



Prevalence and impact of financial toxicity in older patients with cancer: a prospective observational study in India

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Abstract

Purpose We aimed to assess the prevalence of financial toxicity in older Indian patients with cancer and evaluate the association with quality of life (QoL), distress, vulnerabilities in the geriatric assessment, and factors impacting financial toxicity.

Methods This was a prospective observational study at the Tata Memorial Center (Mumbai, India) in patients aged 60 years and over, planned for cancer-directed therapy. We used the COST-FACIT and CFPB Financial Well-Being Scales to assess financial toxicity. QoL was assessed with the European Organization for Research and Treatment of Cancer (EORTC) QLQ C30 questionnaire, and distress with the NCCN distress thermometer.

Results Between June 2022 and September 2023, we enrolled 953 patients. The median age was 66 (IQR 63–72) years; 277 patients (29.1%) were over 70 years old, 737 (77.3%) were male, and 135 (14.2%) had health insurance. Therapy was planned with palliative intent in 607 (63.7%) patients. The prevalence of financial toxicity was 73.7% as per the COST-FACIT scale ($n = 703$), and 66% as per the CFPB ($n = 629$). Higher financial toxicity on the COST-FACIT scale was associated with poor financial well-being on the CFPB scale. Financial toxicity was associated with poor QoL and higher distress. Factors associated with significantly greater financial toxicity included history of tobacco chewing, monthly family income less than ₹50,000, lack of health insurance, illiteracy, depression, and cognitive impairment.

Conclusions Identifying the factors contributing to financial toxicity will help make the cancer treatment journey smoother, more accessible and improve compliance to therapy for older patients.

Clinical Trial Registration ClinicalTrials.gov Identifier: CTRI/2020/04/024675.

Keywords Financial toxicity · Geriatric · COST-FACIT · Palliative

Introduction

The World Health Organization (WHO) predicted that by the year 2050, 2.1 billion of the world's population will be 60 years or older. About two-thirds of these older individuals will be living in low-and middle-income countries (LMICs) [1]. In India, there were 149 million people aged 60 years and older in 2022, comprising around 10.5% of the country's population. By 2050, this proportion of older people is expected to double to 20.8% which will be approximately 347 million people [2]. In India, the incidence of cancer is likely to increase from 1.46 million in 2022 to 1.57 million

in 2025. One in nine people is estimated to develop cancer in their lifetimes [3].

The treatment of cancer is often a long-term process, which exacts a physical and emotional toll not only on the patients but also their caregivers. This is even more apparent in LMICs, where the available resources are scarce in proportion to the population served. The financial burden experienced by patients undergoing cancer treatment and the deleterious effects of such treatments on the financial security of the patient are often referred to as financial toxicity [4]. The financial toxicity of cancer care is an area of research that is ever-growing in importance [5–7]. As newer and more effective therapeutic options are discovered, often with exorbitant price tags, the financial burden faced

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by patients continues to increase. In LMICs, access to even basic chemotherapeutic drugs, supportive care medicines, testing modalities, machines, and other facilities is limited [8–10]. As per a recent report, 32–57.7% of cancer medicines on the WHO Essential Medicines list were available in LMICs, only if patients were willing to incur their full costs [11]. Thus, even standard therapies impose a heavy financial burden. This burden is particularly felt by older people, many of whom are retired from their primary occupation and are dependent on their savings or on their families for financial assistance for therapy. Older adults with cancer are at higher risk of financial toxicity than those receiving treatment for other chronic diseases [12]. Studies conducted in the United States of America (USA) found that patients experiencing financial toxicity developed higher rates of distress and a poor self-image [13]. However, many of the studies on financial toxicity have been conducted in countries where most healthcare funding is through health insurance. Around 69% of households in India face financial insecurity and vulnerability; the average monthly household income in 2024 was ₹35,000 for metropolitan cities and ₹32,000 for tier-1 and tier-2 cities [14]. In India, insurance coverage is not widespread, with insurance companies covering only 37% of the population as per a recent study, 78% of whom were covered by public insurance companies [15]. Health insurance ownership is higher in urban populations (40.97%) compared to the rural populations (29.87%). Among both rural and urban populations, health insurance ownership is higher among those with a higher income [16]. Most patients' healthcare expenses in LMICs like India are borne out-of-pocket [17, 18]. A WHO global survey on the inclusion of cancer care in health-benefit packages showed that people living in lower income countries were unable to access even the basics of cancer care [19].

Thus, reports on financial toxicity experienced by patients in countries with more prevalent insurance coverage may not accurately reflect the scenario in LMICs like India. A previous publication by Bobby et al. detailed the financial toxicity in cancer care in India [18]. A study by Dar et al. also explored the factors that contributed to financial toxicity in patients with cancer who were receiving radiation therapy [20]. However, as far as we know, no study has specifically evaluated the financial toxicity faced by older Indian patients with cancer. We, therefore, conducted this study to understand the prevalence of financial toxicity in older Indian patients with cancer using various validated scales, including the Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy (COST-FACIT) and the Consumer Financial Protection Bureau (CFPB) scale. We also aimed to assess the impact of financial toxicity on the quality of life (QoL) of older patients with cancer, the level of distress caused, and the factors impacting financial toxicity.

Materials and methods

General study details

This prospective observational study was conducted between June 2022 and September 2023 at the Tata Memorial Hospital, a tertiary care cancer center in Mumbai, India. In June 2018, we started a specialized multidisciplinary geriatric oncology clinic in the Department of Medical Oncology [21, 22]. The assessment team includes medical oncologists, geriatricians, clinical pharmacologists, social workers, psycho-oncologists, dieticians, physiotherapists, and occupational therapists. Patients aged 60 years and over, with a diagnosis of malignancy who are either being planned for cancer-directed therapy or have recently been started on therapy are referred to the geriatric oncology clinic for a geriatric assessment (GA) and recommendations/interventions. We maintain a prospective database of patients attending and undergoing evaluation in the geriatric oncology clinic. The study was approved by the Institutional Ethics Committee, and written informed consent was obtained from all patients enrolled in the study. The study was registered with the Clinical Trials Registry-India (CTRI/2020/04/024675). We adhered to the ethical guidelines outlined in the Declaration of Helsinki, Good Clinical Practice Guidelines and those established by the Indian Council of Medical Research. No funding was utilized for this study.

