Financial Burden Among Patients With Lung Cancer in a Publically Funded Health Care System

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Abstract

With increasing costs of cancer treatment, this study examined factors associated with financial burden (FB) in a public health care system. Two hundred patients with lung cancer completed questionnaires examining the FB of cancer treatment. Results showed that patients younger than 65 years, with high out-of-pocket costs, and with no private insurance reported significantly higher FB. Social support and financial assistance programs should target these vulnerable patient populations.

Introduction: Financial distress has been established as a clinically relevant patient-reported outcome associated with worse mortality and quality of life. Our goal was to define factors associated with financial burden (FB) in a public health care system. **Materials and Methods:** Patients with advanced lung cancer were recruited from outpatient clinics at the Princess Margaret Cancer Centre (Toronto, Canada). FB was measured with the validated Comprehensive Score for Financial Toxicity (COST) instrument, a 12-item survey scored from 0 to 44, with lower scores reflecting worse financial well-being. Data on patient and treatment characteristics, total out-of-pocket costs (OOP), and private insurance coverage were collected. Multivariable logistic regression models were fit for COST score and each variable, to determine factors associated with greater FB (COST < 21). **Results:** Of 251 patients approached, 200 (80%) participated. The median age of the cohort was 65 years; 56% were female. The median total OOP ranged between $1000 and $5000 CAD. The median COST score was 21 (range, 0-44). FB was associated with age, with patients < 65 years reporting greater FB than older patients (COST, 18.0 vs. 24.0; $P < .0001$). In multivariable logistic regression analysis, younger age was associated with greater FB, when adjusting for income, employment status, OOP, and private insurance coverage (odds ratio, 3.6; 95% confidence interval, 1.5-9.1; $P < .0001$). **Conclusion:** Age is significantly associated with FB in the Canadian (Ontario) public health care system, with younger patients with lung cancer reporting greater financial distress. This study highlights priority patient populations where FB should be routinely assessed and appropriate resources for support offered.

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Introduction

Contemporary cancer treatment has become increasingly costly and even unaffordable for a growing number of patients. The assessment of patient and caregiver financial stressors associated with cancer care has been characterized as financial toxicity, a term that encompasses both the objective fiscal insecurity and the subjective financial distress associated with cancer treatment.[1] Financial toxicity traditionally has been described in countries with third-party payer systems such as the United States.[2,3] However, patients in countries with a publically funded health care system may experience similar financial burden (FB).[4]

Longo et al identified costs for items not traditionally covered by public health care for patients with breast, colorectal, prostate, or

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lung cancer in Canada.[5,6] These FBs may also include significant travel costs in order to access treatment or clinical trials not available in their home jurisdiction, loss of income including for caregivers, and specialized molecular profiling or other testing costs. Notably, the increasing use of oral anticancer agents has led to shifts in insurance coverage, with insurers often placing expensive oral therapies on specialty tiers that carry high copayments. In the Canadian population of patients with cancer, out-of-pocket (OOP) costs can represent 20% to 25% of total financial costs.[7,8] High copayments for prescriptions have been associated with poor adherence to prescribed oral anticancer therapy.[9] In both private payer and public health care system models, financial toxicity in patients with cancer has been established as an important patient-reported outcome (PRO) with poor financial well-being associated with lower patient satisfaction, worse quality of life, and higher mortality.[10-12]

As personalized medicine and expensive novel therapies play a greater role in lung cancer care, understanding of those patient subpopulations that may be underserved by the "universal" coverage of public health care systems is urgently needed. Some have suggested that grade of financial toxicity be considered as a treatment-related adverse event, which is especially important in those patient populations most at risk of financial strain.[13] In addition, identifying the appropriate population to prioritize for screening for financial distress and support is particularly important in lung cancer, a diagnosis that has been associated with low socio-economic status.[14]

The Comprehensive Score for Financial Toxicity (COST) instrument is a validated PRO tool that was developed in the United States system to measure financial toxicity in patients with advanced solid tumors quantitatively by evaluating financial variables specific to treatment.[1,15] We sought to characterize factors associated with FB, as measured using the COST PRO tool, in patients with advanced lung cancer in the Canadian public health care system. In Ontario, not all approved cancer treatments are publically funded. Funding gaps may prompt some patients to self-pay for cancer treatments if they are not publically funded, and not available on compassionate access programs. We also examined how factors such as income, private insurance coverage, OOP costs, and type of treatment interact with FB in the context of a publically funded health care system.

