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Understanding financial toxicity in head and neck cancer survivors

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ABSTRACT

Objectives: (1) Describe financial toxicity (FT) in head and neck cancer (HNC) survivors and assess its association with personal/health characteristics and health-related quality of life (HRQOL); (2) examine financial coping mechanisms (savings/loans); (3) assess relationship between COmprehensive Score for financial Toxicity (COST) and Financial Distress Questionnaire (FDQ).

Patients and methods: Cross-sectional survey from January – April 2018 of insured patients at a tertiary multidisciplinary HNC survivorship clinic who completed primary treatment for squamous cell carcinoma of the oral cavity, oropharynx, or larynx/hypopharynx.

Results: Of 104 survivors, 30 (40.5%) demonstrated high FT. Patients with worse FT were more likely (1) not married (COST, 25.33 ± 1.87 vs. 30.61 ± 1.34, p = 0.008); (2) of lower education levels (COST, 26.12 ± 1.47 vs. 34.14 ± 1.47, p < 0.001); and (3) with larynx/hypopharynx primaries (COST, 22.86 ± 2.28 vs. 30.27 ± 1.50 vs. 32.72 ± 1.98, p = 0.005). Younger age (4.23, 95%CI 2.20 to 6.26, p < 0.001), lower earnings at diagnosis (1.17, 95%CI 0.76 to 1.58, p < 0.001), and loss in earnings (-1.80, 95%CI −2.43 to −1.16, p < 0.001) were associated with worse FT. COST was associated with HRQOL (0.08, *p = 0.03*). Most survivors (63/102, 60%) reported using savings and/or loans. Worse FT was associated with increased likelihood of using more mechanisms (COST, OR1.06, 95%CI 1.02 to 1.10, *p = 0.004*). Similar results were found with FDQ.

Conclusions: We found differences in FT by primary site, with worst FT in larynx/hypopharynx patients. This finding illuminates potential site-specific factors, e.g. workplace discrimination or inability to return to work, that may contribute to increased risk. FDQ correlates strongly with COST, encouraging further exploration as a clinically-meaningful screening tool.

Introduction

As payers increasingly shift health care costs to individuals, patients and their families are bearing the brunt of the ever-escalating costs of cancer care [1–3]. The financial toxicity (FT) associated with treatment is linked to poorer health-related quality of life (HRQOL), greater symptom burden, decreased adherence to treatment recommendations, and increased mortality risk [4–6]. Like the physical harms of treatment, we must acknowledge and address the financial harms. When patients are unable to manage costs, they turn to financial and non-compliance coping mechanisms. These coping strategies include the use of savings, loans, avoidance or discontinuation of prescriptions, deferment in medical care and follow-up visits, cutting back on leisure activities, reducing spending on clothing and food, and working longer hours [7].

FT may be influenced by sex, age, race, income, employment type, time since diagnosis, cancer stage, and adjuvant and anti-neoplastic therapies [7–9]. Compared to individuals with other chronic illnesses, cancer survivors have higher out-of-pocket (OOP) expenses which may persist years after diagnosis [7,10]. The economic impact of survivorship may be exacerbated by reduced income during treatment and/or recovery and health services associated with late/long-term treatment-

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related sequelae [9,10]. FT is a particularly relevant concern for head and neck cancer (HNC) patients, who may experience functional deficits after treatment which can impact survivors' ability to return to work and overall health, while requiring long-term support from a multidisciplinary team. Following treatment, up to 48% of HNC survivors reduce their workload, among whom 33% leave the workforce entirely [11].

Though numerous studies have investigated aspects of FT, there is wide variability in study methods, measures, and heterogeneity in cancer cohorts [7,9]. While previous investigations provide a foundational understanding of the economic burden associated with diagnosis and treatment in HNC they do not address FT across the survivorship trajectory or identify disease-specific risk factors [12–19].

Over a decade ago, the National Cancer Institute endorsed patient-reported outcomes (PROs) as a priority area for research [20]. Nevertheless, there remains a paucity of studies in the HNC population that utilize PROs to evaluate treatment-related symptoms or HRQOL in the context of a patient's financial burden. The COmprehensive Score for financial Toxicity (COST) is a widely used FT measure, though is lengthy to administer in clinical practice [8,21] Shorter measures, such as the Financial Distress Questionnaire (FDQ) [22], a tool devised at the University of Pittsburgh, may represent clinically-meaningful, user-friendly FT PROs, but require validation.