Participants

We enrolled all consecutive patients who were evaluated in the geriatric oncology clinic during the timeframe of the study, and had filled out the financial toxicity scales. Patients for whom these data were not available were excluded.

Variables of interest

Our primary objective was to assess the prevalence of financial toxicity in older Indian patients with cancer. Our secondary objectives were to study the association of the financial toxicity scores with QoL, and the extent to which financial toxicity was associated with patients' distress as measured by the National Comprehensive Cancer Network (NCCN) Distress Thermometer. We sought to identify factors that were associated with worse financial toxicity and the correlation of financial toxicity with various geriatric domains including psychological well-being as measured by the Geriatric Depression Scale-Short Form (GDS-SF) and Generalized Anxiety Disorder-7 (GAD-7) questionnaire; cognition by the Mini-Mental State Examination (MMSE); nutrition by the Mini-Nutritional Assessment (MNA); function by

the Lawton Instrumental Activities of Daily Living (IADL); Timed-Up and Go (TUG) test and hand grip strength; and caregiver burden by the Zarit Caregiver Burden Scale [23].

Geriatric assessment (GA)

Patients underwent a multidisciplinary GA which included recording their demographic details and anthropometric measurements [24]. We followed the American Society of Clinical Oncology (ASCO) [25] and the International Society of Geriatric Oncology (SIOG) [26] guidelines for conducting the GA. Patients were interviewed and asked to fill out various questionnaires (help was provided by the assessing clinician and/or a volunteer, if necessary). Disease-related and treatment-related information was recorded during the assessment. We assessed various geriatric non-oncologic domains, including comorbidities, cognition, nutrition, psychological well-being, potentially inappropriate medications (PIM), polypharmacy, function, falls, social support, caregiver burden, the predicted risk of chemotherapy-related toxicity, and the non-oncologic life-expectancy. Additional details of GA domains tested, questionnaires used, scores and cut-offs are provided in Supplementary Table 1.

Measuring financial toxicity

We asked patients the question, “How will the cost of your treatment be covered?” and recorded the answers. We used the COST-FACIT [27] and CFPB Financial Well-Being Scales to objectively assess financial toxicity [28]. COST-FACIT comprises 12 questions, of which 11 items are scored, and the 12th question is a summary item (“My illness has been a financial hardship to my family and me”). The COST-FACIT questionnaires have been validated in English as well as in Hindi and Marathi, which are the common regional languages spoken by patients who visit our hospital; we used these translated versions [29]. The COST-FACIT questionnaire is scored from 0 to 44, and the scores are categorized as follows: ≥ 26 = no impact/grade 0, 14–25 = mild impact/grade 1, 1–13 = moderate impact/grade 2, and 0 = severe impact/grade 3 [30]. CFPB scores are reported on a scale of 0–100, with 100 implying the best financial well-being, and 0 representing the worst financial well-being. For analysis, scores were grouped as follows: ≤ 50 = poor financial well-being; > 50 = good financial well-being [31].

Quality of life (QoL)

We used the European Organization for Research and Treatment of Cancer (EORTC) general QoL form: QLQ-C30 [32] to record the QoL data. Three questions on the EORTC

QLQ-C30 questionnaire: Item 28 (“Has your physical condition or medical treatment caused financial difficulties?”), Items 29 and 30 (the Global Health Status questions: Item 29: “How would you rate your overall health during the past week?” and Item 30: “How would you rate your overall quality of life during the past week?”) were separately analyzed. The QoL scores in individual domains were also calculated.

Measuring distress

The NCCN Distress Thermometer was used to grade the distress faced by patients. As per the NCCN recommendation, a distress thermometer score ≥ 4 was used to identify distress in patients with cancer [33].

Statistics

No formal sample size calculation was performed for this study. We included all patients who fulfilled the eligibility criteria and whose data were available. Descriptive analysis was used to summarize the data. Continuous variables were presented as mean \pm standard deviation (SD) or median (interquartile range [IQR]) based on the normality of the data. Categorical data were presented as numbers (percentages). Normality of the data was assessed using the Shapiro–Wilk/Kolmogorov test depending on the number of patients in the cohort being tested. The Chi-square test was used to evaluate the association of COST-FACIT grades and CFPB scores with the baseline characteristics, treating grades as categorical variables to estimate proportions. Thus, for the purpose of analysis, COST-FACIT and CFPB scores were grouped, rather than using the raw scores. CFPB scores were grouped as follows: ≤ 50 = lesser financial well-being; > 50 = greater financial well-being. COST-FACIT grades were categorized into “low financial toxicity” (grades 0 and 1) and “high financial toxicity” (grades 2 and 3). The goal of our analysis was to assess the association between financial toxicity (COST-FACIT categories) and financial well-being (CFPB categories) without explicitly modelling the ordinal structure. The Chi-square test was, thus, appropriate for identifying associations between categorical variables, as it determined whether the observed distribution of financial well-being differed across financial toxicity categories. Our analysis centered on the distribution of patients across predefined categories, and not on the relative ranks or magnitude of differences. The Chi-square test results have been presented as counts and percentages within each category. While the ordinal nature of the variables is recognized, the Chi-square test remains a valid method for analyzing categorical data. For the QoL analysis, the median and IQR of QoL scores were calculated according to the EORTC QLQ scoring manual. Scores that were equal to or greater than the median were considered normal, while scores below

the median were considered abnormal. To compare the QoL scores between two groups (CFPB score groups), we used the Mann–Whitney *U* test. For comparisons across multiple groups (COST-FACIT grade groups), the Kruskal–Wallis test was used. For regression analysis, binary logistic regression was performed with the various clinicodemographic characteristics, QoL, and geriatric assessment domains as the independent variables and financial toxicity, i.e., CFPB and COST-FACIT groups as dependent variables, categorized into “greater financial well-being” versus “lesser financial well-being” and “high financial toxicity” versus “low financial toxicity,” respectively. Univariate logistic regression identified significant factors, which were then included in a multivariate model to obtain adjusted odds ratios (ORs) with 95% confidence intervals (CIs). All statistical analyses were two-sided, and significance was set at a *P* value < 0.05. Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 25.0. Armonk, NY: IBM Corp., R, and RStudio 2024.04.2 version.

