment due to death or financial and other reasons.[31] Supplementary Table S2 shows the summary characteristics of the 429 patients in the concluded sample. A majority of the patients were married and from rural areas. The mean age of the study cohort was 47 years and the mean years of schooling was 7 years. About one-fourth (24%) of the patients belonged to households whose income primarily came from daily wage labour. Thirty-one percent of the patients had a comorbidity. Two-thirds of the patients were diagnosed at an advanced stage, and 90% of all the patients completed the treatment within one year. On average, a cancer patient traveled 1066 kms for treatment. The study cohort comprised a higher proportion of patients from the subsidized payment category (non-chargeable/general) than those belonging to the full payment category (private).

Treatment cost

Table 1 presents a systematic breakdown of TC of breast cancer treatment. The average TC was ₹258,095 (95% CI: 238,255, 277,934). The primary factor of cost before coming to TMC was investigation for breast cancer diagnosis. The pattern of cost of treatment before coming to TMC was different from the pattern during treatment at TMC (Supplementary Table S3). Out of the TC, 56% could be attributed to direct medical cost and 44% to direct non-medical cost. The segmentation of TC further suggests that systemic therapy accounted for the largest share (19.7%), followed by accommodation (18.6%), travel (17.9%), and radiotherapy (13%) (Fig. 1). The breakdown of the direct medical cost suggests that systemic therapy (35.0%) was the most expensive form of treatment, while surgery (17.3%) was the least expensive form. Radiotherapy accounted for 23.1% of the direct medical cost, while investigation made up 14.6% of it. The largest proportion of direct non-medical treatment cost was composed of accommodation (42.7%) and food (40.9%) related costs (Supplementary Figure S1). The direct non-medical cost of cancer treatment increased from ₹1011 (95% CI: 832, 1191) prior to TMC to ₹112,707 (95% CI: 100,578, 124,835) during treatment at TMC (Supplementary Table S3).

Table 2 shows the socio-economic differentials in TC, OOP, and share of OOP to TC. The mean OOP was ₹186,461 (95% CI: 167,666, 205,257), accounting for 72.2% of the TC. The median OOP and median TC are shown in Supplementary Table S4. The socio-economic gradient of TC and OOP showed a significant association. The OOP ($p < 0.001$) increased linearly with the economic condition of the households (measured by MPCE quintile), distance to Mumbai ($p < 0.001$) from the native place, stage of cancer ($p = 0.044$), and duration of treatment ($p < 0.001$). The pattern was similar for TC. The mean OOP for the richest quintile was more than thrice higher than for the poorest quintile ($p < 0.001$). OOP as a share of TC varied from 61.1% in the poorest quintile to 78.4% in the richest quintile. The mean OOP for patients in the early stage of cancer was ₹164,721 (95% CI: 136,915, 192,527), which accounted for 71.2% of the TC. Patients in the advanced stage of cancer had a mean OOP of ₹195,395 (95% CI: 173,880, 223,639), which accounted for 72% of the TC. Patients who underwent less than nine months of treatment incurred almost half as much OOP as patients who were treated for more than one year ($p < 0.001$). Patients who completed the full course of treatment at TMC had a lower OOP (<0.001) and a lower TC (<0.001) compared to those who underwent at least one modality of treatment (surgery, systemic therapy, or radiotherapy) outside TMC. The pattern of cost segregation by stage showed a higher cost for systemic therapy in the advanced stage compared to the early stage (Supplementary Table S5). Over 84% patients had taken three modes of treatment and their cost was higher than those who taken only a single mode of treatment (Supplementary Table S6).

Table 3 presents the mean reimbursement and percentage reimbursed by socio-economic characteristics. Almost three-fourths of the breast cancer patients received some reimbursement, and the mean reimbursement amount was ₹71,724 (95% CI: 61,747, 81,701). The median reimbursement is shown in Supplementary Table S4. Patients belonging to the richest MPCE quintile received the highest reimbursement (₹94,040; 95% CI: 60,510, 127,569), while those

Type of costs	During treatment at TMC		
	Mean cost (in ₹)	95% CI	% Share[b]
1. Total medical cost	***145,388***	***(133,402, 157,375)***	56.3
Registration cost	247	(180, 313)	0.1
Consultation cost	1684	(1265, 2104)	0.7
Admission cost	4833	(4116, 5550)	1.9
Investigation cost	21,239	(19,486, 22,993)	8.2
Medicine cost	7751	(6720, 8782)	3.0
Surgery cost[a]	25,075	(21,385, 28,766)	9.7
Systemic therapy cost[a]	50,869	(44,391, 57,346)	19.7
Radiotherapy cost[a]	33,483	(28,873, 38,092)	13.0
2. Total non-medical cost	***112,707***	***(100,578, 124,835)***	43.7
Food cost	46,149	(41,926, 50,372)	17.9
Travel cost	18,460	(16,198, 20,723)	7.2
Accommodation cost	48,097	(39,689, 56,505)	18.6
3. Total cost (1 + 2)	***258,095***	***(238,255, 277,934)***	100.0

Note: 1 US$ = ₹73.1 at 2020 prices. [a]Only treatment naïve cases were accrued. [b]The percentage share of each cost component (registration, admission, investigation...etc) was calculated out of the total cost (100%).