Materials and Methods

Sample

Patients were eligible if they were $\geq$ 18 years of age with a diagnosis of advanced (stage IIIB/IV) lung cancer for at least 3 months. Patients or caregivers were required to be English-speaking. All eligible patients receiving systemic therapy (oral tyrosine kinase inhibitor, intravenous [IV] cytotoxic therapy, and/or immunotherapy) or suitable for consideration of systemic therapy were approached for participation. Data related to patient and treatment characteristics were collected. Patient characteristics collected included self-reported age, gender, family income source, income amount, marital status, postal code, race, country of birth, private insurance coverage, and OOP costs. For total OOP costs, patients were asked: "During the past year, about how much did you/your family spend out-of-pocket for your medical care? Include out-of-pocket expenses for prescription drugs, travel, childcare/babysitting, copayments, and deductibles, but do not include health insurance premiums or any costs paid by your health insurance." Treatment characteristics collected included type of treatment (surveillance, oral, or IV therapy), provincial funding status, and whether the patient was enrolled in a clinical trial.

Consecutive eligible patients in outpatient thoracic oncology clinics were recruited at the Princess Margaret Cancer Centre in Ontario, Canada. The Princess Margaret is one of the 5 largest cancer centers in the world and serves as the largest adult cancer referral center in Canada with a population of 36.3 million. This study received ethics approval by the University Health Network Research Ethics Board, and all participants provided informed consent. Patients were recruited from December 2017 to April 2018.

PRO Assessment

The 12-item COST tool is a validated questionnaire comprised of questions on financial satisfaction, concern about income loss, ability to meet monthly expenses, OOP costs, and control over financial situation in relation to cancer care (see Supplemental Appendix 1 in the online version).[16] The survey incorporates single-item measures of financial burden, and one global financial status scale. Scoring COST involves summing up the individual items, some of which are reverse-scored. Subsequently, the sum is divided by the number of items that contribute to the scale (ie, the number of items answered). COST scores range from 0 to 44, with lower COST scores indicating worse financial well-being. The COST questionnaire was administered at a single time point to consenting patients. Missing items in data were addressed with the COST instrument scoring algorithm.

Statistical Analysis

Demographic variables were analyzed using descriptive statistics and frequency tabulation. For participants, univariable analysis assessing associations between COST score and the collected variables was performed using the Wilcoxon and Kruskal-Wallis tests, as appropriate.

The Spearman correlation coefficient was used to assess the relation between age and COST score, and distance from the cancer center and COST score. Correlations were defined as mild if between 0.20 and 0.39, moderate if between 0.40 and 0.59, strong if between 0.60 and 0.79, and very strong if between 0.80 and 1.0.

Multivariable logistic regression models were built using the change in estimate approach, to determine factors associated with high financial burden (COST score $<$ 21 [median COST score in our sample]). Variables in the final model were selected in a stepwise fashion to include those that changed the parameter estimate of the key predictor variable by $\geq$ 10%, such as age, or those deemed clinically important to include (annual income, distance from Princess Margaret Cancer Center, type of treatment). Model fit was assessed using Hosmer-Lemeshow goodness-of-fit statistics. The statistical significance level was set at 0.05 for the model. All statistical analyses were conducted (D.E., L.L.) using SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

Of the 251 consecutive patients that were approached, 200 (80%) participated. Reasons for nonparticipation were "not

Table 1 Patient Characteristics and COST Values[a]

	Number (%) N = 200	COST Score, Median (IQR)	Univariable *P*
Age, y	< 65 (N = 98)	18.0 (13.0)	< .0001[c]
	≥ 65 (N = 101)	24.0 (14.0)	
	Range: 32-86		
Unknown	1		
Male gender	88 (44.2)	20.0 (11.0)	.63[c]
Female gender	111 (55.8)	22.0 (15.0)	
Missing	1		
Ethnicity			
White	98 (50.8)	22.0 (15.0)	.32[d]
Asian	72 (37.3)	20.0 (12.0)	
Other	23 (11.9)	19.0 (10.0)	
Unknown	7		
Married			
Yes	146 (74.5)	20.0 (14.0)	.38[c]
No	50 (25.5)	22.0 (16.0)	
Unknown	4		
Country of birth			
Canada	70 (36.1)	22.0 (14.0)	.07[c]
Other	124 (63.9)	20.0 (14.0)	
Unknown	6		
Distance from PMCC, km			
< 17	86 (43.0)	22.5 (14.0)	.09[c]
≥ 17	82 (41.0)	20.0 (11.3)	
Unknown	32		
Systemic therapy			
Not on clinical trial	163 (81.5)	20.0 (14.0)	.07[c]
Clinical trial	36 (18.0)	25.0 (11.0)	
Unknown	1		
Income source			
Employed or on pension	94 (53.1)	22.5 (12.0)	.002[c]
Unemployed	83 (46.9)	18.5 (14.0)	
Unknown	23		
Annual income[b]			
< $40,000	67 (47.2)	20.0 (13.0)	.20[d]
$40,000-80,000	45 (31.7)	20.0 (14.0)	
> $80,000	30 (21.1)	22.5 (14.0)	
Unknown	58		
Total OOP expenditures[b]			
< $1000	76 (44.2)	27.0 (17.0)	< .0001[d]
$1000-5000	64 (37.2)	18.5 (12.0)	
$5000-10,000	15 (8.7)	16.5 (15.0)	
> $10,000	17 (9.9)	17.0 (12.0)	
Unknown	28		
Private insurance			
Yes	84 (45.1)	23.0 (10.5)	.03[c]
No	102 (54.9)	19.0 (15.0)	
Unknown	14		