The main aim of this study was to describe FT in HNC survivors and assess the association of FT with patients' personal characteristics, health factors, and HRQOL. Secondary aims were to (1) examine financial coping strategies used by patients to manage the costs of care, and (2) assess the relationship between the COST and FDQ measures.

Patients and methods

Study design and cohort

This is a cross-sectional study of patient-reported FT performed from January to April 2018 at the University of Pittsburgh Medical Center Head and Neck Cancer Survivorship Clinic (Fig. 1). The study was approved by the University of Pittsburgh Institutional Review Board. To be eligible, participants must be ≥ 18 years and have completed primary treatment for squamous cell carcinoma (SCC) of the oral cavity, oropharynx, or larynx/hypopharynx. Participants were administered a survey assessing sociodemographic variables, FT, HRQOL, and financial strategies used to cope with OOP expenses. Clinical characteristics were obtained via chart review.

Among those surveyed, two survey respondents were excluded due to contradictory (non-valid) responses on the FT survey items. Respondents with private/employer based or Medicare insurance were included in the analysis sample, while Medicaid and uninsured patients were omitted due to their underrepresentation in the sample (8/114, 7.02%) and the potential for confounding variables (e.g. poorer initial health status and overall well-being, unemployment, and worse general financial burden in low-income populations). Further, patients with traditional Medicare and employer-based insurance plans represent beneficiaries with the greatest cost-sharing requirements and out-of-pocket spending [23,24].

Patient-reported outcome measures

Overview of outcome measures are summarized below, with full details and scoring listed in the Supplementary material. Two measures were used to assess FT: (1) the COmprehensive Score for financial Toxicity (COST) questionnaire and (2) the Financial Distress Questionnaire (FDQ). The 11-item COST instrument has demonstrated reliability and validity in measuring FT in cancer patients [8,21]. Responses are measured on a continuous scale (0 – 44) with lower COST scores indicating worse FT. The FDQ is a 2-item questionnaire ["Does household income meet basic needs?" (Yes/No) and "How difficult is it to pay for basic needs?" (Not at all difficult/Somewhat difficult/Extremely difficult)] developed at the University of Pittsburgh and provides a quick assessment of an individuals' level of financial ability relative to affording everyday items. The FDQ has strong face validity and has been used in numerous populations including COPD, HIV/AIDS, heart disease, and multiple cancer types [22]. FT severity was scored using an ordinal classification scheme to describe Grade 1 (mild), Grade 2 (moderate), and Grade 3 (severe) toxicity. FDQ responses were further examined as a dichotomous variable to describe low (Grade 1) or high (Grade 2 + Grade 3) toxicity.

HRQOL was assessed by the University of Washington Quality of Life Scale (UWQOL) Version-4 [18,25]. Responses are derived from 12 domains which may be averaged into two subscale scores, physical QOL (QOL_P) and social-emotional QOL (QOL_S). Scores are measured on a continuous scale (0 – 100), wherein higher scores indicated better HRQOL. The minimal clinically important difference (MCID) has been