Table 1: **Mean costs (in ₹) segregation of breast cancer treatment at TMC, Mumbai.**

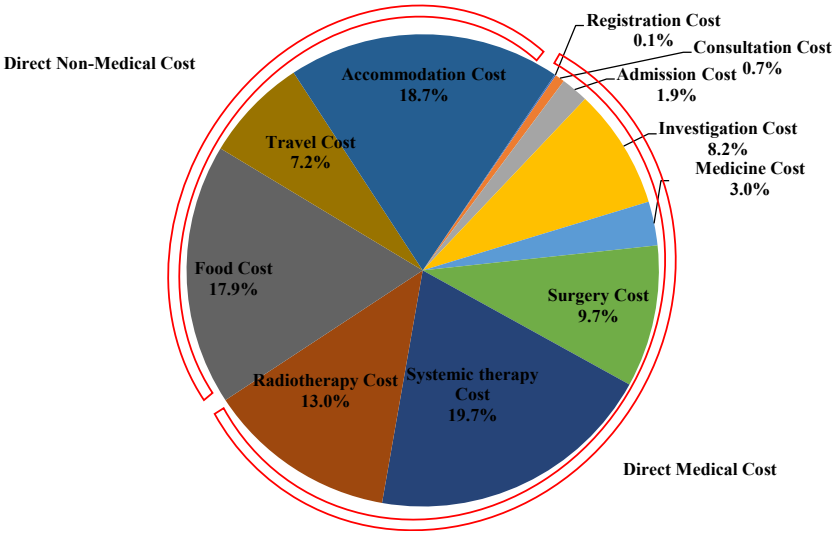

Fig. 1: **Percent distribution in cost of breast cancer by component at TMC, Mumbai.**

belong to the poorest quintile received the lowest amount (₹57,526; 95% CI: 43,531, 71,522). Compared to their respective counterparts, the share of reimbursement to total cost was higher among patients belonging to the poorest MPCE quintile (79.5%), urban patients (42%), patients belonging to SC/ST/other category (40%), patients who had labour and service as the major sources of household income (each 33%), patients whose cancer was diagnosed at an early stage (31%), and patients who completed treatment in less than nine months (37%).

Fig. 2 presents the state-wise variation in OOP and reimbursement as a share of TC among breast cancer patients. OOP was the highest for patients from Uttar Pradesh and higher for those from the other states compared to patients from Maharashtra. In contrast, the share of reimbursement was higher for patients from Maharashtra compared to patients from outside Maharashtra.

Table 4 and Fig. 3 show the sources of reimbursement. Social health insurance (SHI) schemes were the biggest source of reimbursement (33.1%), followed by charitable trusts (29.6%) and employee health insurance (5.1%). 25.6% of the patients received no reimbursement, whereas 8% received full reimbursement. Employee health insurance (58.5%) was the source of highest reimbursement as a share of TC, followed by private health insurance (57.1%) and SHI schemes like Swasthya Sathi (38.3%), MJPJAY (32.0%), and PM-JAY (28.9%).

Table 5 provides the adjusted and unadjusted mean OOP for breast cancer treatment. Controlling for the covariates, the adjusted mean OOP for breast cancer treatment was ₹188,666 (95% CI: 169,526, 207,805), higher than the unadjusted mean OOP of ₹186,461 (95% CI: 167,666, 205,257). Patients who were older, were living in urban areas, had low educational levels, belonged to the poorest or poorer quintiles, had SHI, and were in the advanced stage of cancer had a higher adjusted mean OOP than the unadjusted mean OOP. Private category patients had an adjusted mean OOP of ₹283,897 (95% CI: 228,486, 339,308), which was lower than the unadjusted mean OOP. Patients with SHI belonging to the poorest and poorer quintiles had 45% and 40% less OOP, respectively, than patients with no reimbursement in the poorest quintile. Patients with no reimbursement in the richest quintile were more likely to have more OOP than patients with no reimbursement in the poorest quintile (Supplementary Table S8). The predicted OOP was higher among patients with SHI in the poorest quintile than patients with employee/private health insurance and financial assistance from trusts. Among patients with SHI in the richer and richest quintiles, the predicted OOP was much lower than their counterparts (Supplementary Figure S2).

