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Association of Self-Reported Financial Burden with Quality of Life and Oncologic Outcomes in Head and Neck Cancer

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Running Title: Financial Toxicity in Head and Neck Cancer

Abstract

Background: There is a paucity of data on financial toxicity among patients with head and neck squamous cell carcinoma (HNSCC).

Materials: This was a retrospective, cross-sectional study of patients with HNSCC surveyed at an outpatient oncology clinic.

Results: The sample included 202 patients with HNSCC with a mean age of 59.6 years (SD 10.0). There were 53 patients (26%) with self-reported financial burden. Education of high school or less was a significant predictor of self-reported financial burden (OR 2.52, 95% CI 1.03 to 6.14; p=0.042). Patients reporting financial burden had significantly worse physical (p=0.003), mental (p=0.003), and functional (p=0.036) HRQOL. Patients reporting financial burden appeared to have lower 5-year overall survival (74.3% vs. 83.9%; p=0.165), but this association did not reach statistical significance.

Conclusion: Financial burden or toxicity may affect approximately a quarter of HNSCC patients and appears to be associated with worse HRQOL outcomes.

Introduction

Financial toxicity (FT) is a concept increasingly being adopted within oncology to describe the economic burden of a cancer diagnosis and its adverse consequences for the patient.[1,2] It is recognized as an important aspect of cancer survivorship, as it may affect outcomes such as patient quality of life, ability to work, adherence to treatment, and even survival.[3,4,5,6,7] Financial toxicity may be especially relevant for patients with head and neck cancer because these patients face higher out-of-pocket expenses and have lower socioeconomic status compared to patients with other types of cancer.[8] Additionally, head and neck cancer patients often receive multimodal treatment with a combination of surgery, radiation therapy, and/or chemotherapy. Despite the potential for financial hardship in this population, few studies have examined FT among head and neck cancer patients.

To help address this gap in current literature, we assessed self-reported financial burden among an institutional cohort of patients with head and neck squamous cell carcinoma (HNSCC). We used self-reported financial burden as a proxy for FT in this sample. We examined its association with health-related quality of life (HRQOL), overall survival (OS), and cancer specific survival (CSS). A better understanding of FT in head and neck cancer patients will be important for optimizing patient care and outcomes in this population.

Materials and Methods

This study was approved by the Institutional Review Board at the University of North Carolina at Chapel Hill. All participants provided informed consent to participate in this study.

Study Design and Sample Selection

We performed a retrospective, cross-sectional analysis of head and neck cancer patients identified through the University of North Carolina Health Registry/Cancer Survivorship Cohort (HR/CSC). The UNC HR/CSC is an incident-prevalent cohort of patients who presented to UNC oncology outpatient clinics at the North Carolina Cancer Hospital. Patients were enrolled between May 2012 and July 2016. In this sample, 144 (71.3%) of cases were incident (enrolled during initial visit for HNSCC diagnosis) and 58 (28.7%) of cases were prevalent (enrolled after HNSCC diagnosis). Prevalent cases included patients who were initially diagnosed and treated before the enrollment period (2012-2016) and were returning to clinic for cancer surveillance. Patients completed the study questionnaires at a median number of 27 days after enrollment via a computer-assisted telephone interview. Given the incident-prevalent study design, patients completed the study questionnaires on average 13.8 months after initial diagnosis. Patients were eligible to participate in the UNC HR/CSC if they were at least 18 years of age and had English or Spanish language proficiency. Patients meeting these eligibility criteria were approached by research staff in the oncology clinic, and upon informed consent, were enrolled in the HR/CSC. Of the eligible HNSCC patients approached in clinic for enrollment, 64% consented to participate. Patients from the HR/CSC were included in this analysis if they had a pathologically confirmed diagnosis of HNSCC.