Results

Demographic, disease, and financial status details

Between June 2022 and September 2023, 1168 patients were evaluated in the geriatric oncology clinic, of whom 953 patients (81.6%) filled out the financial toxicity forms and were enrolled in the study. The median age was 66 (IQR, 63–72) years; 277 patients (29.1%) were over 70 years old, and 737 (77.3%) were male. Therapy was planned with palliative intent in 607 (63.7%) patients. The median monthly family income was ₹47,969, shared between a median of 5 (IQR, 3–6) family members (Table 1). There were 818 (85.8%) patients with no health insurance; 44 (4.6%) had private insurance, and 91 (9.5%) had government insurance.

Financial toxicity scores

COST-FACIT

The prevalence of financial toxicity as per the COST-FACIT was 73.7% (*n* = 703). There were 250 (26.2%) patients who had no financial toxicity, 375 (39.3%) had grade 1 financial toxicity (mild impact), 299 (31.4%) had grade 2 (moderate impact), and 29 (3.0%) had grade 3 (high impact) (Table 2).

CFPB

The prevalence of financial toxicity, i.e., poor financial well-being as per the CFPB was 66% (*n* = 629). The median CFPB financial well-being score was 46 (IQR, 38–54).

Only 324 (34%) patients reported good financial well-being (Table 2).

The answers to the question, “How will the cost of your treatment be covered?” are provided in Table 2. Although only 117 (12.3%) patients initially said that they had health insurance, 18 more patients were found to be eligible for health insurance after discussion with a social worker. Thus, overall, 135 (14.2%) patients were able to pay for their healthcare expenses through health insurance.

Correlation between CFPB and COST-FACIT scores

A higher grade of financial toxicity on the COST-FACIT scale was associated with poor financial well-being on the CFPB scale (Table 3).

QoL scores and the results of the GA

The median global QoL score was 50 (IQR, 33.3–66.7). Details of the scores in the various QoL domains are provided in Supplementary Table 2. Results of the GA revealed that 350 (36.7%) patients were depressed, 117 (12.3%) had anxiety, 204 (21.4%) faced caregiver burden, and 467 (49%) experienced distress. Vulnerabilities were also noted in the domains of nutrition in 689 (72.3%) patients, cognition in 49 (5.1%), and polypharmacy in 274 (28.8%). In the domain of function, 374 (39.2%) patients had an abnormal TUG, 362 (38.0%) had impaired IADL, 622 (65.3%) had impaired left handgrip, and 600 (63.0%) had impaired right handgrip. The details of the GA are provided in Supplementary Table 3.

Factors predicting financial toxicity-univariate analysis

COST-FACIT

On univariate logistic regression, we found that the following factors were significantly associated with higher financial toxicity as measured by COST-FACIT grade group—illiteracy, poor performance status (Eastern Cooperative Oncology Group Performance Status [ECOG PS] ≥ 2; history of tobacco use (both smoked and smokeless tobacco), monthly family income below ₹50,000, lack of health insurance, and genitourinary primary tumors. Patients who were skilled/semi-skilled workers and homemakers had lower financial toxicity than farmers. Place of residence, sex, marital status, and metastatic status of the malignancy did not correlate with financial toxicity. Higher financial toxicity correlated with vulnerabilities in the geriatric domains of mood (depression and anxiety), poor function as assessed by TUG, IADL, and handgrip), and malnutrition, whereas there was no correlation with polypharmacy, comorbidity, or cognition. There was a significant correlation between financial

Table 1 Demographic, disease-related, therapy-related, and baseline financial/insurance details of the older patients with cancer enrolled in the financial toxicity study

Variable	Categories	Total in number (%) <i>n</i> = 953
Age, in years	Median [interquartile range]	66 [63, 72]
	≤70	676 (70.9)
	> 70	277 (29.1)
Sex	Male	737 (77.3)
	Female	216 (22.7)
Residence ^a	Mumbai	309 (32.4)
	Temporary accommodation	644 (67.6)
Geographic place of residence ^b	India-West zone (Maharashtra, Gujarat, Goa)	393 (41.2)
	India-East zone (Bihar, Jharkhand, Odisha, West Bengal)	307 (32.2)
	India-Central zone (Uttar Pradesh, Madhya Pradesh, Chhattisgarh, Uttarakhand)	153 (16.1)
	India-Northeast zone (Assam, Arunachal Pradesh, Manipur, Mizoram, Tripura, Meghalaya)	56 (5.9)
	India-North zone (Delhi, Himachal Pradesh, Jammu and Kashmir, Rajasthan)	26 (2.7)
	India-South zone (Telangana, Karnataka)	5 (0.5)
	Outside India (Bangladesh, Nepal, Tibet)	13 (1.4)
Marital status	Married	788 (82.7)
	Widow/widower/single	165 (17.3)
Education	Illiterate	215 (22.6)
	School	458 (48.1)
	College and higher	280 (29.4)
Comorbidity	Absent	334 (35.0)
	Present	619 (65.0)
Type of comorbidity	Hypertension	396 (41.6)
	Diabetes	260 (27.3)
	Heart disease	89 (9.3)
	Chronic obstructive pulmonary disease	40 (4.1)
	Other ^c	276 (29.0)
ECOG performance status	0–1	682 (71.6)
	≥2	271 (28.4)
Monthly family income, in ₹	Mean (standard deviation)	47,969.1 (177,884.2)
Health insurance	No	818 (85.8)
	Yes	135 (14.2)
Type of health insurance	Private	44 (4.6)
	Government	91 (9.5)
Metastatic status of the primary malignancy	Metastatic	588 (61.7)
	Non-metastatic	365 (38.3)
Intent of therapy	Palliative	607 (63.7)
	Curative	346 (36.3)
Site of primary	Head and neck	139 (14.6)
	Lung	267 (28.0)
	Esophageal	143 (15.0)
	Hepatobiliary	146 (15.3)
	Stomach	45 (4.7)
	Colorectal	43 (4.5)
	Genitourinary	143 (15.0)
	Other primary tumors ^d	27 (2.8)

Table 1 (continued)

Variable	Categories	Total in number (%) <i>n</i> = 953
Smoking status	Never-smoker	361 (37.9)
	Smoker (current or former)	373 (39.1)
	Smokeless tobacco user	219 (23.0)
Occupation (prior to retirement or current)	Farmer	241 (25.3)
	Homemaker	204 (21.4)
	Skilled/semi-skilled ^c	401 (42.1)
	Unskilled ^c	107 (11.2)

ECOG, Eastern Cooperative Oncology Group

^aResident of Mumbai: living in own house, travelling daily from the outskirts of Mumbai. Temporary accommodation: Living with relatives, or in a rented house, hotel, guesthouse, ashram (religious shelter), or homeless, i.e., living on the footpath.