Lower COST score is worse.
Abbreviations: COST = COmprehensive Score for financial Toxicity; IQR = interquartile range; OOP = out-of-pocket; PMCC = Princess Margaret Cancer Centre.
[a]Lower cost values indicate higher financial burden.
[b]All values in 2018 $CAD.
[c]Wilcoxon *P*-value.
[d]Kruskal-Wallis *P*-value.

interested in research" (31 patients) and "too unwell to participate" (20 patients).

Participant demographic data and COST scores are shown in Table 1. Participants had a median age of 65 years (range, 32-86 years; mean ± standard deviation [SD], 64.3 ± 10.9 years), 56% were female, and they lived a median distance of 17 km (11 miles; range 0.35-212 km) from the cancer center. The median self-reported household income was $41,000-$80,000 CAD. The median total OOP expenditures reported by participants was between $1000 and $5000 CAD. The median COST value reported was 21 (range, 0-44; mean ± SD, 21.2 ± 10.1).

The Spearman correlation for COST score and increasing age was 0.34 ($P < .0001$), indicating that younger age is associated with worse financial well-being (lower COST score). There was a trend towards greater FB as distance from the cancer center increased (Spearman correlation coefficient, −0.14; $P = .08$).

In univariable analysis, variables associated with greater FB were age, employment status, total OOP expenditures, and private insurance (see Table 1). Univariable analysis also suggested a trend towards an association between COST scores and country of birth as well as distance from the cancer center (Table 1). There was a trend towards clinical trial patients reporting better financial well-being than those not on trial (COST score 20.0 vs. 25.0, respectively; $P = .07$). However, there was no difference in FB among patients receiving IV treatment, tyrosine kinase inhibitor, or surveillance (COST score, 20 vs. 21 vs. 20, respectively; $P = .22$).

Factors associated with greater FB (COST score < 21) are presented in Figure 1 (forest plot). Age was chosen as the key predictor variable because it demonstrated the strongest association with COST score on univariable analysis and was clinically relevant. In the multivariable analysis, the following variables were independently associated with worse financial well-being: age < 65 years (odds ratio [OR], 3.6; 95% confidence interval [CI], 1.5-9.1), OOP costs > $1000 (OR, 5.0; 95% CI, 2.0-12.1), and no private insurance coverage (OR, 3.7; 95% CI, 1.5-9.1). For OOP costs, an exposure-response relationship exists, with the odds of greater FB increasing as the OOP cost category increases (OR 4.3 at the lowest OOP cost category $1000-5000 to OR 8.8 at the highest OOP cost category). The multivariable analysis results are also shown in Table 2.

Discussion

Using the COST PRO tool, we performed a cross-sectional survey of advanced outpatients with lung cancer seen in the