Questionnaires and Data Extraction

Information on demographics, socioeconomic status, and medical history was obtained via a baseline questionnaire. Self-reported financial burden was elicited from the Patient Satisfaction Questionnaire (PSQ-18), a validated scale that has previously been used to examine FT.[9–11] Self-reported financial burden was defined as a response of "agree" or "strongly agree" to the statement "you have to pay more for medical care than you can afford." Socioeconomic variables collected in the survey included health insurance status, educational attainment, and employment status. Household income level was not collected in the initial survey, so we were unable to include this variable in the analysis. Clinical data such as tumor site, AJCC stage (7th edition) and p16 tumor status were extracted from patient medical records. HRQOL outcomes were measured using the Patient-Reported Outcomes Measurement Information System (PROMIS)[12] questionnaire and the Functional Assessment of Cancer Therapy-General Population (FACT-GP),[13] which is further divided into physical, social, emotional, and functional domains.

Statistical Analysis

Descriptive statistics were used to examine sociodemographic and clinical characteristics of patients with and without self-reported financial burden. Bivariate testing methods included two-sided t-tests, Chi-square tests, and Fisher's exact test (for expected observations<5). All variables were examined for missing observations and excluded *a priori* if >10% of observations were missing; this did not apply to any of the variables. Missing observations included 3 for marital status (1.4%), 4 for education (2.0%), 13 for overall stage (6.4%), and 1 for treatment type and number of treatment modalities, respectively (0.5%). Univariate logistic regression models were used to estimate significant predictors of self-reported financial burden. Two-sided t-tests were used to examine the association of self-reported financial burden with HRQOL scores. The PROMIS scales used T scores linked to population norms. Kaplan-Meier curves

were constructed to assess 5-year OS and CSS in patients with and without self-reported financial burden. The log-rank test was used to compare the survival curves and obtain p-values. Updates on patient vital status were provided monthly up until October 1st, 2020 by the North Carolina Department of Health and Human Services. Vital status and cause of death was known for all subjects at 5 years of follow-up from initial diagnosis. A sensitivity analysis to determine if incident vs. prevalent case status (proxy for time between diagnosis and enrollment) had any impact on our primary outcome. We used a statistical significance criterion of $p<0.05$ for all testing and Stata 16.0 (StataCorp LP, College Station, TX) for all analyses.

Results

Baseline characteristics

The sample consisted of 202 patients with HNSCC with a mean age of 59.6 years (SD 10.0). Eighty-two percent of patients were male and 87% were white. The majority of patients had private insurance or Medicare (88%), and 70% of patients had advanced stage (III/IV) cancer at diagnosis. The majority of patients received definitive surgery with or without adjuvant therapy (65%). Nearly half of the patients reported currently working for pay at the time of the study (47%). A total of 53 patients (26%) had self-reported financial burden.

Associations with self-reported financial burden

Baseline characteristics are stratified by patients with and without self-reported financial burden **(Table 1)**. Patients with self-reported financial burden were significantly more likely to have an education of high school or less (78.4% vs. 57.1%; p=0.025). There was a higher percentage of patients with self-reported financial burden who were unmarried compared to patients without

self-reported financial burden (41.2% vs. 27.0%; p=0.059), but this association did not reach

statistical significance. There was no association between self-reported financial burden and the

type (p=0.361) or number (p=0.498) of treatment modalities. Tumor p16 status was available for

35 of the patients with oropharyngeal squamous cell carcinoma. In a subset analysis, there

were 26 p16+ OPSCC and 9 p16- OPSCC patients. The rate of p16 positivity did not differ

between patients with and without self-reported financial burden (79.9% vs. 72.3%, respectively;

p=1.000). Finally, in a sensitivity analysis, there was no difference in prevalent/incident case

status in patients with and without self-reported financial burden (26.4% vs. 29.5% prevalent

cases, respectively; p=0.667).

In a univariate logistic regression model examining predictors of self-reported financial burden,

patients with an education of high school or less were over twice as likely to have self-reported

financial burden compared to patients with at least a college degree (OR 2.52, 95% CI 1.03 to

6.14; p=0.042) **(Table 2)**. There were no other demographic, social, or clinical variables that

significantly predicted self-reported financial burden in the logistic regression model.

Health Related Quality of Life (HRQOL) Outcomes

Patients with self-reported financial burden had significantly worse physical [mean difference

(MD) -4.24 (95% CI -7.01 to -1.46); p=0.003] and mental (MD -4.31, 95% CI -7.09 to -1.52;

p=0.003) HRQOL outcomes on the PROMIS questionnaires **(Table 3)**.