^bGeographic residence of the participants was categorized according to the zonal councils of India, based on the India States Re-organization Act, 1956

^cOther comorbidities: hypothyroidism, 40 (4.2%); seizure disorder, 4 (0.4%); past history of tuberculosis, 22 (2.3%); benign prostatic hypertrophy, 21 (2.2%); past history of surgery, 135 (14.2%); stroke, 19 (1.9%); glaucoma, 1 (0.1%); pulmonary embolism, 1 (0.1%); past malignancy, 5 (0.5%); psychiatric illness, 2 (0.2%); cardiac pace-maker, 2 (0.2%); interstitial lung disease, 1 (1%); dyslipidemia, 2 (0.2%); Parkinson's disease, 6 (0.6%); asthma, 3 (0.3%); hyperuricemia, 1 (0.1%); HIV seropositive, 1 (0.1%); hepatitis B, 1 (0.1%); hepatitis C, 2 (0.2%); cirrhosis 1, (0.1%); rheumatoid arthritis, 1 (0.1%); chronic kidney disease, 5 (0.5%)

^dOther primary tumor types: Carcinoma unknown primary, 13 (1.3%); thymoma, 4 (0.4%); sarcoma, 3 (0.3%); neuroendocrine tumor, 2 (0.2%); leiomyosarcoma, 2 (0.2%); mesothelioma, 2 (0.2%); melanoma, 1 (0.10%)

^eSkilled/semi-skilled: accounts and finance, business, government, law, managerial, medical, police, teaching, transport, clerical, machine operator, priest, postman, cook, welder. Unskilled: barber, craftsman, florist, furniture polisher, fruit seller, domestic helper, janitor, laborer, lift man, security guard, shepherd, sweeper, tea vendor, vegetable vendor, watchman, wood-worker, workers in: battery manufacturing, chemical factory, cloth mill, cloth shop, coal mine, cotton mill, construction, dairy, fisheries, office, steel factory, sugar mill, bookstore (categorization of the occupations was as per a publication in the Gazette of India 2009, issued by the Government of India)

toxicity and distress, as well as poor QoL in all the domains (physical, role, emotional, cognitive, and social functions) as well as in global QoL as measured by questions 28, 29, and 30.

Patients with poor financial well-being had a mean monthly family income of ₹34,245 (SD = 202,414.5) while those with good financial well-being had a mean monthly income of ₹74,612.7 (SD = 111,910.8). When correlated with the COST-FACIT grade groups, patients with no financial toxicity had a mean monthly family income of ₹85,422 (SD = 126,101), those with mild-grade financial toxicity had a mean monthly income ₹45,925.3 (SD = 259,781.8), while those with moderate or high-grade financial toxicity had a mean monthly income of ₹22,391.6 (SD = 33,687) and ₹15,241.4 (SD = 16,234.1), respectively.

CFPB

The factors associated with higher financial toxicity as measured by CFPB score groups included illiteracy, ECOG PS ≥ 2 , genitourinary primary tumors, history of smoking/smokeless tobacco use, occupation, monthly family less than ₹50,000, and lack of health insurance. Factors that did not correlate included sex, place of residence, marital status, and metastatic status of the malignancy. Higher financial toxicity

correlated with vulnerabilities in the geriatric domains of mood (depression), poor function as assessed by TUG and IADL, malnutrition, and cognitive impairment; there was no correlation with polypharmacy, anxiety, or function as measured by handgrip. Patients with comorbidities appeared to have greater financial well-being. There was a significant correlation between financial toxicity and distress, as well as poor QoL in the domains of physical, emotional, cognitive, and social functions, and in global QoL as measured by questions 28, 29, and 30, but not in role function.

Impact of financial toxicity on QoL, depression, anxiety, distress, and caregiver burden

Higher financial toxicity as measured by COST-FACIT grade groups was significantly associated with a worse QoL, both in the global QoL, and across all domains. Higher financial toxicity as measured by the COST-FACIT grade groups also showed a correlation with worse depression as measured by the GDS-SF ($P < 0.001$), worse anxiety as measured by the GAD-7 ($P < 0.001$), higher distress as measured by the NCCN Distress Thermometer ($P < 0.001$) and higher caregiver burden ($P < 0.001$). Similarly, lower CFPB scores, reflecting higher financial toxicity, were associated with worse QoL, both overall and across all domains.

Table 2 Sources of coverage for the cost of cancer-directed treatment and the impact of financial toxicity in older patients with cancer as measured by the COST-FACIT and CFPB Scores

Variable	Categories	Total in number (%) <i>n</i> = 953
How will the cost of your treatment be covered?	Family	598 (63.0)
	Own savings	121 (10.0)
	Insurance	117 (12.0)
	Borrow money from relatives	83 (9.0)
	Selling assets	19 (2.0)
	Loan	12 (1.0)
	Other	3 (0.3)
COST-FACIT scores	No impact	250 (26.2)
	Mild impact	375 (39.3)
	Moderate impact	299 (31.4)
	Severe impact	29 (3.0)
CFPB scores	Poor financial well-being (> 50)	629 (66.0)
	Good financial well-being (≤ 50)	324 (34.0)

COST-FACIT, Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy; *CFPB*, Consumer Financial Protection Bureau

COST-FACIT scores for financial toxicity were categorized as follows: grade 0=no impact (score ≥ 26), grade 1=mild impact (score 14–25), grade 2=moderate impact (score 1–13), grade 3=severe impact (score 0)

CFPB scores were reported on a scale of 0–100, with 100 implying the best financial well-being and 0 representing the worst financial well-being. For analysis, the scores were grouped as follows: Poor financial well-being: score ≤ 50, Good financial well-being: score > 50

Linear regression analysis of the COST-FACIT grade groups versus EORTC QoL scores showed a statistically significant association between the COST-FACIT groups and the EORTC QoL domains as well as questions 28 and 29 on the QoL questionnaire (Supplementary Table 4).