Discussion

This is the first ever prospective study in India that provides estimates of the cost of, OOP for, and reimbursement of cost of breast cancer treatment using a longitudinal design from the patient perspective. Our approach to data collection over multiple visits during treatment is likely to have minimized the recall bias (common in cross-sectional surveys) and double counting. The study was comprehensive as it had an adequate sample size for disaggregated analyses by socio-economic, demographic, and disease-specific characteristics. The following are the salient findings of the study.

SES variables	N	Cost of treatment at TMC (in ₹)			OOP (in ₹)			OOP as a share of TC
		Mean	95% CI	p-value	Mean	95% CI	p-value	%
Age of patients				0.026			0.177	
Up to 45 years	202	266,258	(237,607, 294,909)		188,367	(161,950, 214,784)		70.7
Over 45 years	227	250,831	(223,170, 278,492)		184,765	(157,948, 211,582)		73.7
Marital status				0.009			0.046	
Other	63	192,676	(156,627, 228,725)		124,540	(96,088, 152,993)		64.6
Currently married	366	269,355	(247,094, 291,617)		197,120	(175,791, 218,449)		73.2
Location of residence				<0.001			<0.001	
Urban	196	206,389	(182,637, 230,142)		131,193	(110,802, 151,584)		63.6
Rural	233	301,590	(271,993, 331,187)		232,953	(204,088, 261,818)		77.2
Education level				<0.001			0.002	
Never attended	99	236,252	(201,359, 271,145)		166,617	(136,225, 197,009)		70.5
Primary	36	235,438	(163,538, 307,339)		176,455	(106,896, 246,014)		74.9
Secondary	167	209,950	(188,041, 231,860)		141,081	(120,760, 161,401)		67.2
Higher secondary	50	275,740	(214,278, 337,202)		214,277	(156,430, 272,124)		77.7
Above HS	77	389,730	(322,750, 456,711)		297,013	(229,610, 364,417)		76.2
Religion				0.239			0.082	
Hindu	332	263,135	(239,598, 286,673)		189,326	(167,232, 211,421)		72.0
Muslim	80	252,210	(212,125, 292,296)		193,549	(153,028, 234,070)		76.7
Others	17	187,350	(115,262, 259,439)		97,149	(44,797, 149,501)		51.9
Caste				0.007			0.007	
General	226	287,088	(256,362, 317,814)		214,131	(184,973, 243,289)		74.6
OBC	145	239,628	(209,348, 269,908)		168,999	(140,702, 197,297)		70.5
SC/ST/Other	58	191,289	(157,426, 225,152)		122,299	(88,868, 155,730)		63.9
Distance to Mumbai				<0.001			<0.001	
<500 kms	185	164,606	(144,749, 184,463)		95,887	(80,337, 111,437)		58.3
501–1500 kms	60	348,865	(292,630, 405,100)		290,706	(230,106, 351,306)		83.3
>1500 kms	184	322,493	(289,199, 355,787)		243,534	(211,893, 275,176)		75.5
Income source				0.055			0.028	
Agriculture	54	280,074	(234,368, 325,780)		214,717	(171,665, 257,770)		76.7
Labour	103	216,336	(186,723, 245,950)		150,144	(123,667, 176,620)		69.4
Self-employed	66	300,722	(232,620, 368,824)		230,801	(168,221, 293,382)		76.7
Service	206	259,556	(229,884, 289,227)		183,007	(154,103, 211,911)		70.5
MPCE				<0.001			<0.001	
Poorest	83	147,955	(126,233, 169,677)		90,430	(72,868, 107,993)		61.1
Poorer	78	175,336	(148,825, 201,846)		115,596	(89,997, 141,196)		65.9
Middle	89	218,674	(191,974, 245,374)		152,673	(125,935, 179,412)		69.8
Richer	89	293,421	(244,702, 342,140)		215,062	(166,951, 263,173)		73.3
Richest	90	435,442	(380,660, 490,225)		341,569	(288,275, 394,863)		78.4
Type of patient				<0.001			<0.001	
General/Non-chargeable	369	210,246	(195,308, 225,183)		149,315	(135,179, 163,451)		71.0
Private	60	552,368	(478,449, 626,287)		414,910	(331,623, 498,197)		75.1
Stage of cancer				0.017			0.044	
Early stage (I/II)	155	231,335	(200,106, 262,564)		164,721	(136,915, 192,527)		71.2
Advance stage (III/IV)	274	273,233	(247,714, 298,751)		195,395	(173,880, 223,639)		72.0
Comorbidities				0.735			0.435	
No comorbidity	296	251,805	(230,358, 273,252)		182,909	(162,108, 203,710)		72.6
At least 1 comorbidity	133	272,093	(229,086, 315,101)		194,367	(154,802, 233,931)		71.4
Place of treatment				<0.001			<0.001	
TMC	243	217,448	(193,008, 241,888)		148,239	(125,711, 170,767)		68.2
At least one outside TMC	186	311,198	(279,777, 342,619)		236,397	(205,794, 267,000)		76.0