Patients with self-reported financial burden had significantly worse functional HRQOL on the

FACT-GP functional scale (MD -2.44, 95% CI -4.72 to -0.16; p=0.036). The total HRQOL score

on the FACT-GP was also lower for patients with self-reported financial burden, although this

association did not reach statistical significance (MD= -4.85, 95% CI -10.05 to 0.35; p=0.067).

Survival Outcomes

The mean time from diagnosis to last follow-up was 5.5 years (SD 2.30) and vital status at 5 years was known for all participants in this study. The 5-year OS rate was 81.7%, and the 5-year CSS rate was 84.6 % for the cohort. There was no significant difference in 5-year OS (74.3% vs. 83.9%; log-rank p-value=0.165) or 5-year CSS (79.7% vs. 85.7%; log-rank p-value=0.366) in patients with and without self-reported financial burden, respectively **(Figures 1 and 2)**.

Discussion

In this study, we used a cross-sectional institutional cohort of HNSCC patients to examine patient-reported financial burden and its association with HRQOL and survival outcomes. The prevalence of self-reported financial burden in this cohort was 26%. We found that an education of high school or less was a significant predictor of self-reported financial burden (p=0.042). Unmarried patients also appeared to be more likely to have financial burden compared to married patients, although this association did not reach statistical significance (p=0.059). Patients with self-reported financial burden had significantly worse physical (p=0.003), mental (p=0.003), and functional (p=0.036) quality of life outcomes. Despite lack of statistical significance, patients reporting financial burden had approximately a 10% absolute difference in 5-year OS compared to those without financial burden (74.3% vs. 83.9%). To our knowledge, this is the first study to examine the impact of self-reported financial burden on both HRQOL and survival outcomes among HNSCC patients.

These findings are corroborated by three other studies in current literature, all of which were institutional-based cohorts of head and neck cancer patients. Mady et al. reported FT in 40.5% of their 104-patient sample, and they found associations of FT with lower education levels, unmarried status, and worse HRQOL.[14] In another study of 63 patients with head and neck cancer, Beeler et al. found that younger age and lower household income were significant predictors of FT, and that patients with FT were more likely to skip clinic visits or report medication noncompliance.[15] Collectively, these findings suggest that certain sociodemographic characteristics (e.g. age, education, marital status, household income) are associated with FT, and FT can lead to adverse outcomes in HNSCC such as worse HRQOL and non-adherence to recommended treatment or follow-up.

In the largest study available to date, Ma et al. assessed FT in 284 head and neck cancer patients treated with definitive or postoperative radiation therapy.[16] The prevalence of FT in their cohort was 14%, and it was significantly associated with younger age, distant metastasis at diagnosis, HPV-negative tumor status, surgical treatment, and higher comorbidity burden.[16] They also found that patients with FT had significantly worse OS and CSS in both multivariable and matched analyses, although the absolute survival differences were not reported.[16] The differences between our findings and Ma et al. may be due to limitations in our sample size, differences in patient populations, or differences in how FT was measured. Our study was not restricted to patients receiving radiation therapy, and we only included patients with HNSCC rather than all patients with head and neck cancer. In addition, our sample was predominately white (87%) and well-insured (57% with private insurance) which is not representative of all HNSCC patients in the United States. Finally, Ma et al. measured FT by a response of "very much" to the question "Has your physical condition or medical treatment caused you financial difficulties?"

Efforts are warranted to better address the financial well-being of HNSCC survivors. In a study of unmet needs among head and neck cancer survivors, 23% of respondents said they needed more help managing financial issues.[17] One potential solution may involve cancer survivorship care plans, where patients are provided with information about treatment costs and financial resources such as medication assistance programs, job protection policies, and credit management.[18] Ideally these care plans should be provided early after cancer diagnosis and as part of a multidisciplinary approach. A related solution is the use of financial navigators embedded in oncology clinics to help patients proactively optimize insurance policies, identify external assistance programs, and understand the cost of different treatment options.[19,20] Additionally, hospitals should take steps to provide physicians and patients with information about the costs of different interventions to make the decision-making process as transparent as possible.[21] Interventions aimed at improving the mental, physical, and functional well-being of head and neck cancer survivors may also be warranted.[22] Given the relationship between self-reported financial burden and worse HRQOL, such interventions may have the greatest impact on patients with a high degree of financial burden.