Higher financial toxicity as measured by the CFPB score groups also showed a correlation with worse depression as measured by GDS-SF ($P < 0.001$), higher distress as measured by the NCCN Distress Thermometer ($P < 0.001$), and greater caregiver burden ($P < 0.00$). Linear regression analysis of CFPB score groups versus EORTC QoL scores showed a statistically significant association between the CFPB score groups and the EORTC QoL domains as well as questions 28 and 29 on the QoL questionnaire (Supplementary Table 5).

Multivariate analysis

Patient-related independent variables which were significantly associated with greater financial toxicity as measured by the COST-FACIT grade groups were a history of tobacco chewing, monthly family income less than ₹50,000, lack of health insurance, depression, and poor global and social function domains of the QoL (Fig. 1). Patient-related independent variables which were significantly associated with lesser financial well-being as measured by the mean CFPB score groups were illiteracy, a history of tobacco chewing, monthly family income less than ₹50,000, lack of health insurance, depression, cognitive impairment, and global QoL (Fig. 2).

Table 3 Correlation between the financial well-being as per the CFPB scores and the financial toxicity faced by older patients with cancer as measured by the COST-FACIT scores, using the Chi-square test

Variable	Level	Number (%) of patients with poor financial well-being on CFPB (<i>n</i> = 629)	Number of patients (%) with good financial well-being on CFPB (<i>n</i> = 324)	Total (<i>n</i> = 953)	<i>P</i> value
Number of patients (%) with financial toxicity on COST-FACIT	No impact (grade 0 financial toxicity)	59 (9.4)	191 (59.0)	250 (26.2)	< 0.001 ^a
	Mild impact (grade 1 financial toxicity)	271 (43.1)	104 (32.1)	375 (39.3)	
	Moderate impact (grade 2 financial toxicity)	271 (43.1)	28 (8.6)	299 (31.4)	
	Severe impact (grade 3 financial toxicity)	28 (4.5)	1 (0.3)	29 (3.0)	

^aAs $P < 0.05$, this is statistically significant

COST-FACIT, Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy; *CFPB*, Consumer Financial Protection Bureau

COST-FACIT scores for financial toxicity were categorized as follows: grade 0=no impact (score ≥ 26), grade 1=mild impact (score 14–25), grade 2=moderate impact (score 1–13), grade 3=severe impact (score 0)

CFPB scores were reported on a scale of 0–100, with 100 implying the best financial well-being and 0 representing the worst financial well-being. For analysis, the scores were grouped as follows: Poor financial well-being: score < 50, Good financial well-being: score > 50

In the analysis, COST-FACIT and CFPB categories were compared as categorical variables. The *P* value signifies that patients with good financial well-being as per CFPB were more likely to have no or mild impact on COST-FACIT