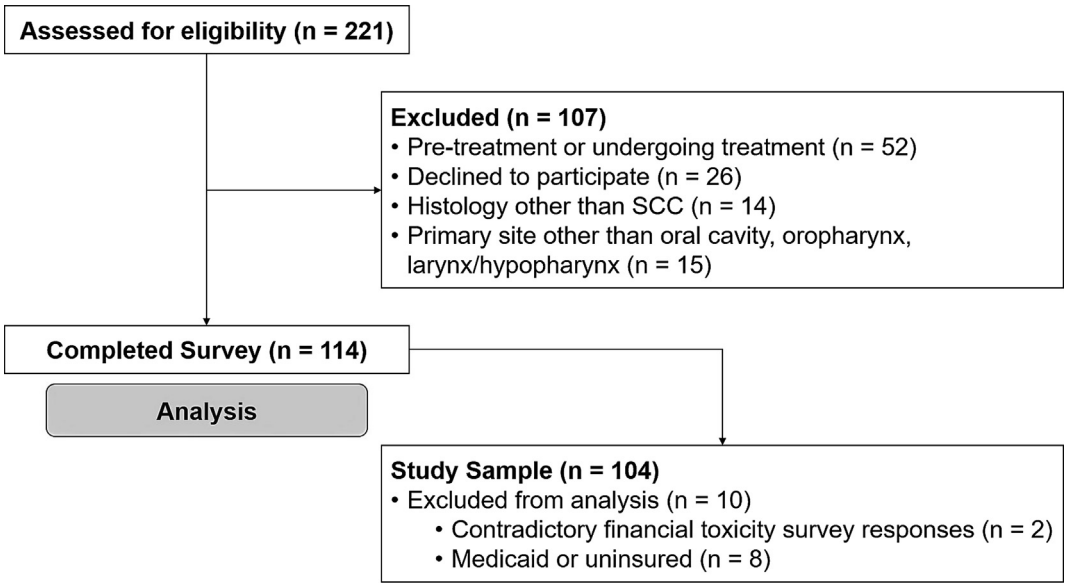

Fig. 1. Study cohort and design. Analysis represents 104 insured head and neck squamous cell carcinoma (SCC) survivors of oral cavity, oropharynx, and larynx/hypopharynx.

reported as 7-points [26,27].

Participants were surveyed regarding financial coping mechanisms used to manage treatment-related costs not covered by insurance including the use of savings, credit cards, and/or loans.

Statistical analysis

Data analysis was performed using SAS (9.4) and RStudio (1.1.419). For marital status, "not married" represents patients who were single, divorced, separated, or widowed whereas "married" included those married or living with a partner. For treatment modality "non-operative" and "adjuvant" represent radiotherapy or chemoradiotherapy. "Recurrence" included those with locoregional recurrence, distant metastasis, and/or second primaries.

COST scores are reported by the mean and standard error of the mean (SEM). Margin of error based on 95% confidence was not calculated due to observations with small sample sizes wherein asymptotic normal distribution of the mean could not be assumed. Differences in COST and FDQ by demographic and clinical characteristics were examined using Kruskal-Wallis and Fisher's Exact tests, respectively. Association between COST and FDQ were determined using constrained inference methods [28,29]. Factors associated with FT, as measured by COST, were examined using multiple linear regression modeling. Factors associated with high FT, as evaluated by FDQ, were examined using multiple logistic regression.

Since physical (QOL_P) and social-emotional (QOL_S) subscale scores were highly correlated, multivariate linear regression models were fitted to examine the association between FT (COST or FDQ) and the two HRQOL outcomes together (Supplementary material eFig. 1). Approximate F statistics generated from Roy's Greatest Root Test were used to determine significance levels.

Ordinal logistic regression analysis was performed to examine financial coping mechanisms. Since financial coping mechanisms were examined as an ordinal variable taking values from most favorable to least favorable, the cumulative probabilities for this variable were modeled as a sum from most to least favorable values.

Specification of covariates in regression models

Covariates included in multiple regression models of FT were age at the time of survey administration, time since treatment completion, earnings at diagnosis, change in earnings between diagnosis and survey administration, primary cancer site, treatment modality, and marital status. Earnings were assessed as estimated average income from employment reflected by gross/pre-tax earnings. Additional sources of patient income (e.g. unearned, retirement, social security benefits) were not captured. Inclusion of covariates were limited by sample size; as such, sex, education level, and stage were not included. Rationale for exclusion were: (1) predominantly male cohort; (2) correlation of education with earnings, which is included; and (3) correlation of stage with treatment modality, which is included. Variables examined in regression models of factors associated with HRQOL and financial coping mechanisms included COST or FDQ, age at the time of survey administration, primary site, treatment modality, and marital status.

Results

Patient characteristics and financial toxicity

Of 221 patients assessed for study eligibility, 104 survivors were included in our study (Fig. 1). Demographic and clinical characteristics, as well as COST across different patient groups are summarized in Table 1. Results by FDQ are depicted in the Supplementary material, eTable 1. Among oropharynx primaries, 45 (88.2%) had HPV-related cancer. Overall, mean COST measured 25.33 ± 1.87, with 30 (40.5%) survivors who demonstrated moderate (Grade 2) or severe (Grade 3) toxicity by FDQ. There were no significant differences in FT by age (p = 0.40). Overall, less toxicity was observed with increasing time since treatment completion, though this was not statistically significant with either measure.