Our study has several limitations. There is a potential for selection bias because sampling relied on voluntary participation in an outpatient oncology clinic. Sixty-four percent of eligible HNSCC patients approached in clinic consented to participate in the study, and it is plausible that patients experiencing financial stress were less willing to participate in research given the time and effort required. In addition, participation among underrepresented minorities was lower than expected. Studies have found that African Americans are less likely to volunteer for medical research and may have more distrust of medical research compared to whites patients.[23] This is not surprising given the history of racism and medical discrimination against African Americans in the United States. Our sample was from a single, large, public, outpatient clinic setting and may not be generalizable to all HNSCC patients in the United States. Given the

sociodemographic makeup of our sample, which was predominately white and privately insured, we would expect our findings to underestimate FT in the HNSCC population.

Our definition of financial burden was limited by the initial survey design for this study. Defining financial burden as "you have to pay more for medical care than you can afford" is subjective, and survey respondents may have varying degrees of interpretation. Some cancer survivors may underestimate their true financial burden, while others may overestimate it. Ideally, more objective and validated tools such as the Comprehensive Score for Financial Toxicity (COST) survey should be used.[24] Finally, our study lacked data on household income which is an important marker of socioeconomic status and has been shown in previous studies to be associated with financial toxicity.[14,15] To date, all studies examining FT in head and neck cancer have relied on institutional cohorts with relatively small sample sizes. Additional research using multi-institutional or population-based cohorts may help build on these initial studies to provide a better understanding of FT and its adverse consequences in HNSCC.

Conclusion

Self-reported financial burden may affect at least one fourth of head and neck cancer patients and is associated with significantly worse HRQOL outcomes. Socioeconomic variables such as low educational attainment and unmarried status appear to be associated with a higher degree of financial burden in this population. The physical, mental, functional, and financial implications of cancer survivorship may exacerbate already poor HRQOL in patients facing a high degree of financial burden. More research is warranted to better understand and address the financial burden faced by head and neck cancer survivors.

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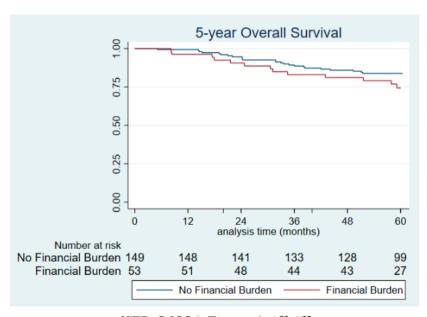
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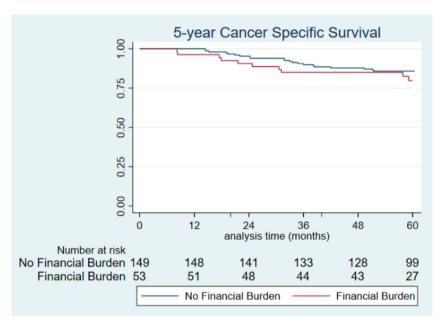
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Tables and Figures:

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Table 2: Univariate Logistic Regression Model Examining Predictors of Self-reported Financial Burden

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Figure 1: Kaplan-Meier Curves for 5-year Overall Survival in Patients with and without Self-reported Financial Burden

Figure 2: Kaplan-Meier Curves for 5-year Cancer Specific Survival in Patients with and without Self-reported Financial Burden

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5-year Cancer Specific Survival

Number at risk						
No Financial Burden	149	148	141	133	128	99
Financial Burden	53	51	48	44	43	27

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Table 1: Baseline Characteristics in Patients with and without Self-reported Financial Burden

