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Evaluating meaningful levels of financial toxicity in gynecologic cancers

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HIGHLIGHTS

- Nearly half of respondents reported moderate financial toxicity (COST <26), of which a third was severe (COST <14)
- Economic cost-coping strategies were used by patients with moderate or severe financial toxicity
- Behavioral cost-coping strategies (medication non-compliance) were used by patients with severe financial toxicity

ABSTRACT

Objective The Comprehensive Score for Financial Toxicity (COST) is a validated instrument measuring the economic burden experienced by patients with cancer. We evaluated the frequency of financial toxicity at different COST levels and stratified risk factors and associations with cost-coping strategies by financial toxicity severity.

Methods We analyzed previously collected survey data of gynecologic oncology patients from two tertiary care institutions. Both surveys included the COST tool and questions assessing economic and behavioral cost-coping strategies. We adapted a proposed grading scale to define three groups: no/mild, moderate, and severe financial toxicity and used χ^2 , Fisher's exact test, and Wilcoxon rank sum test to compare groups. We used Poisson regression to calculate crude and adjusted risk ratios for cost-coping strategies, comparing patients with moderate or severe to no/mild financial toxicity.

Results Among 308 patients, 14.9% had severe, 32.1% had moderate, and 52.9% had no/mild financial toxicity. Younger age, non-white race, lower education, unemployment, lower income, use of systemic therapy, and shorter time since diagnosis were associated with worse financial toxicity (all $p < 0.05$). Respondents with moderate or severe financial toxicity were significantly more likely to use economic cost-coping strategies such as changing spending habits (adjusted risk ratio (aRR) 2.7, 95% CI 1.8 to 4.0 moderate; aRR 3.6, 95% CI 2.4 to 5.4 severe) and borrowing money (aRR 5.5, 95% CI 1.8 to 16.5 moderate; aRR 12.7, 95% CI 4.3 to 37.1 severe). Those with severe financial toxicity also had a significantly higher risk of behavioral cost-coping through medication non-compliance (aRR 4.6, 95% CI 1.2 to 18.1).

Conclusions Among a geographically diverse cohort of gynecologic oncology patients, nearly half reported financial toxicity (COST <26), which was associated with economic cost-coping strategies. In those 14.9% of patients reporting severe financial toxicity (COST <14) there was also an increased risk of medication non-compliance, which may lead to worse health outcomes in this group.

INTRODUCTION

'Financial toxicity' describes the financial hardship and associated distress that patients with cancer experience due to the costs of care.¹ It is estimated that approximately 40–70% of patients with cancer experience financial toxicity, which has been assessed using various objective (out of pocket costs, lost productivity, debt, or bankruptcy) and subjective measures (distress).^{2–4} One of the most widely used instruments to measure financial toxicity is the Comprehensive Score for Financial Toxicity (COST), a validated 11-item tool that measures financial distress as it relates to cancer diagnosis and treatment.^{5,6} Various thresholds for financial toxicity have been proposed using the COST score, often based on the median or percentile within discrete patient cohorts.^{7–9} A system proposed by the creators of the COST tool used effect sizes for quality of life scores to develop financial toxicity grades (grades 0–3) using COST scores. The grading system was further validated based on the odds of patients declaring bankruptcy within each group.⁹ Currently, there are limited data on what levels of financial toxicity measured by COST are linked to cost-coping strategies such as economic behavior change and non-compliance with medications, which can lead to clinically meaningful worse health outcomes.^{7,8}

There have been two single institution studies examining financial toxicity using the COST tool in patients with gynecologic cancer, which found that 40–50% of patients experience financial toxicity. To broaden our understanding of financial toxicity in gynecologic oncology, we combined data from these single institutional series to create a more diverse cohort of patients. First, we evaluated the frequency of financial toxicity at different COST levels and associated risk factors. Second, we measured the association of financial toxicity with meaningful cost-coping strategies, including economic behavior changes and medication non-compliance, stratified by proposed levels of financial toxicity severity.

Original research

METHODS

Study Population

Institutional Review Board approval was obtained to conduct a multi-institutional analysis of previously collected survey data from Beth Israel Deaconess Medical Center (BIDMC) from October 2017 to March 2018 and University of Alabama at Birmingham (UAB) from April 2018 to January 2019.^{7,8} Informed consent was obtained from all subjects. The initial survey studies conducted at BIDMC and UAB have been previously described.^{7,8} Briefly, patients at BIDMC were women presenting to a gynecologic oncology practice at any point in treatment, including during active therapy or surveillance. Patients at UAB were women starting a new line of therapy for new or recurrent gynecologic cancer within the last 8 weeks. At BIDMC, patients with benign and pre-cancerous diagnoses were also included in the survey; however, these patients were excluded from the current analysis.