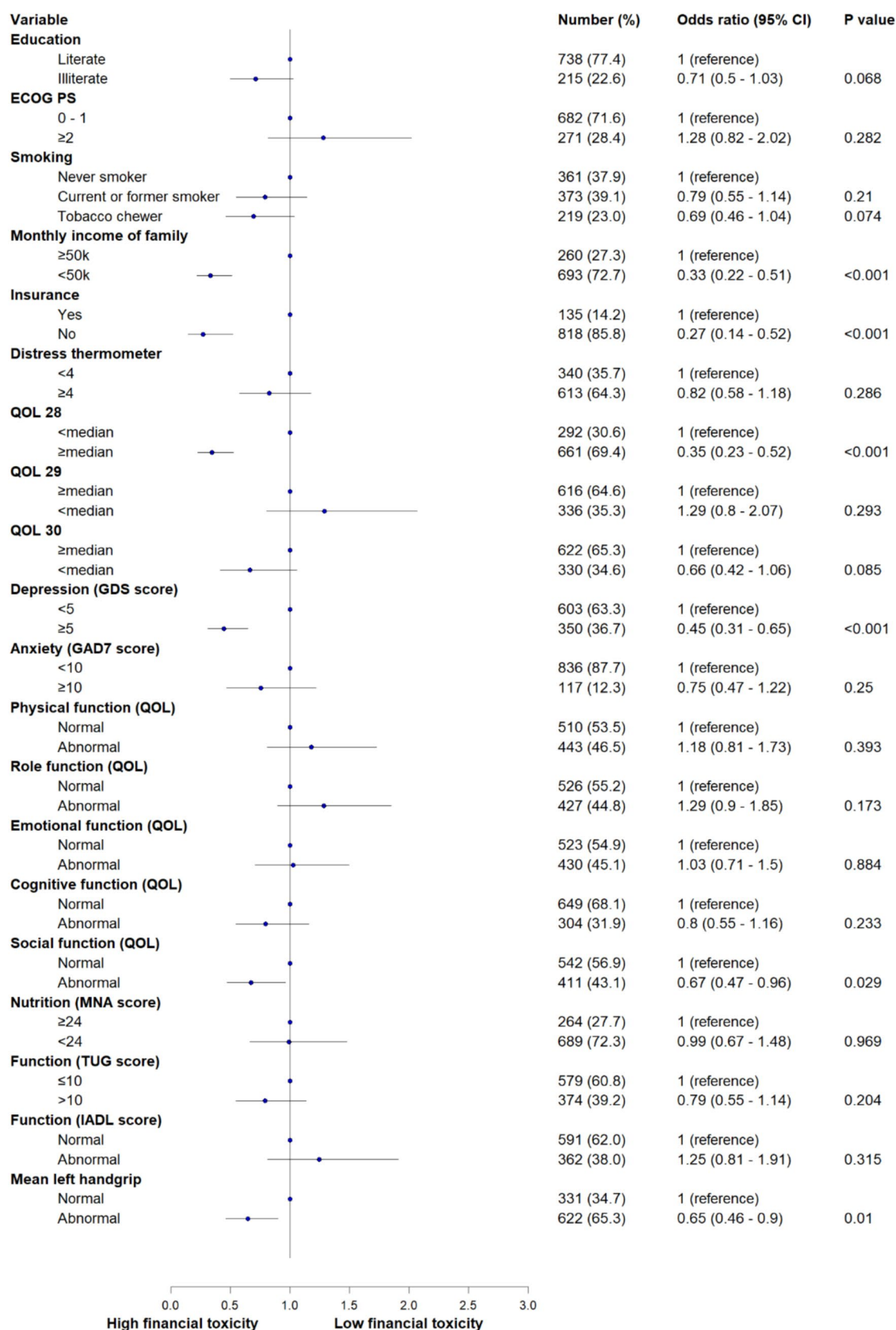


Fig. 1 Forest plot depicting the multivariate analysis of factors contributing to financial toxicity faced by older patients with cancer as measured by the COST-FACIT grade groups. (COST-FACIT, Comprehensive Score for Financial Toxicity-Functional Assessment of Chronic Illness Therapy; ECOG, Eastern Co-operative Oncology Group; ECOG, Eastern Cooperative Oncology Group; Polypharmacy- 5 or more medications; EORTC, European Organization for Research and Treatment of Cancer; QoL, quality of life; Q28, Question 28 on the EORTC Quality of Life Questionnaire-C30: “Has your physical condition or medical treatment caused you financial difficulties?”- Scoring system: 1- Not at All, 2- A little, 3- Quite a bit, 4- Very Much; Q29, Question 29 on the EORTC Quality of Life Questionnaire-C30: “How would you rate your overall health during the past week?,” scored from 1 to 7 with 1-very poor and 7-excellent; Q30, Question 30 on the EORTC Quality of Life Questionnaire-C30: “How would you rate your overall quality of life during the past week?,” scored from 1 to 7 with 1-very poor and 7-excellent, MNA, mini-nutritional assessment, MMSE, mini-mental state examination; TUG, timed-up and go; IADL, instrumental activities of daily living; GDS, Geriatric Depression Scale, GAD-7, Generalized Anxiety Disorder-7 score)

Discussion

While there have been some studies from India on financial toxicity, to the best of our knowledge, this is the first study detailing the financial toxicity faced by older patients with cancer being planned for cancer-directed systemic treatment in India. We found that between 66 and 74% of patients experienced financial toxicity, when measured by CFPB and COST-FACIT scales, respectively. The mean COST-FACIT score in our population was 18.6 (± 10.51), which was broadly similar to the score of 15.38 (± 9.18) in Indian patients receiving radiotherapy for cancer, as reported by Dar et al. [20] and the score of 16.4 (95% CI, 14.8 to 17.9) in older Mexican patients with cancer, as reported by Sanchez et al. [31]. The mean CFPB score in our population was 46.21 (± 14.93), which was also similar to the score of 45.2 (95% CI 43.3–47.1), as reported by Sanchez et al. in older Mexican patients with cancer [31]. Higher financial toxicity significantly correlated with the presence of depression, distress, and poor QoL. Thus, between two-thirds to three-quarters of older Indian patients with cancer experience financial toxicity, which may impact treatment completion, access to supportive care, emotional well-being, as well as other critical aspects that contribute to overall oncologic outcomes like obtaining adequate nutrition and transportation. This is an aspect of cancer care that is often overlooked. Understanding and characterizing financial toxicity are important aspects of providing optimal cancer-directed care.

We found a significant association between financial toxicity (as measured by both COST-FACIT and CFPB scales) and various factors like lower family income, lack of health insurance, use of smokeless tobacco, depression, and QoL. Factors found to be significantly associated with financial toxicity on only one of the two scales included function as

measured by handgrip (with COST-FACIT), and illiteracy, cognition, and distress (with CFPB). We were unable to find a statistical correlation between sex and financial toxicity in our patients, which was in contradistinction to the findings of Dar et al. who reported that female patients with cancer receiving radiation had lesser financial impact as per COST-FACIT (19.19 \pm 9.21) than men (12.28 \pm 7.79), $P < 0.001$ [20]. Contrarily, a systematic review by Lentz et al. showed that female sex was associated with higher financial toxicity [34]. We also found that educational status significantly correlated with financial toxicity. Illiterate patients were more likely to have poor financial well-being (CFPB) and higher-grade financial toxicity on the COST-FACIT scale. Conversely, patients who were educated were more likely to have good financial well-being and lower (grade 0/1) financial toxicity on the COST-FACIT scale. A similar effect of educational status on financial toxicity was seen in the study by Knight et al., that showed that a lower educational status predicted the risk of financial toxicity with a relative risk (RR) of 2.41 [35]. We found that function as measured by handgrip correlated significantly with financial toxicity. This was in agreement with the study by Giri et al. [36] which showed that patients with financial difficulties as per the Patient Satisfaction Questionnaire were more likely to report IADL dependence (OR, 1.68; 95% CI, 1.02–2.76; $P = 0.042$). We found that cognitive impairment as reflected by lower MMSE scores was significantly associated with worse financial wellbeing as per the CFPB scale. We were unable to find any other studies that have reported this correlation between poor cognition and financial toxicity. It is possible that patients with pre-existing cognitive impairment may perceive a greater degree of financial stress and may also have greater difficulty in completing logistic tasks like filling out the paperwork to apply for financial assistance and support. Nutrition as assessed by the MNA was found to correlate significantly with financial toxicity on the univariate analysis, although this was not borne out on the multivariate analysis. We could not find any previous papers where this comparison has been assessed formally. Raber et al. [37] reported that financial toxicity contributed to food insecurity in patients undergoing cancer treatment, which in turn compromised the patients' nutritional status and caused treatment interruptions. Patients with compromised nutritional status may also incur additional expenses to purchase nutritional supplements or foodstuff. Surprisingly, patients with comorbidities did not have significantly greater financial toxicity. We expected that patients with chronic medical conditions may have had greater ongoing healthcare expenditures and thus, greater financial toxicity during treatment. This was also seen in a study by Guy et al. [38]. Cancer survivors who had comorbidities had higher annual medical expenditures, especially those with heart disease (\$4595; 95% CI, 3262–5927) and stroke (\$3843; 95%