Table 1
Patient characteristics and financial toxicity.

Characteristic	N = 104	COST[a] (Mean ± SEM)	P[b]
Age, median (range), y	64 (29–92)	29.03 ± 1.12	
Sex			
Female	24 (23.1%)	25.48 ± 2.55	0.09
Male	80 (76.9%)	30.03 ± 1.22	
Marital status			
Not married	32 (30.8%)	25.33 ± 1.87	*0.008*
Married	72 (69.2%)	30.61 ± 1.34	
Race/ethnicity			
White	95 (91.4%)	29.04 ± 1.17	0.95
Non-white	9 (8.6%)	28.73 ± 3.96	
Education level			
≤Associate degree	64 (62.7%)	26.12 ± 1.47	*< 0.001*
≥Bachelor's degree	38 (37.3%)	34.14 ± 1.47	
Employment (diagnosis)			
Not full time	46 (44.2%)	28.85 ± 1.75	0.97
Full time	58 (55.8%)	29.15 ± 1.45	
Insurance (diagnosis)			
Private or employer	73 (71.6%)	28.96 ± 1.38	0.92
Medicare	29 (28.4%)	29.59 ± 1.98	
Employment (visit)			
Not full time	72 (69.2%)	27.82 ± 1.46	0.21
Full time	32 (30.8%)	31.67 ± 1.48	
Insurance (visit)			
Private or employer	49 (49.5%)	29.92 ± 1.74	0.47
Medicare	50 (50.5%)	29.19 ± 1.46	
Primary site			
Oral cavity	26 (25.0%)	32.72 ± 1.98	*0.005*
Oropharynx	51 (49.0%)	30.27 ± 1.50	
Larynx/hypopharynx	27 (26.0%)	22.86 ± 2.28	
Treatment modality			
Surgery alone	24 (23.1%)	32.10 ± 1.92	0.46
Non-operative	41(39.4%)	28.39 ± 1.63	
Surgery plus adjuvant	39 (37.5%)	27.86 ± 2.11	
AJCC 7th Stage			
I-II	21 (20.8%)	30.57 ± 2.57	0.56
III-IV	80 (79.2%)	29.03 ± 1.25	
Time since treatment, y			
0 to 1	31 (30.7%)	27.45 ± 2.17	0.35
2 to 5	39 (38.6%)	27.70 ± 1.97	
≥6	31 (30.7%)	31.68 ± 1.70	
Recurrence			
Present	21 (20.19%)	30.27 ± 2.17	0.92
Absent	83 (79.81%)	28.72 ± 1.29	

Abbreviations: COST, Comprehensive Score for financial Toxicity; AJCC, American Joint Committee on Cancer.
[a] Lower COST scores represent higher toxicity.
[b] Kruskal-Wallis Test.

There was a highly significant association between COST and FDQ values ($p < 0.001$) (Fig. 2). Results herein are reported for COST as Mean ± SEM (Table 1). Patients that were not married had significantly worse FT compared to their counterparts (Fig. 3A: COST, 25.33 ± 1.87 vs. 30.61 ± 1.34, $p = 0.008$). Patients with lower education levels also demonstrated worse FT (Fig. 3B: COST, 26.12 ± 1.47 vs. 34.14 ± 1.47, $p < 0.001$). By primary site, those with larynx/hypopharynx tumors demonstrated the worst FT (Fig. 3C: COST, 22.86 ± 2.28 vs. 30.27 ± 1.50 vs. 32.72 ± 1.98, $p = 0.005$). Similar results were found with FDQ (Supplementary material, eFig. 2).