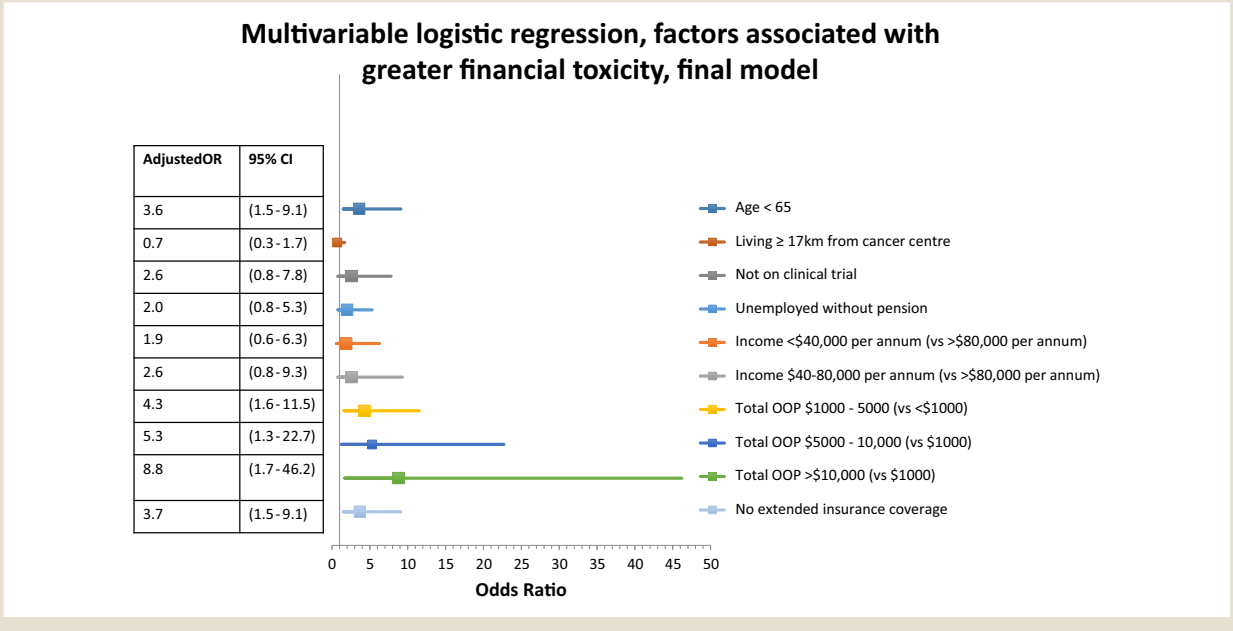
Canadian health care system to determine factors associated with FB. Our findings demonstrate that younger age, high OOP costs, and no private insurance are associated with poor financial well-being. We found that the odds of reporting financial distress are 3.6 times higher in patients younger than 65 years, a population that does not uniformly benefit from "universal" health coverage in Ontario, Canada. Patients over 65 years of age in Ontario have universal coverage of all prescription medications that are publically funded, including oral cancer drugs. In contrast, patients under 65 years of age, 50% of our study population, are subject to the unique challenges of income loss and reliance on insurance plans to cover prescribed oral anticancer treatment. It follows that lack of private insurance was also shown to be significantly associated with greater FB in our study. De Souza et al reported similar drivers of FB in the American system.[15]

High OOP costs are a key driver of financial distress, as demonstrated by our data. We found an incremental increase in the odds of reporting greater FB as the OOP cost category increased. Approximately 1 in 12 patients in our sample faced OOP costs that exceeded $10,000 CAD in the past year, and the odds of greater FB are almost 9 times higher in this group. These costs may include travel, direct payment for cancer treatment, copayments, and childcare costs required while receiving cancer care. It is reasonable to speculate that a substantial proportion of OOP costs in our study cohort were for prescription copayments, and prior data has linked type of insurance drug plan to OOP expenditures.[2] Yet we found that the majority (70%) of patients report OOP costs less than $5000. Our reported OOP costs did not differ from prior published Canadian data in the population with breast cancer reporting annual OOP costs of approximately $1300 to $2500, despite some differences in the metric of OOP expenditures and changes in the current market.[6,7] Doshi et al recently reported similar OOP costs of < $2000 in the United States, which highlights that younger patients within a publically funded system like Ontario, Canada may remain vulnerable to similar financial challenges as patients in a single-payer system.[3]

Within the publically funded health care framework, various models exist that differentially impact patient financial experience with cancer treatment. In the publically funded Italian health care system, Perrone et al report data on over 3500 patients that extends the issue of FB beyond the cost of anticancer treatment, because no copayment is required for anticancer drugs in Italy.[11] This differs from the Ontario setting, where drug copayment is required for patients < 65 years of age. However, there is substantial interprovincial variability of oral anticancer drug coverage in Canada, and the nature and extent of financial distress will likely vary between provinces. Thus, our findings of greater FB in the Ontario patient population draws attention to the need to study patient financial distress in the context of the system in which the cancer treatment is being provided. Understanding the true determinants of financial toxicity, an adverse event of cancer treatment, requires the development of a tool that focuses on the specific concerns affecting patients in a single-payer system. These drivers may include financial insecurity, loss of patient and/or caregiver income, and costs of travel, accommodation, and parking to gain access to clinical trials and therapies inaccessible in various jurisdictions.