Main Outcomes and Covariates

Financial toxicity was measured by the 11-item COST tool.⁵ The COST score can range from 0 to 44 with lower scores indicating more severe financial toxicity. We excluded respondents who did not complete at least six items based on scoring guidelines. We adapted a financial toxicity grading scale previously proposed by the creators of the COST tool to define three levels: no/mild (COST \geq 26), moderate (COST 14–25), and severe financial toxicity (COST 0–13).⁹

Economic cost-coping strategies included changing spending habits or borrowing money. Changing spending habits was measured by participant responses to the questions: “Have you spent less on basic goods or leisure activities?” (BIDMC) and “Due to your cancer diagnosis, have you had to change your spending habits?” (UAB). Borrowing money was measured by participant responses to the questions “Have you borrowed money from friends, or family, or the bank?” (BIDMC) and “Due to your cancer diagnosis, have you had to borrow money?” (UAB). Behavioral cost-coping strategies, which were collectively referred to as medication non-compliance, were measured by participant responses to the questions: “Have you delayed or avoided buying medication?” (BIDMC) and “Have you not taken medications as instructed or not refilled meds?” (UAB).

Patient and disease characteristics were abstracted from the medical record. Patient characteristics included age, race/ethnicity, partnership status, highest education level, employment status, health insurance, and household income. Disease characteristics included type of gynecologic cancer diagnosis, months since diagnosis, and history of prior treatment (any surgery, radiation, systemic treatment, or hormonal treatment).

Statistical Analysis

We compared demographic and disease characteristics between institutions and financial toxicity groups using χ^2 or Fisher's exact test for categorical variables and Wilcoxon rank sum test for continuous variables. We used Poisson regression to calculate risk ratios (RR) for cost-coping strategies comparing moderate or severe financial toxicity groups with no/mild financial toxicity, adjusting for income and insurance type (aRR).

RESULTS

Out of 240 patients surveyed at BIDMC and 121 surveyed at UAB, a total of 308 respondents met the inclusion criteria for this multi-institutional study. Patient characteristics of these study participants are stratified by institution in [Table 1](#). There was no significant difference in severity of financial toxicity based on institution ($p=0.17$) ([Table 2](#)). However, BIDMC respondents had a higher median COST score (28; IQR 21–36) than UAB respondents (24; IQR 17–31; $p=0.002$) ([Table 1](#)). Important demographic differences were noted between institutions and are summarized in [Table 1](#). There was a higher proportion of black respondents (27% vs 5%, $p<0.001$) and a lower proportion of Hispanic (0% vs 4%) and white (71% vs 84%) respondents ($p<0.001$) at UAB compared with BIDMC. Median household income was \$87 500 (IQR \$37 599–\$100 000) at BIDMC compared with \$40 000 (\$20 000–\$70 000) at UAB ($p<0.001$). Notably, there were also differences in education and employment status with BIDMC respondents more likely to have a bachelor's degree or more (63% vs 33%) and to be employed (46% vs 27%), whereas UAB respondents were more likely to be retired (54% vs 34%) (all $p<0.05$). There were no significant differences in age or partnership status. With regard to clinical factors, patients surveyed at UAB were more recently diagnosed than patients at BIDMC (7 months (IQR 2–29) vs 28 months (IQR 12–59)) ($p<0.001$), and all received systemic therapy compared with only 45% of BIDMC respondents. There were no significant differences in type of gynecologic cancer diagnosis or use of surgery, radiation, or hormonal therapies (all $p>0.05$).

Patient characteristics of study participants stratified by financial toxicity level are presented in [Table 2](#). In our cohort, 14.9% (46/308) had severe, 32.1% (99/308) had moderate, and 52.9% (163/308) had no/mild financial toxicity. When stratified by level of toxicity, the median age was significantly lower for more severe levels of financial toxicity: 63 years (IQR 56–70) in the no/mild financial toxicity group, 60 years (IQR 49–68) in the moderate financial toxicity group, and 54 years (IQR 50–61) in the severe financial toxicity group ($p<0.001$). Increasing proportions of non-white race ($p=0.003$) and lower levels of educational attainment ($p=0.03$) were seen in patients with moderate and severe financial toxicity compared with no/mild financial toxicity. Median household income in the severe financial toxicity group (median \$37 500) and moderate financial toxicity group (median \$37 500) were significantly lower than in the no/mild toxicity group (median \$87 500). Employment status ($p<0.001$) and insurance type ($p<0.001$) were also associated with severity of financial toxicity. Type of gynecologic cancer diagnosis was not associated with severity of toxicity ($p=0.24$); however, shorter time since diagnosis, undergoing cancer surgery, and use of any systemic therapy were associated with level of financial toxicity (all $p<0.05$).