Factors associated with financial toxicity

In COST modeling, younger age (4.23, 95% CI 2.20 to 6.26, $p < 0.001$), lower earnings at diagnosis (1.17, 95% CI 0.76 to 1.58, $p < 0.001$), and loss in earnings after diagnosis (−1.80, 95% CI −2.43 to −1.16, $p < 0.001$) were significantly associated with worse FT

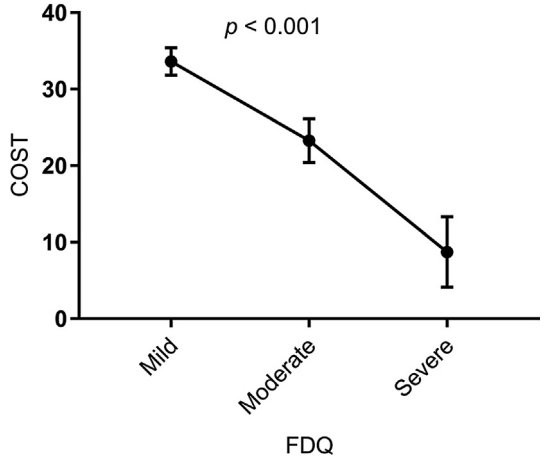

Fig. 2. COST and FDQ were highly correlated. There was a highly significant strong correlation (p < 0.001) between the two metrics. Lower COST scores represent worse FT, corresponding to worse grades of FT as measured by FDQ. Abbreviations: COST, COmprehensive Score for financial Toxicity; FDQ, Financial Distress Questionnaire; FT, financial toxicity.

Table 2
Factors associated with financial toxicity.

COST[a] - multiple linear regression		
Variable	Coefficient (95% CI)	*P*
Age at visit (Δ10y)	4.23 (2.20 to 6.26)	*< 0.001*
Time since treatment completion (Δ 1y)	0.02 (−0.36 to 0.41)	0.91
Earnings at diagnosis (Δ $10,000)	1.17 (0.76 to 1.58)	*< 0.001*
Loss in earnings (Δ $10,000)	−1.80 (−2.43 to −1.16)	*< 0.001*
Primary site		
Larynx/hypopharynx	(Base)	0.08
Oral cavity	6.21 (0.68 to 11.73)	
Oropharynx	3.57 (−1.01 to 8.15)	
Treatment modality		
Surgery alone	(Base)	0.2
Non-operative	−0.87 (−6.34 to 4.60)	
Surgery plus adjuvant	−3.78 (−8.67 to 1.10)	
Marital status		
Not married	(Base)	0.25
Married	2.45 (−1.80 to 6.70)	

Abbreviations: COST, Comprehensive Score for financial Toxicity; OR, odds ratio; 95% CI, 95% confidence interval; y, years.
[a] Lower COST scores represent higher toxicity.

(Table 2). For every increase of 10 years in age, COST scores improved by 4.20-points, indicating less toxicity in older individuals. For every $10,000 more in earnings at diagnosis, COST scores improved by 1.17-points, signifying less toxicity in patients with higher earnings at time of diagnosis. For every $10,000 lost in earnings between diagnosis and follow-up (time of survey), COST scores deteriorated by 1.18-points, demonstrating worse toxicity in survivors who experienced a decrease in earnings over time. Modeling with FDQ identified the same associated factors; in addition, the odds of having high FT was 4.35-times higher in those who were not married compared to married individuals (95% CI 1.14 to 16.57, $p = 0.03$) (Supplementary Material, eTable 2).

Factors associated with HRQOL

In multivariate analysis, COST was significantly associated with HRQOL (Roy's Greatest Root Value 0.08, F-value 3.61, $p = 0.03$) (data not shown). QOL_S demonstrated the greatest contribution to the significant overall effect observed. On average, QOL_S scores were 0.47-points higher for every 1-point increase in COST, demonstrating improved HRQOL with less FT. However, FDQ was not significantly associated with HRQOL. In both models, primary site ($p = 0.01$), treatment modality ($p < 0.0001$), and marital status ($p = 0.02$) were significantly associated with HRQOL while age was not.