As our knowledge of precision medicine grows in lung cancer care and other tumor sites, therapy options have expanded. Patients on oral or IV therapies may choose to pay OOP to access

Figure 1 **Forest Plot: Multivariable Logistic Regression Analysis of Factors Associated With Greater Financial Burden. This Figure Demonstrates the Adjusted ORs for Greater Financial Burden (COST Score < 21) in a Multivariable Model. The Variables of Interest Are Plotted on the Y-axis and OR With 95% Confidence Interval (CI) on the X-axis**



Abbreviations: CI = confidence interval; COST = COmprehensive Score for financial Toxicity; OR = odds ratio.

Table 2 Multivariable Analysis of Factors Associated With Greater FB (COST < 21)

	Adjusted Odds Ratio	95% CI	Multivariable *P*
Age, y			
< 65	3.6	1.5-9.1	< .0001
≥ 65 (reference)	—		
Distance from PMCC, km			
≥ 17	0.7	0.3-1.7	.461
< 17 (reference)	—		
Systemic therapy			
Not on clinical trial	2.6	0.8-7.8	.097
Clinical trial (reference)	—		
Income source			
Unemployed	2.0	0.8-5.3	.150
Employed or on pension (reference)	—		
Annual income			
< $40,000	1.9	0.6-6.3	.293
$40,000-80,000	2.6	0.8-9.3	.128
> $80,000 (reference)	—		
Total OOP expenditures			
< $1000 (reference)	—		
$1000-5000	4.3	1.6-11.5	.003
$5000-10,000	5.3	1.3-22.7	.023
> $10,000	8.8	1.7-46.2	.010
Private insurance			
No	3.7	1.5-9.1	.005
Yes (reference)	—		

Abbreviations: CI = Confidence interval; COST = COmprehensive Score for financial Toxicity; FB = financial burden; OOP = out-of-pocket; PMCC = Princess Margaret Cancer Centre.
The Hosmer-Lemeshow goodness-of-fit statistic demonstrated that our multivariable model was a good fit ($P = .21$).
A sensitivity analysis was carried out with missing values as separate categories, and the results were similar. The adjusted odds ratio for age < 65 was 3.3, 95% CI 1.5-7.0 ($P < .0001$). Distance from PMCC, income source, and annual income were included in the multivariable model for clinical importance.

breakthrough lung cancer therapies that are not yet publically funded. Our study draws light to important conversations that should start at the bedside, particularly for patients identified as "high risk" of FB. It is imperative that patient-provider conversations take place to discuss not only the clinical implications of cancer treatment, but also the financial implications, to allow for the selection of appropriate anticancer treatment to lower OOP costs.

Some limitations of our study should be noted. First, our cross-sectional design revealed consistent associations, but did not allow us to examine trends over time. Second, owing to the sensitivity of the information collected, some variables included in our model had > 10% of missing data. However, sensitivity analyses were conducted by classifying the missing variables as a separate category, and the results did not change. Additionally, the single-center nature of our study design limits the generalizability of the findings. Finally, the possibility of selection bias is felt to be minimal, given our sample comprised patients diagnosed for at least 3 months, because it often takes this length of time to determine a care plan and the ensuing financial implications, for newly diagnosed patients.

Conclusion

In conclusion, there exists a unique population of patients within publically funded health care systems that remain susceptible to the FB of cancer treatment. Our findings identify this priority patient population where FB should be routinely assessed and targeted for aid. Early recognition of financial distress in high-risk patients should prompt the intensification of support from social work and financial assistance programs to minimize, and potentially eliminate these burdens. Acknowledging financial distress in patients with lung cancer also promotes the continual support by patient advocacy groups, pharmaceutical company assistance programs, and charities. Future research will develop specific measures for financial toxicity in a publically funded health care system, define care components that induce financial toxicity, and examine how this toxicity evolves throughout cancer treatment.

Clinical Practice Points

- Financial burden (FB) is a clinically relevant patient-reported outcome that has been linked to worse quality of life and higher mortality.
- Costs of novel lung cancer drugs are rising, and FB can be seen in both private and public health care systems.
- Our study found that patients with advanced lung cancer younger than 65 reported more FB.
- We also found that higher OOP costs and lack of private insurance were also associated with greater financial distress.
- The FB of lung cancer treatment should be discussed with this high-risk subgroup of patients (younger than 65 years, high OOP, and no private insurance) and support services should be intensified.

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Disclosure

The authors have stated that they have no conflicts of interest.

Supplemental Data

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