(Table 2 continues on next page)

SES variables	N	Cost of treatment at TMC (in ₹)			OOP (in ₹)			OOP as a share of TC
		Mean	95% CI	p-value	Mean	95% CI	p-value	%
(Continued from previous page)								
Duration of treatment				<0.001			<0.001	
<9 M	214	232,674	(207,563, 257,786)		156,228	(134,364, 178,092)		67.1
9 M–12 M	174	262,883	(232,652, 293,115)		196,180	(166,389, 225,971)		74.6
12 M	41	370,456	(275,925, 464,987)		303,018	(208,908, 397,128)		81.8
Total	429	258,095	(238,255, 277,934)		186,461	(167,666, 205,257)		72.2

Note: 1 US$ = ₹73.1 at 2020 prices.

Table 2: **Socio-economic differentials in the cost of treatment at TMC (in ₹), out-of-pocket payment (in ₹) and out-of-pocket payment as a share of total cost at TMC for breast cancer at TMC, Mumbai.**

First, breast cancer treatment is expensive. The average cost of breast cancer treatment, OOP payment, and reimbursement showed a strong socio-economic gradient and variation by disease characteristics. TC, OOP, and reimbursement were higher for better educated patients, those belonging to the general social group, younger patients, rural inhabitants, patients who came from states other than Maharashtra, treated as private patients, those who were diagnosed at an advance stage, and those who had co-morbidities. Second, medical cost accounted for 56.3% of the total cost of treatment at TMC. Out of the direct medical cost, the cost was the highest for systemic therapy, followed by radiation and surgery. The main contributors to the direct non-medical cost were accommodation and travel costs. Third, about three-fourths of patients got reimbursement, but it did not reduce the high OOP burden. Reimbursement accounted for 58.9% of TC for patients in the richest MPCE quintile compared to 79.5% among patients in the poorest MPCE quintile. OOP accounted for 72.2% of the total cost of treatment. Fourth, patients relied on multiple sources to get support for breast cancer treatment. Only one-third of the patients were covered by SHI schemes, which are publicly funded; only 5% patients had a private health insurance and one-fourth of all patients did not have any form of reimbursement. SHI had a larger coverage compared to private and employee health insurance, but reimbursement as a share of total cost was higher among patients with private and employee health insurance. About one-third patients were reimbursed by charitable organizations and trusts.

Finally, after controlling for socio-demographic correlates, type of insurance, co-morbidities, type of patient, economic status, stage of cancer, and duration of treatment emerged as significant predictors of OOP for breast cancer treatment.

We provide some plausible explanations in support of these findings. The high TC of and OOP for breast cancer among the richer, more educated, and non-Scheduled Caste/Tribe patients may be attributed to their ability to pay. These patients were more likely to be treated as private patients and incurred a higher direct non-medical cost. However, our finding as to higher TC and OOP among rural residents and patients from states other than Maharashtra was possibly due to distance, non-familiarity with place of treatment, and lack of social networking.[35] Patients from rural areas and those with a co-morbidity may have had limited access to insurance. The high mean and median TC and OOP observed in our study confirm the findings of previous studies that TC and OOP increase with advancing stage of the disease.[2,36–38] Advanced stage patients may need intense/additional treatment that is likely to increase the cost. Moreover, stage IV patients receive multiple lines of treatment either due to lack of adequate control of disease or due to disease recurrence. Hence their existing insurance scheme is likely to cover treatment costs only partially.

An interesting finding in our study was with regard to the respective share of cost of systemic, radiation, and surgical modalities of treating cancer, with the cost of systemic therapy being the highest, followed by the cost of radiation and surgery in that order, while most previous studies often place radiation therapy at the bottom of the list of contributors to costs of breast cancer treatment.[2,39] The higher contribution of radiation therapy to costs in comparison to previous studies in India can be explained by the adoption of newer techniques by breast radiation oncologists and, more often, curative treatment of oligometastatic disease with ablative radiation. The high contribution of systemic therapy can be explained by the increased use of targeted therapies which have been shown to contribute to 67% of the drug costs, of which trastuzumab alone accounts for 94%.[39] Hormone therapy, on the other hand, has been shown to contribute to 30% of the total spend on drugs, with letrozole and fulvestrant contributing to 65% of it in one study.[39]

Our finding as to non-medical costs accounting for 45% of the total cost is consistent with literature.[40–42] One way of interpreting the high non-medical costs in the current study could be in terms of relocation of most of the patient population to metropolitan cities for