Using COST as a measure of FT, patients with larynx/hypopharynx primaries had significantly better HRQOL than those with oral cavity or oropharynx primaries (Roy's Greatest Root Value 0.10, F-value 4.64, $p = 0.01$). Patients who underwent surgery alone showed significantly higher HRQOL compared to non-operative or surgery plus adjuvant therapy (Roy's Greatest Root Value 0.27, F-value 12.69, $p < 0.001$). Survivors that were not married had significantly worse HRQOL compared to those married (Roy's Greatest Root Value 0.08, F-value 3.75, $p = 0.03$). Similar results were found with FDQ (data not shown). QOL_P scores demonstrated the greatest contributions to the significant overall effect observed. In the model with COST and QOL_P as the dependent variable, QOL_P scores of larynx/hypopharynx primaries were, on average, 9.18-points (95% CI 0.20 to 18.16, $p = 0.04$) and 11.41-points (95% CI 0.42 to 22.41, $p = 0.04$) higher compared to oropharynx and oral cavity primaries, respectively. Average QOL_P for patients who received surgery alone was 17.55-points greater (95% CI 7.05 to 28.06, $p = 0.001$) than those with non-operative treatment, and 21.85-points higher (95% CI 12.21 to 31.49, $p- < 0.001$) than those who received surgery plus adjuvant treatment. Married patients showed, on average, 8.85-points higher in QOL_P (95% CI 0.80 to 16.90, $p = 0.03$) than those who were not married. Similar findings were observed in the model with FDQ.

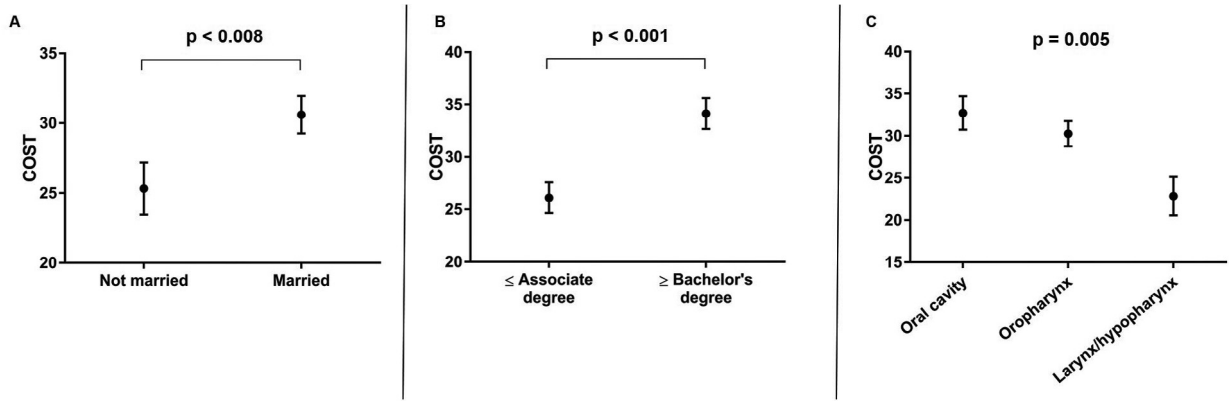

Fig. 3. FT differs by marital status, education level, and primary site. (A) Patients that were not married had worse FT with lower average COST scores (25.33 ± 1.87 vs. 30.61 ± 1.34, $p = 0.008$). (B) Patients with lower education levels had worse FT with lower average COST scores (26.12 ± 1.47 vs. 34.14 ± 1.47, $p < 0.001$). (C) Patients with larynx/hypopharynx had, on average, the lowest COST scores (22.86 ± 2.28 vs. 30.27 ± 1.50 vs. 32.72 ± 1.98, $p = 0.005$). Abbreviations: FT, financial toxicity; COST, COmprehensive Score for financial Toxicity; Mean ± SEM; p-values generated from Kruskal-Wallis Test.

Table 3
Factors associated with financial coping mechanisms (ordinal logistic regression).[a]

COST		
Variable	OR (95% Cl)	*P*
Age	1.01 (0.97 to 1.05)	0.64
COST[b]	1.06 (1.02 to 1.10)	*0.004*
Primary site		
Larynx/hypopharynx	(Base)	0.12
Oral cavity	0.29 (0.08 to 1.05)	
Oropharynx	0.38 (0.14 to 1.04)	
Treatment modality		
Surgery alone	(Base)	0.4
Non-operative	0.47 (0.14 to 1.57)	
Surgery plus adjuvant	0.50 (0.17 to 1.49)	
Marital status		
Not married	1.24 (0.52 to 2.96)	0.63
Married	(Base)	

Abbreviations: COST, Comprehensive Score for financial Toxicity; OR, odds ratio; 95% CI, 95% confidence interval.