Respondents with severe financial toxicity were 4.6 times (95% CI 1.2 to 18.1) significantly more likely to report medication non-compliance than those with no/mild financial toxicity after adjusting for income and insurance type. They also were significantly more likely to report changing spending habits (aRR 3.6, 95% CI 2.4 to 5.4) and borrowing money (aRR 12.7, 95% CI 4.3 to 37.1) due to the costs of cancer care. Women reporting moderate financial toxicity, however, were not more likely to report medication non-compliance than those with no/mild financial toxicity (aRR

Table 1 Demographic and disease characteristics by institution

	BIDMC (n=187)	UAB (n=121)	P value
COST score	28 (21–36)	24 (17–31)	0.002
Age	62 (53–69)	60 (52–67)	0.29
Race/ethnicity			
White/Caucasian	158 (84)	86 (71)	<0.001
Black/African American	10 (5)	33 (27)	
Hispanic/Latina/Spanish	7 (4)	0 (0)	
Other/missing	12 (6)	2 (2)	
Partnership status			
Married or partnered	115 (62)	65 (54)	0.19
Single, divorced, or widowed	70 (37)	56 (46)	
Missing	2 (1)	0 (0)	
Education level			
High school or less	21 (11)	33 (27)	<0.001
Completed some college	19 (10)	48 (40)	
Bachelor's degree or more	117 (63)	40 (33)	
Missing	30 (16)	0 (0)	
Employment			
Employed	86 (46)	33 (27)	0.002
Not employed	30 (16)	15 (12)	
Retired	65 (35)	65 (54)	
Missing	6 (3)	8 (7)	
Health insurance			
Private	99 (53)	51 (42)	<0.001
Medicare with supplement	44 (24)	39 (32)	
Medicare without supplement/military*	23 (12)	12 (10)	
Medicaid	21 (11)	10 (8)	
Uninsured	0 (0)	9 (7)	
Household income (\$)	87.5K (37.5K–100K)	40K (20K–70K)	<0.001
Diagnosis			
Ovarian	82 (44)	64 (53)	0.08
Uterine	79 (42)	34 (28)	
Cervical	22 (12)	18 (15)	
Vulvar/vaginal	4 (2)	5 (4)	
Months since diagnosis	28 (12–59)	7 (2–29)	<0.001
Treatment†			
Surgery	167 (89)	99 (82)	0.06
Radiation	38 (20)	30 (25)	0.36

Continued

Table 1 Continued

	BIDMC (n=187)	UAB (n=121)	P value
Systemic treatment	85 (45)	121 (100)	<0.001
Hormonal treatment	2 (1)	5 (4)	0.12

Data are shown as median (IQR) or number (%).

*Two respondents had military insurance.

†Treatment categories are not mutually exclusive.

BIDMC, Beth Israel Deaconess Medical Center; COST, Comprehensive Score for Financial Toxicity; K, 1000; UAB, University of Alabama at Birmingham.

1.1, 95% CI 0.2 to 4.7). Similar to patients with severe financial toxicity, patients with moderate financial toxicity did have a significantly higher risk of changing spending habits (aRR 2.7, 95% CI 1.8 to 4.0) and borrowing money (aRR 5.5, 95% CI 1.8 to 16.5), although the risk was lower (Table 3).

DISCUSSION

Summary of Main Results

Among a geographically diverse cohort of gynecologic oncology patients, nearly half reported at least moderate financial toxicity using COST score <26, of whom a third reported severe financial toxicity using COST score <14. Financial toxicity at moderate and severe levels was associated with utilization of cost-coping strategies, particularly economic behavior changes, whereas medication non-compliance was only significantly used by those with severe financial toxicity. These findings suggest that cost-coping strategies vary based on the financial toxicity level and can be used in clinical practice to proactively direct financial resources and counseling to patients.

Results in the Context of Published Literature

Nearly 50% of surveyed patients reported financial toxicity, which approximates or exceeds estimates of financial burden in broader cancer populations.^{3,4,10} Within our multi-institutional patient cohort, we also confirmed previously described risk factors for financial toxicity including younger age, lower income, insurance status, and need for systemic therapy. While many of these factors are not modifiable, they can be used to identify patients at increased risk for financial toxicity.^{3,4,7,8,10} In two systematic reviews of financial toxicity that included 25 and 50 studies, respectively, younger age was associated with higher financial toxicity.^{3,4} Younger age is a risk factor that can be readily accessed and likely contributes to financial toxicity for a variety of reasons, such as younger patients are not eligible for Medicare, diagnosis and treatment may impact their ability to work, and they have had less earning years to accumulate a financial safety net. In our current analysis, increasing financial toxicity is associated with decreasing median age (Table 2).