SES variables	% Reimbursed	Reimbursement (in ₹)	
	%	Mean	95% CI
Age of patients			
Up to 45 years	76.2	77,999	(61,564, 94,435)
Over 45 years	72.7	66,140	(54,163, 78,117)
Marital status			
Others	82.5	68,216	(44,658, 91,774)
Currently married	73.0	72,328	(61,318, 83,338)
Location of residence			
Urban	79.1	75,339	(59,936, 90,743)
Rural	70.4	68,683	(55,569, 81,797)
Education level			
Never attended	77.8	69,705	(52,443, 86,966)
Primary	69.4	59,091	(25,870, 92,312)
Secondary	82.6	68,952	(56,111, 81,793)
Higher secondary	72.0	61,514	(33,127, 89,901)
Above HS	55.8	92,869	(56,505, 129,234)
Religion			
Hindu	72.3	73,892	(61,943, 85,841)
Muslim	81.3	58,780	(42,773, 74,826)
Others	82.4	90,202	(26,453, 153,950)
Caste			
General	70.4	73,049	(57,761, 88,337)
OBC	79.3	70,739	(55,895, 85,583)
SC/ST/Other	77.6	69,024	(44,603, 93,445)
Distance to Mumbai			
<500 kms	82.7	68,764	(53,994, 83,534)
501–1500 kms	58.3	58,415	(32,170, 84,659)
>1500 kms	71.2	79,040	(63,121, 94,960)
Income source			
Agriculture	74.1	65,515	(42,288, 88,743)
Labour	86.4	66,247	(51,728, 80,766)
Self-employed	65.2	69,954	(43,373, 96,535)
Service	71.4	76,657	(60,001, 93,313)
MPCE			
Poorest	79.5	57,526	(43,531, 71,522)
Poorer	83.3	59,803	(45,601, 74,006)
Middle	79.8	66,063	(48,773, 83,353)
Richer	71.9	78,506	(54,580, 102,433)
Richest	58.9	94,040	(60,510, 127,569)
Type of patient			
General/Non-chargeable	78.3	61,023	(53,760, 68,375)
Private	50.0	137,538	(84,038, 191,037)
Stage of cancer			
Early stage (I/II)	71.0	66,725	(47,871, 85,579)
Advance stage (III/IV)	76.3	74,552	(63,056, 86,048)
Comorbidities			
No comorbidity	74.3	68,988	(57,688, 80,288)
At least 1 comorbidity	74.4	77,813	(57,533, 98,093)
Place of treatment			
TMC	77.6	74,827	(57,531, 92,123)
At least one outside TMC	71.8	69,349	(57,625, 81,073)

(Table 3 continues on next page)

SES variables	% Reimbursed	Reimbursement (in ₹)	
	%	Mean	95% CI
(Continued from previous page)			
Duration of treatment			
<9 M	68.3	76,586	(60,034, 93,138)
9 M–12 M	71.0	66,754	(54,694, 78,815)
12 M	77.0	67,438	(36,549, 98,326)
Total	74.4	71,724	(61,747, 81,701)

Note: 1 US$ = ₹73.1 at 2020 prices.

Table 3: **Percentage reimbursed and mean reimbursement (in ₹) by socio-economic characteristics.**

treatment, where the cost of living is higher. This is supported by the fact that 55.2% patients at TMC came from other states of India, largely the states of West Bengal, Bihar, and Uttar Pradesh. Another reason may be the frequent number of visits required for cancer treatment, which made patients choose accommodation close to the hospital that may have been expensive.[40]

An important means of affordability of health care across all social strata is coverage via insurance/welfare schemes. Almost three-fourths of the patients in our cohort were covered under various insurance/welfare schemes or reimbursed by charitable trusts, which is very important with regard to financial risk protection. The most common source of reimbursement was social health insurance (SHI) schemes such as MJPJAY, which is a popular flagship insurance program of the Maharashtra State Government that covers any hospitalization or treatment cost up to ₹150,000 per family per year. Other such welfare schemes include PM-JAY and state-specific health schemes offered to residents by their respective states. The SHI schemes were the biggest source of reimbursement. One-third of patients undergoing treatment at our centre who were eligible for financial aid were supported by multiple charity sources, a few of which include *the Tata Trusts, the Nargis Dutt Foundation, the Madat Foundation*, and different funds of the *Indian Cancer Society*.

The share of reimbursement to TC was found to be about 27.8% in our study. This can be explained by the higher costs of cancer care and the lower cap for reimbursement under different schemes. Patients in our study were characterised by diverse socio-cultural backgrounds, educational status, and awareness/health attitudes and by residence in various states when compared to a former study which was conducted within a single state. Private insurance coverage in India has not seen a great rise in last two decades.[28,43] The low reimbursement rates among patients in our breast cancer cohort corroborate the findings of previous studies. Our study was conducted during a period when PM-JAY had just been rolled out and did not cover most of the states.