[a] Financial coping mechanisms were categorized into ordered groups from most to least favorable [1 (no savings/loans), 2 (savings), 3 (savings and loans)]. The cumulative probabilities for this variable were modeled as a sum from most to least favorable values.

[b] Lower COST scores represent higher toxicity.

Factors associated with financial coping mechanisms

Of 102 available survey responses, 43 (42.1%) reported the use of savings alone while 20 (19.6%) described the use of savings and loans. Regression analysis demonstrated that the odds of using fewer financial coping strategies (no savings/loan) was 1.06-times higher for every 1-point increase in COST (95% CI 1.02 to 1.10, $p = 0.004$) (Table 3). Similarly, with FDQ, the odds of using fewer financial coping strategies (no savings/loan) for patients with mild FT was 4.76-times higher than those with high FT (95% CI 1.80 to 12.61, $p = 0.002$) (Supplementary material, eTable 3).

Discussion

This study represents one of the few investigations of FT in a dedicated cohort of HNC survivors and is the first to report findings by subsite. Compared to studies looking across cancer types [8], average COST score in our sample studied was higher (less toxicity), but there was substantial heterogeneity by primary site. Larynx/hypopharynx patients had the lowest average scores (worse toxicity), followed by those with oropharynx and oral cavity primaries. Studies have shown that female sex, younger age, race, rural living, low income at baseline, loss of wages, employment status, recent diagnosis, advanced cancer, and adjuvant therapies are risk factors associated with FT [7–9]. Similarly, in univariate analyses, we found significant differences in FT by marital status, education level, and primary site. In regression modeling, younger age, lower earnings at diagnosis, and loss in earnings after diagnosis were significantly associated with worse FT as measured by the COST score.

In a recent retrospective study of the Medical Expenditure Panel Survey (MEPS), HNC patients had disproportionately higher financial burden in the form of higher total and relative OOP expenses compared to other cancers [30]. HNC patients were more often of a minority race/ethnicity, poor, less educated, publicly insured, and of lower health status. The authors concluded that financial burden is particularly salient in HNC survivors compared to other cancer survivors. The discrepancy between less subjective FT compared to other cancers in our study and relatively higher financial burden described by the MEPS data highlights important considerations in investigating FT. Though the terms financial toxicity, financial distress, financial burden, and financial hardship have been used synonymously in the oncology literature [31,32], perceived financial well-being is not tantamount to objective OOP expenditures. It is well documented that FT may impact insured and uninsured individuals, from any socioeconomic group, both in low- and high-income countries [33,34]. Indisputably, financial toxicity is disproportionately understudied in the HNC population compared to other cancer types.

Several large-scale studies have suggested a link between cancer-related financial strain and decreased HRQOL [6,17,35]. In this study, FT as measured by COST was significantly associated with HRQOL. Notably, worse FT appeared to contribute most to poorer QOL_S. Additionally, primary site, treatment modality, and marital status were significantly associated with HRQOL in modelling using COST. Interestingly, though patients with larynx/hypopharynx tumors demonstrated the worst FT by subsite, this group demonstrated the best HRQOL. Strikingly, QOL_P scores of larynx/hypopharynx primaries were, on average, higher compared to oropharynx and oral cavity primaries. Previous studies have reported that QOL is generally impacted during the first few months after laryngectomy, however after 1-year, many patients adapt [36,37]. The potential for voice restoration and swallowing preservation for post-laryngectomy patients may contribute to improved QOL in this group. The findings in this study highlight the complex interplay between financial strain, treatment modality, treatment-related sequelae, and psychosocial factors in the HRQOL of cancer survivors.