Strengths and Weaknesses

We sought to understand financial toxicity in a more diverse population by combining data from two very geographically distinct institutions to provide a more comprehensive understanding of how patients with gynecologic cancer are affected by financial distress. Not surprisingly, there were many differences in the

Table 2 Demographic and disease characteristics by financial toxicity level

Characteristic	All respondents n=308	Severe financial toxicity (COST 0–13) n=46	Moderate financial toxicity (COST 14–25) n=99	No/mild financial toxicity (COST ≥26) n=163	P value
Location					0.17
BIDMC	187 (61)	26 (57)	54 (55)	107 (66)	
UAB	121 (39)	20 (43)	45 (45)	56 (34)	
COST score	26 (19–34)	9 (6–11)	21 (18–23)	33 (30–38)	<0.001
Age	61 (52–69)	54 (50–61)	60 (49–68)	63 (56–70)	<0.001
Race/ethnicity					0.003
White/Caucasian	244 (79)	30 (65)	73 (74)	141 (87)	
Black/African American	43 (14)	8 (17)	20 (20)	15 (9)	
Hispanic/Latina/ Spanish	7 (2)	4 (9)	2 (2)	1 (1)	
Other/missing	14 (5)	4 (9)	4 (4)	6 (4)	
Partnership status					0.15
Married or partnered	180 (58)	23 (50)	52 (53)	105 (64)	
Single, divorced, or widowed	126 (41)	23 (50)	46 (46)	57 (35)	
Missing	2 (1)	0 (0)	1 (1)	1 (1)	
Education level					0.03
High school or less	54 (18)	10 (22)	25 (25)	19 (12)	
Completed some college	67 (22)	10 (22)	26 (26)	31 (19)	
Bachelor's degree or more	157 (51)	22 (48)	38 (38)	97 (60)	
Missing	30 (10)	4 (9)	10 (10)	16 (10)	
Employment					<0.001
Employed	119 (39)	21 (46)	30 (30)	68 (42)	
Not employed	45 (15)	13 (28)	19 (19)	13 (8)	
Retired	130 (42)	7 (15)	45 (45)	78 (48)	
Missing	14 (5)	5 (11)	5 (5)	4 (2)	
Health insurance					<0.001
Private	150 (49)	21 (46)	41 (41)	88 (54)	
Medicare with supplement	83 (27)	4 (9)	23 (23)	56 (34)	
Medicare without supplement/military*	35 (11)	6 (13)	14 (14)	15 (9)	
Medicaid	31 (10)	9 (20)	19 (19)	3 (2)	
Uninsured	9 (3)	6 (13)	2 (2)	1 (1)	
Household income (\$)	62.5K (30K–100K)	37.5K (20K–62.5K)	37.5K (30K–70K)	87.5K (50K–100K)	<0.001
Diagnosis					0.24
Ovarian	146 (47)	22 (48)	46 (46)	78 (48)	
Uterine	113 (37)	13 (28)	34 (34)	66 (40)	
Cervical	40 (13)	10 (22)	16 (16)	14 (9)	
Vulvar/vaginal	9 (3)	1 (2)	3 (3)	5 (3)	
Months since diagnosis	19 (6–47)	11 (4–38)	17 (4–41)	26 (8–55)	0.046
Treatment†					0.02
Surgery	266 (86)	36 (78)	81 (82)	149 (91)	
Radiation	68 (22)	12 (26)	26 (26)	30 (18)	0.26

Continued

Table 2 Continued

Characteristic	All respondents n=308	Severe financial toxicity (COST 0–13) n=46	Moderate financial toxicity (COST 14–25) n=99	No/mild financial toxicity (COST ≥26) n=163	P value
Systemic treatment	206 (67)	37 (80)	78 (79)	91 (56)	<0.001
Hormonal treatment	7 (2)	0 (0)	5 (5)	2 (1)	0.11

Data are shown as median (IQR) or number (%).

*Two respondents had military insurance.

†Treatment categories are not mutually exclusive.