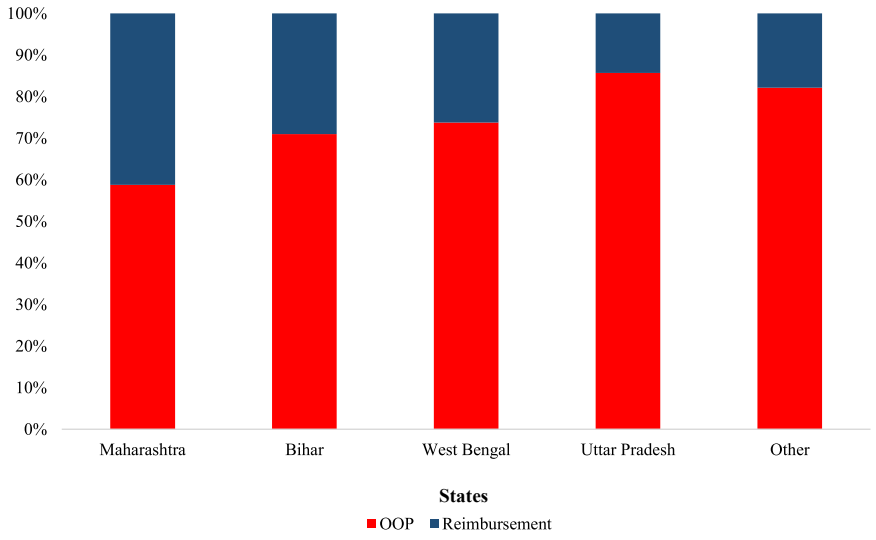

Fig. 2: **Out-of-pocket payment and reimbursement as a percentage of total cost for breast cancer treatment at TMC by state of origin.**

Type of reimbursement	N (%)	Reimbursement (in ₹)		TC of treatment (in ₹)		Reimbursement as share of TC
		Mean	95% CI	Mean	95% CI	% Share
No reimbursement	**110 (25.6)**	**NA**	**NA**	**335,152**	**(289,330, 380,975)**	NA
Social health insurance	**142 (33.1)**	**59,088**	**(50,582, 67,594)**	**147,249**	**(130,563, 163,935)**	40.1
PM-JAY/& trust[a]	11 (2.6)	71,968	(42,690, 101,247)	249,360	(156,910, 341,810)	28.9
MJPJAY only	74 (17.2)	36,386	(29,724, 43,499)	113,867	(96,257, 131,478)	32.0
MJPJAY, trust & ESIS[b]	50 (11.7)	82,649	(65,715, 99,582)	154,399	(128,589, 180,208)	53.5
Swasthya Sathi (WB)[c]	7 (1.6)	110,542	(53,695, 167,390)	288,618	(187,659, 389,577)	38.3
Employee health insurance	**22 (5.1)**	**196,632**	**(117,595, 275,669)**	**336,048**	**(238,931, 433,166)**	58.5
Private health insurance	**19 (4.4)**	**308,152**	**(207,099, 409,205)**	**539,710**	**(351,655, 727,765)**	57.1
Charitable trust/s only	**127 (29.6)**	**89,594**	**(75,652, 103,535)**	**260,799**	**(234,177, 287,421)**	34.4
Others[d]	**9 (2.1)**	**110,542**	**(53,695, 167,390)**	**241,950**	**(124,592, 359,308)**	45.7
Total	**429**	**71,724**	**(61,747, 81,701)**	**258,095**	**(238,255, 277,934)**	27.8

Note: PM-JAY: Pradhan Mantri Jan Arogya Yojana; MJPJAY: Mahatma Jyotirao Phule Jan Arogya Yojana; ESIS: Employee State Insurance Scheme, Charitable Funds includes financial help from all philanthropic sources. 1 US$ = ₹73.1 at 2020 prices. [a]Contains 5 cases where patients got reimbursement from ABY and Trust. [b]There were 2 cases of patients where they got reimbursement from ESIS & Trust along with MJPJAY, respectively. [c]Contains 4 cases where patients got reimbursement from Swasthya Sathi as well as Trust. [d]Others contain unspecified sources.

Table 4: **Type of reimbursement and its share to total cost of treatment at TMC.**

Under recent changes in PM-JAY, the cap has been enhanced to ₹500,000, which may be sufficient for breast cancer treatment.