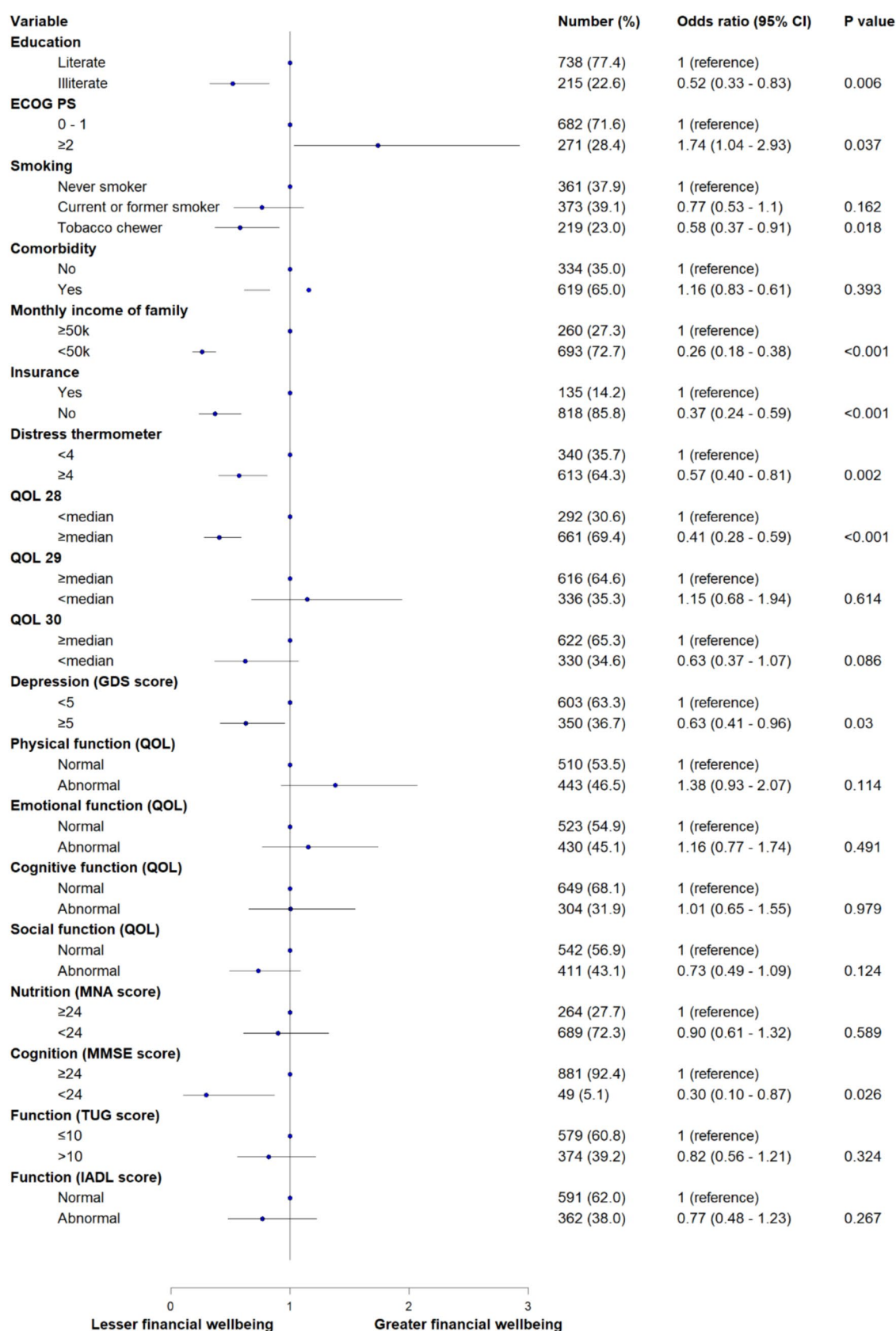


Fig. 2 Forest plot depicting the multivariate analysis of factors contributing to financial toxicity faced by older patients with cancer as per CFPB score groups. (CFPB, Consumer Financial Protection Bureau, ECOG, Eastern Co-operative Oncology Group; ECOG, Eastern Cooperative Oncology Group; Polypharmacy- 5 or more medications; EORTC, European Organization for Research and Treatment of Cancer; QoL, quality of life; Q28, Question 28 on the EORTC Quality of Life Questionnaire-C30: “Has your physical condition or medical treatment caused you financial difficulties?”- Scoring system: 1- Not at All, 2- A little, 3- Quite a bit, 4- Very Much; Q29, Question 29 on the EORTC Quality of Life Questionnaire-C30: “How would you rate your overall health during the past week?”, scored from 1 to 7 with 1-very poor and 7-excellent; Q30, Question 30 on the EORTC Quality of Life Questionnaire-C30: “How would you rate your overall quality of life during the past week?”, scored from 1 to 7 with 1-very poor and 7-excellent, MNA, mini-nutritional assessment, MMSE, mini-mental state examination, TUG, timed-up and go, IADL, instrumental activities of daily living, GDS, Geriatric Depression Scale, GAD-7: Generalized Anxiety Disorder-7 score)

CI, 1983–5704). The presence of four or more comorbidities was associated with an additional annual expenditure of \$10,280 (95% CI, 7435–13125) per cancer survivor. In our study, the multivariate analysis showed no correlation between the type of primary tumor or metastatic versus non-metastatic disease and the financial toxicity faced by patients. This was similar to the findings of a systematic review by Smith et al. [12].

In our study, financial toxicity significantly correlated with depression, distress, and poor QoL. This was similar to findings reported in the study on older American persons with cancer by Arastu et al., which showed on multivariate regression analysis that financial toxicity was associated with higher levels of depression ($\beta = 0.81$; 95% CI, 0.15–1.48), anxiety ($\beta = 1.67$; 95% CI, 0.74–2.61), distress ($\beta = 0.73$; 95% CI, 0.08–1.39), and lower health-related QoL ($\beta = -5.30$; 95% CI, -8.92 to -1.69) [39]. A German study among patients with advanced colorectal and neuroendocrine tumors showed that high financial loss relative to income was associated with a lower patient reported QoL ($P < 0.05$) and more distress ($P < 0.05$) [40]. A study from a palliative care clinic of a tertiary cancer care hospital in India also showed that there was a significant association between the financial toxicity faced by patients and lower global health-related QoL (alpha 0.05) [41]. Our findings and those of other studies suggest that interventions tailored to relieve the financial toxicity faced by older patients with cancer are likely to improve their QoL, decrease patient distress, and alleviate the caregiver burden, making the journey of cancer care an easier one.