BIDMC, Beth Israel Deaconess Medical Center; COST, Comprehensive Score for Financial Toxicity; K, 1000; UAB, University of Alabama at Birmingham.

demographic characteristics of the surveyed patients at each institution, including important risk factors for financial toxicity such as race, income, education, employment status, and insurance status. Despite these differences as well as lower median COST score at UAB compared with BIDMC, the distribution of financial toxicity levels was not significantly different at the two institutions. This suggests that, regardless of perceived risk factors, some of which are not routinely collected in the electronic health record (income, education, employment status), the COST score is a useful tool that can be broadly applied to identify gynecologic cancer patients with financial needs. Importantly, we also further assessed a proposed three-level grading system of the COST score and demonstrated that there are differences in the use of cost-coping strategies across these three groups.⁹

One of the weaknesses of our analysis is that it is a retrospective review of prospectively collected data with different inclusion criteria. At UAB, patients were surveyed who were actively undergoing systemic treatment whereas, at BIDMC, patients were surveyed who were on treatment and in surveillance regardless of type of treatment employed. These differences in methodology account for important differences in time since diagnosis and use of

systemic therapy that were noted between the two cohorts. Further, the COST tool asks respondents to recall their experience over the last 7 days. As financial toxicity is likely dynamic over the course of a patient's illness, this study is limited by the cross-sectional administration of the survey to patients at various points in their disease trajectory. Finally, although this is a more geographically diverse cohort, it remains limited to two large academic tertiary care centers and may not be representative of other health systems or regions of the country.

Implications for Practice and Future Research

Cost-coping strategies varied based on the severity level of financial toxicity. Patients with severe financial toxicity (14.9% of our cohort) had a nearly five-fold increased risk of medication non-compliance. A systematic review of the financial burden in cancer care showed that those with an increased financial burden (measured as having higher financial distress, co-pays, or prescription costs) had 1.7 increased odds of cancer medication non-compliance (95% CI 1.13 to 2.56),³ while respondents in our study with either moderate or severe financial toxicity had a significantly increased risk of using economic cost-coping strategies. Our findings suggest that patients

Table 3 Risk of cost-coping strategies for respondents with moderate or severe financial toxicity compared with respondents with no/mild financial toxicity

Financial toxicity level	N	Cost-coping strategy N (%)	Crude risk ratio (95% CI)	Risk ratio adjusted for income (95% CI)	Risk ratio adjusted for insurance (95% CI)	Risk ratio adjusted for income and insurance (95% CI)
Medication non-compliance						
No/mild	163	3 (2)	Ref	Ref	Ref	Ref
Moderate	99	3 (3)	1.6 (0.3 to 8.0)	0.9 (0.2 to 4.3)	1.6 (0.4 to 7.0)	1.1 (0.2 to 4.7)
Severe	46	8 (17)	9.4 (2.6 to 34.2)	4.2 (1.1 to 16.7)	9.2 (2.5 to 33.8)	4.6 (1.2 to 18.1)
Changed spending habits						
No/mild	163	29 (18)	Ref	Ref	Ref	Ref
Moderate	99	53 (54)	3.0 (2.1 to 4.4)	2.6 (1.7 to 4.0)	3.0 (2.1 to 4.4)	2.7 (1.8 to 4.0)
Severe	46	37 (80)	4.5 (3.2 to 6.5)	3.7 (2.5 to 5.6)	4.2 (2.9 to 6.2)	3.6 (2.4 to 5.4)
Borrowed money						
No/mild	163	4 (2)	Ref	Ref	Ref	Ref
Moderate	99	21 (21)	8.6 (3.1 to 24.4)	5.6 (1.8 to 17.4)	8.4 (3.0 to 24.0)	5.5 (1.8 to 16.5)
Severe	46	23 (50)	20.4 (7.4 to 55.9)	12.8 (4.2 to 38.9)	19.6 (6.8 to 56.3)	12.7 (4.3 to 37.1)

Original research

with COST scores <26, particularly COST scores <14, should be identified and provided with resources necessary to avoid non-compliance with medications.

Future research should incorporate these COST levels, particularly COST <14, as a threshold for severe financial toxicity to study whether compliance with recommended care (dose intensity of therapy, treatment delays, or missed appointments) and clinical cancer outcomes (time to completion of therapy, survival) differ based on severity level of financial toxicity. In addition, future studies should evaluate whether financial toxicity occurs on a continuum where proactive efforts to address financial toxicity at more mild levels have the potential to avoid the development of more severe financial toxicity and thus worse cost-coping behaviors.

CONCLUSIONS

Financial toxicity (COST <26) affects nearly half of patients with gynecologic cancer and is associated with the use of economic cost-coping strategies. Further application of a severity scale showed that those reporting the most severe financial toxicity level (COST <14) are also at increased risk for use of behavioral cost-coping strategies measured by medication non-compliance, which is particularly important to target as these types of coping behaviors may lead to worse health outcomes.

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