We strongly believe this work can serve as an index measure to define the breadth of monetary coverage in SHI schemes, which, at present, does not lower the OOP reasonably. India's public health care expenditure has remained abysmally low but has increased since the launch of PM-JAY due to which the coverage of SHI schemes has increased significantly among the poorer and marginalised population in the country.[44] There is a need for automatic inclusion of cancer treatment in PM-JAY. Our work also sensitises breast cancer physicians in clinics across the country to the ongoing financial toxicity pandemic and the need to arrange for subsidies/philanthropic help locally for the vulnerable populations so that they are able to continue treatment. We suggest systematic collection of data by the National Sample Survey in the form of inclusion of cancer types, stage of disease, treatment cost, and supportive care costs. We suggest taking into consideration the rising cancer care costs, which prohibit oncologists in India from offering

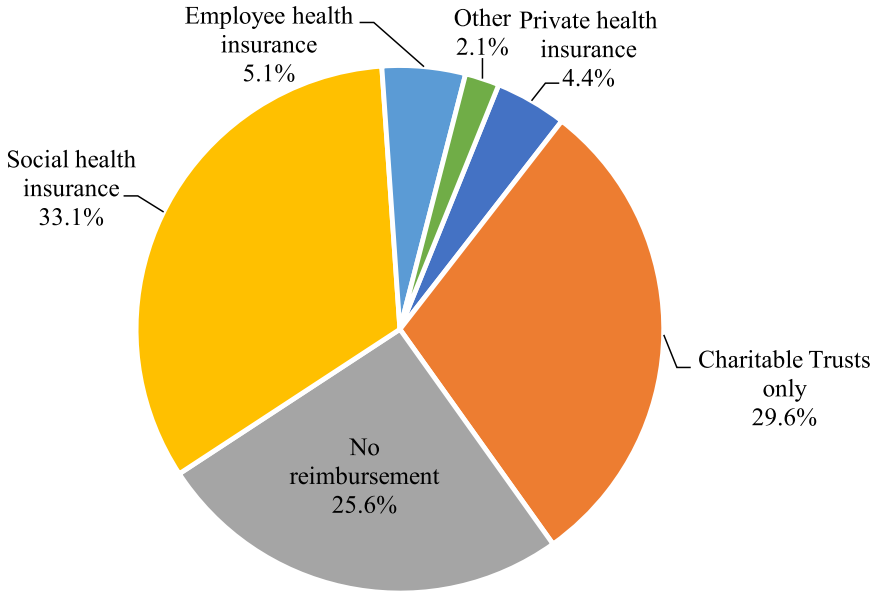

Fig. 3: **Percent distribution of source of reimbursement received by patients at TMC.**

SES characteristics	Adjusted OOP (in ₹)		Unadjusted OOP (in ₹)	
	Mean	95% CI	Mean	95% CI
Age of patients				
Up to 45 years	184,686	[160,444, 208,927]	188,367	[161,950, 214,784]
Over 45 years	192,660	[169,007, 216,313]	184,765	[157,948, 211,582]
Marital status				
Others	175,919	[141,987, 209,850]	124,540	[96,088, 152,993]
Currently married	190,168	[170,473, 209,863]	197,120	[175,791, 218,449]
Location of residence				
Urban	170,817	[146,730, 194,904]	131,193	[110,802, 151,584]
Rural	198,348	[175,631, 221,065]	232,953	[204,088, 261,818]
Education level				
Never attended	178,103	[148,014, 208,192]	166,617	[136,225, 197,009]
Primary	158,774	[116,543, 201,006]	176,455	[106,896, 246,014]
Secondary	182,539	[157,280, 207,798]	141,081	[120,760, 161,401]
Higher secondary	187,841	[150,360, 225,323]	214,277	[156,430, 272,124]
Above HS	215,471	[176,608, 254,335]	297,013	[229,610, 364,417]
Religion				
Hindu	185,915	[165,792, 206,038]	189,326	[167,232, 211,421]
Muslim	202,814	[166,814, 238,815]	193,549	[153,028, 234,070]
Others	174,479	[101,775, 247,182]	97,149	[44,797, 149,501]
Caste				
General	187,182	[164,219, 210,145]	214,131	[184,973, 243,289]
OBC	198,823	[170,438, 227,207]	168,999	[140,702, 197,297]
SC/ST/Other	167,290	[131,086, 203,493]	122,299	[88,868, 155,730]
Distance to Mumbai				
<500 kms	134,055	[109,552, 158,557]	95,887	[80,337, 111,437]
501–1500 kms	208,742	[174,152, 243,333]	290,706	[230,106, 351,306]
>1500 kms	213,587	[189,068, 238,106]	243,534	[211,893, 275,176]
Income source				
Agriculture	210,442	[170,178, 250,707]	214,717	[171,665, 257,770]
Labour	192,860	[159,770, 225,949]	150,144	[123,667, 176,620]
Self-employed	190,780	[152,429, 229,130]	230,801	[168,221, 293,382]
Service	180,268	[157,630, 202,905]	183,007	[154,103, 211,911]
MPCE				
Poorest	111,003	[89,752, 132,254]	90,430	[72,868, 107,993]
Poorer	144,909	[117,291, 172,526]	115,596	[89,997, 141,196]
Middle	188,945	[156,284, 221,606]	152,673	[125,935, 179,412]
Richer	177,612	[150,478, 204,746]	215,062	[166,951, 263,173]
Richest	263,544	[227,612, 299,477]	341,569	[288,275, 394,863]
Type of insurance				
Social health insurance	143,041	[117,509, 168,574]	88,275	[74,516, 102,034]
Employee health insurance	122,682	[69,179, 176,184]	139,551	[65,120, 213,982]
Private health insurance	130,019	[69,044, 190,994]	231,558	[59,926, 403,190]
Trust and other	161,473	[139,628, 183,318]	169,940	[146,374, 193,507]
No insurance	267,036	[236,175, 297,896]	335,229	[289,397, 381,061]
Type of patient				
General	164,067	[147,932, 180,203]	149,315	[135,179, 163,451]
Private	283,897	[228,486, 339,308]	414,910	[331,623, 498,197]
Stage of cancer				
Early stage (I/II)	166,050	[143,449, 188,651]	164,721	[136,915, 192,527]
Advance stage (III/IV)	200,312	[177,373, 223,251]	198,759	[173,880, 223,639]
Comorbidities				
No comorbidity	190,653	[169,407, 211,898]	182,909	[173,880, 223,639]
At least 1 comorbidity	184,574	[157,102, 212,045]	194,367	[162,108, 203,710]