Poor healthcare allocation and scarcity of comprehensive insurance coverage result in heavy reliance on out-of-pocket expenditure to finance cancer treatment. More than 75% of the total cancer treatment in India is financed through out-of-pocket payments by patients [18]. In our cohort of older patients with cancer, 14.2% had health insurance, which was

higher than the 4.2% figure reported by patients receiving cancer-directed radiotherapy in India by Dar et al. [20], but much less than the 100% coverage by some form of health insurance (Medicare/Medicaid/private/health savings account/Veterans Affairs, as the sole means of healthcare coverage, or in various combinations) reported by Arastu et al. [39] in older individuals from the USA with advanced cancer. We found that patients who lacked health insurance experienced significantly worse financial toxicity, as measured by both CFPB and COST-FACIT. This reflects an important unmet need in our patients. The monthly family income also correlated significantly with financial toxicity. Finally, we also found that patients facing higher financial toxicity were more likely to experience a higher degree of distress. This was similar to the findings by Yu et al. in a cohort of Chinese patients with cancer, who reported that worse financial toxicity (lower COST-FACIT score) correlated with increased psychological distress, as reflected by higher distress thermometer scores [42].

There are various financial toxicity screening tools currently accepted and validated for use. However, they require basic familiarity with the instrument and add to the time required for each patient visit. COST-FACIT is a widely used tool to measure financial toxicity [27]. This tool has already been validated internationally in the context of cancer care. We used the COST-FACIT and the CFPB Financial Well-Being Scales to assess the financial toxicity faced by our patients. The COST-FACIT scale has been validated in a pilot study in patients treated by radiation oncologists in India [20]. It has also been validated and translated at our center [29]. The CFPB scale was used in the study by Sanchez et al. from Mexico [31]. It has not been specifically validated in the Indian context; however, it is considered to be a holistic outcome metric that reflects success in consumers' own terms and allows for variation in individual preferences and goals [20]. We found a significant correlation between the COST-FACIT and CFPB financial toxicity scores, with patients having poor financial well-being as per CFPB being more likely to have a higher grade of financial toxicity on COST-FACIT. We could not find other studies where a similar correlation had been studied. As the scores on the two scales significantly correlated, this gives clinicians confidence that use of either one of the scales is acceptable and would provide an accurate assessment of the patient's financial toxicity. A limitation of this correlation may be the subjective difference in responses by the patients. A larger study focusing on the correlation between these values may help further clarify the matter.

Potential areas of intervention, as identified by our study, include financial support through trusts/social workers as well as government insurance schemes like the Mahatma Jyotirao Phule Jan Arogya Yojana [43], expanding the coverage of existing government and private insurance schemes,

geriatric interventions in the form of nutritional support including dietician consultations and supplementation, improving cognition through onco-psychological interventions, and improving function through physiotherapy and occupational therapy interventions tailored to each patient's needs. Proactively implementing these changes would be critical to reducing the financial burden faced by older patients with cancer and may help improve access to cancer care for this vulnerable group of individuals.

Our study was limited by its cross-sectional design, i.e., we assessed financial toxicity only at a single time-point at the start of treatment. Thus, we were unable to capture the trends in financial toxicity as well as the potential impact of interventions later in the treatment continuum. We found that only 3% of patients reported severe financial toxicity as graded by COST-FACIT. The reason for this is unclear. Two of the 12 questions in the COST-FACIT relate to the person's job ("I am concerned about keeping my job and income, including work at home," and "I am frustrated that I cannot work or contribute as much as I usually do"). The vast majority of patients in our study were retired and thus, these two questions would not have applied. In addition, 72% of participants reported that they planned to borrow money from family/relatives to cover the cost of cancer treatment. Perhaps, these were the reasons for the relatively low proportion of patients with severe financial toxicity noted in our study. Patients and their carers fill out the financial toxicity forms, and help is provided by a social worker to patients who need it. It is possible that the low level of financial toxicity noted in our study may have been because the forms were filled by people other than the patient themselves, or with help from the social worker. Unfortunately, we did not record how many forms were filled by the patient alone. Additionally, the study results may have been biased by the fact that so many exercises were done in terms of data collection, and that form-fatigue may have led to persons responding with incorrect answers (for example, marking "not at all" for all questions without fully reading the question). This could have falsely categorized patients by changing a possibly "severe" score to "mild" or "moderate". Considering the limitations of retrospective data, we may have been unable to entirely capture all the factors affecting financial toxicity. Another drawback is that the various tools used to assess financial toxicity as well as QoL need further validation in the Indian population and context to improve their accuracy and applicability. Given the scattered healthcare facilities in India, patients often need to travel long distances to reach hospitals for treatment and also need to arrange for housing and accommodation in cities far from their homes, often for extended periods of time. Such aspects cannot be accurately captured by tools which primarily focus on the financial implications of therapy. However, these factors are very important and play a major role in deciding the

availability and feasibility of healthcare. They need to be explored in further detail in future studies.

Conclusions

Financial toxicity affects more than two-thirds of older Indian patients with cancer being planned for cancer-directed therapy. Financial toxicity is associated with a significantly worse quality of life, depression, and distress. Patients with health insurance faced significantly less financial toxicity than those who were paying out of pocket. Identifying and attempting to modify the factors affecting and contributing to financial toxicity will help make the cancer treatment journey smoother, make treatment more accessible, and improve the compliance to therapy for older patients with cancer.

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Author contribution VN: conceptualization, methodology, resources, project administration; writing—original draft preparation; writing: review and editing.

AT: data curation, writing: review and editing, final approval.

AP: data curation, writing: review and editing, final approval.

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KP: conceptualization, methodology, project administration, supervision; writing: review and editing, final approval.

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Data availability The authors confirm that the data supporting the findings of this study are available within the article.

Declarations

Ethics approval The study was approved by the Institutional Ethics Committee. We adhered to the ethical guidelines outlined in the Declaration of Helsinki, Good Clinical Practice Guidelines and those established by the Indian Council of Medical Research.

Consent to participate Written informed consent was obtained from all patients enrolled in the study.

Competing interests The authors declare no competing interests.

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