When patients are unable to manage the cost of care, they turn to coping mechanisms, including non-compliance with treatment recommendations, to find tangible solutions for their financial burden [7]. Studies suggest that even small adjustments in patient cash flow, on the order of less than $100 per month, can trigger non-compliance to medications [38]. Up to 69% of HNC patients were found to rely on coping strategies to offset the cost of care [13]. We examined financial coping mechanisms and demonstrate that over 60% of survey respondents (63/102) used savings and/or loans to manage treatment-related costs. Given higher OOP spending, cost-sharing requirements, and less comprehensive coverage, this investigation was limited to patients with Medicare and private insurance. With relatively high deductibles and no annual out-of-pocket spending limits, most Medicare enrollees require supplemental coverage to help defray costs and benefit gaps. In 2016, Medicare beneficiaries spent on average nearly $6,000 in out-of-pocket costs for premiums, supplemental insurance, and medical and long-term care services [23]. In contrast, federal regulations strictly limit cost sharing in Medicaid [39]. Despite their low income, Medicaid enrollees demonstrate comparable access to care as patients with private insurance [23]. In fact, there is increasing evidence that Medicaid beneficiaries have superior access to care than the uninsured and are less likely to postpone or forego care due to cost [40]. State Medicaid expansions have been associated with increased access to care, improved self-reported health, and reduced mortality among adults [41,42]. In this investigation of privately or Medicare insured patients, our findings highlight that the need for coping strategies to address financial burden is not limited to underinsured or low-income individuals. We also found that worse FT was significantly associated with an increased likelihood of using more financial coping mechanisms.

This analysis represents one of the first examinations of FDQ with respect to its psychometric properties and correlates the measure with a valid metric of FT. Assessment by FDQ demonstrated that overall, 12 (11.54%) survivors described severe and 18 (17.31%) had moderate FT. Like COST findings, patients with larynx/hypopharynx tumors demonstrated the greatest proportion of moderate or severe FT. Comparable results to COST by FDQ regression modelling also found younger age, lower earnings at diagnosis, and loss in earnings after diagnosis were associated with high FT. Additionally, not being married was significantly associated with high FT as modeled by the FDQ. Though primary site, treatment modality, and marital status were

significantly associated with HRQOL in modelling using FDQ as a measure of FT, we failed to demonstrate an association between FDQ and HRQOL. We suspect that this may be a result of the binomial nature of this instrument, which may lack some of the nuances captured by COST. Consequently, the FDQ may not be as predictive of HRQOL, or a larger cohort may be needed to detect differences. Nevertheless, with its 2-item question format, the FDQ may represent a simple, easy to administer, and complete screening tool for FT in clinical practice. We do not suggest that the results demonstrated by the FDQ are meant to supplant the COST instrument. Rather, the findings from this investigation encourage further exploration and validation of the FDQ. Given its ease of use and interpretability, the FDQ has potential to serve as a clinically meaningful, initial assessment of a patient's self-reported financial toxicity. With a quick, reliable, screening tool that may identify high-risk patients, providers may be able to triage those who require more in-depth examination of their financial burden using COST.

Limitations

Though there are many strengths of this study, our findings are representative of patients treated in a single health-system, with similar treatment-related costs and relatively homogenous demographics that may not be representative or generalizable across all HNC patients nationwide. Furthermore, though our high participation rate (114/140, 81.43%) suggests no obvious response bias, study responders may represent those self-selected with high financial burden. Future studies should be multi-institutional in nature, include the analysis of additional financial coping mechanisms and include larger sample sizes to increase the generalizability of findings and allow for subgroup analysis in regression modeling.

Conclusions

Our study suggests that while HNC survivors experience similar financial challenges faced by patients with other cancers, there may be unique factors that should be considered when evaluating their risk for FT. We found that a considerable proportion of survivors demonstrated high FT. Discrepancies in FT by primary site illuminate potentially site-specific factors, such as workplace discrimination or inability to return to work, that may contribute to loss of earnings or employment. Through maladaptive coping, patients may delay or forego healthcare opportunities due to excessive financial pressures, increasing the risk of health inequalities. As payors continue to shift costs to consumers, addressing FT is a critical component in shared-decision making and understanding how patients define high-value care. Our findings in Medicare and private beneficiaries demonstrates that among patient populations conventionally perceived as well-insured who lack the same socioeconomic barriers as traditional Medicaid patients, financial toxicity is a major concern. Future research is needed to understand the risk factors and impact of FT in a longitudinal cohort of HNC patients as well as the efficacy of interventions such as financial navigators, policies addressing drug price transparency, and value-based insurance design, in alleviating cancer-related financial burden. What we must strive to understand when assessing the influence of financial burden on HNC care is the patient-level impact of perceived financial harm on clinically meaningful outcomes.

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Declaration of Competing Interest

None declared by any of the authors.

Appendix A. Supplementary material

Supplementary data to this article can be found online at https://doi.org/10.1016/j.oraloncology.2019.06.023.

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