(Table 5 continues on next page)

SES characteristics	Adjusted OOP (in ₹)		Unadjusted OOP (in ₹)	
	Mean	95% CI	Mean	95% CI
(Continued from previous page)				
Place of treatment				
TMC	203,004	[178,060, 227,947]	148,239	[125,711, 170,767]
At least one outside TMC	173,350	[150,795, 195,906]	236,397	[205,794, 267,000]
Duration of treatment				
<9 M	161,312	[141,224, 181,400]	156,228	[134,364, 178,092]
9 M–12 M	196,092	[170,784, 221,401]	196,180	[166,389, 225,971]
12 M	293,824	[232,568, 355,080]	303,018	[208,908, 397,128]
Total	188,666	[169,526, 207,805]	186,461	[167,666, 205,257]

Table 5: **Adjusted and unadjusted mean out-of-pocket payment (in ₹) for breast cancer treatment at TMC, Mumbai.**

what is called 'standard of care' treatments in the developed nations while framing the sum insured for SHI policies. A majority of our patients came to Mumbai from the other states of India to avail treatment, which raised their non-treatment costs. In this context, there is an argument that OOP could have been lower had patients availed treatment at their local place. Future research on breast cancer may focus on multicentric study and estimate the economic impact of breast cancer in the long run.

Although a longitudinal study that captured data over multiple visits, our study is not without limitations. One of the important limitations is that our study was based on a single centre that operates on a health economic model that is characterised by widespread financial help, subsidies, and social support. Few cancer institutes in the country offer financial support for patient care at such a large scale as TMC while dealing with the same cost of treatment. Such disparity in the provision of healthcare is a common occurrence in LMICs and impedes the generalisability of our findings for patients in other parts of the country. We also acknowledge that our sample may have suffered from selection bias as there was a lower representation of patients from the higher socioeconomic stratum. Such patients may have opted for treatment from private health centres, which was beyond our scope. However, even in the presence of selection bias, our estimates of cost of and OOP for treatment provide at best the lower bounds of the true estimates. Another limitation is that we included systemic therapy, which encompasses targeted therapy, hormonal therapy, and chemotherapy, which may have led to higher systemic therapy cost compared to radiotherapy and surgery costs. Lastly, we did not consider indirect costs like wage and productivity loss of patients and accompanying persons in estimation.

Contributors

TW and SKM equally contributed to the study, and both share first authors. TW is the corresponding author. The study was conceptualized by TW & SKM. The data was collected by NP & SS and analyzed by SS & SM. The first draft was prepared by SKM, SS, TW, SM, & TS. This was followed by editing of the final draft by SM, SKM, TW, TS, SG, RS, & VP. The project administration was done by TW and SKM. All the authors read the final version of the manuscript. (SKM: Sanjay K Mohanty, SM: Suraj Maiti).

Data sharing statement

All the authors involved in the study have access to the data collected as part of this project. Sharing of the data with outside parties is at the discretion of the corresponding author and may be considered on request.

Declaration of interests

The authors declare no conflict of interest.

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Appendix A. Supplementary data

Supplementary data related to this article can be found at https://doi.org/10.1016/j.lansea.2023.100346.

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