	Patients with Financial Burden (n=53)	Patients without Financial Burden (n=149)	p-value
Age (mean, SD)	58.3 (10.1)	60.1 (10.0)	0.245
Sex			0.286
Male	41 (77.4)	125 (83.9)	
Female	12 (22.6)	24 (16.1)	
Race			0.174
White	47 (88.7)	129 (86.6)	
Black	6 (11.3)	12 (8.1)	
Other	0 (0)	8 (5.4)	
Marital status			0.059
Married	30 (58.8)	108 (73.0)	
Not married	21 (41.2)	40 (27.0)	
Education			**0.025**
High school or less	40 (78.4)	84 (57.1)	
College graduate	7 (13.7)	37 (25.2)	
Post-graduate/professional degree	4 (7.8)	26 (17.7)	
Insurance Status			0.295
Private	31 (58.5)	84 (56.4)	
None	4 (7.6)	4 (2.7)	
Medicare	13 (24.5)	50 (33.6)	
Medicaid	5 (9.4)	11 (7.4)	
Currently work for pay	23 (45.1)	72 (48.7)	0.662
Mean distance to hospital in miles (SD)	60.2 (53.2)	76.5 (71.0)	0.142
History of tobacco use	35 (66.0)	86 (61.0)	0.518
History of alcohol use	23 (43.4)	76 (51.0)	0.341
Comorbid Depression	7 (13.2)	22 (15.2)	0.729
Comorbid Anxiety	9 (17.0)	25 (17.2)	0.966
Tumor site			0.883
Oral cavity	22 (41.5)	52 (34.9)	
Oropharynx*	23 (43.4)	73 (49.0)	
Hypopharynx	1 (1.9)	5 (3.4)	
Larynx	5 (9.4)	12 (8.1)	
Other	2 (3.8)	7 (4.7)	
Overall Stage (AJCC 7th edition)			0.861
Early (I/II)	15 (30.6)	41 (29.3)	
Advanced (III/IV)	34 (69.4)	99 (70.7)	
Treatment			0.361
Surgery alone	20 (37.7)	38 (25.7)	
Surgery + aRT	7 (13.2)	18 (12.2)	
Surgery + aCRT	10 (18.9)	38 (25.7)	
RT or Chemotherapy alone	2 (3.8)	14 (9.5)	
Chemoradiation therapy	14 (26.4)	40 (27.0)	

Number of Treatment Modalities			0.498
1	22 (41.5)	52 (35.1)	
2	21 (39.6)	58 (39.2)	
3	10 (18.9)	38 (25.7)	

*p16 status was available for 35 of the patients with oropharyngeal squamous cell carcinoma

Table 2: Univariate Logistic Regression Model Examining Predictors of Self-reported Financial Burden

	OR and 95% CI	p-value
Age > 60 years (vs. </=60 years)	0.63 (0.33 to 1.19)	0.152
Female sex	1.52 (0.70 to 3.32)	0.288
Black race (vs. white)	1.37 (0.49 to 3.86)	0.549
Not married (vs. married)	0.53 (0.27 to 1.03)	0.061
Education (vs. college graduate)		
High school or less	2.52 (1.03 to 6.14)	**0.042**
Post-graduate/professional degree	0.81 (0.22 to 3.07)	0.760
Insurance (vs. private)		
None	2.71 (0.64 to 11.50)	0.177
Medicare	0.70 (0.34 to 1.47)	0.351
Medicaid	1.23 (0.40 to 3.83)	0.719
Currently work for pay	0.87 (0.46 to 1.64)	0.662
Distance to hospital above median (>52 miles)	0.73 (0.38 to 1.40)	0.342
History of tobacco use	1.24 (0.64 to 2.41)	0.518
History of alcohol use	0.74 (0.39 to 1.38)	0.342
Comorbid Depression	0.85 (0.34 to 2.13)	0.729
Comorbid Anxiety	0.98 (0.43 to 2.27)	0.966
Tumor site (relative to oral cavity)		
Oropharynx	0.74 (0.38 to 1.48)	0.398
Hypopharynx	0.47 (0.05 to 4.28)	0.505
Larynx	0.98 (0.31 to 3.13)	0.979
Other	0.68 (0.13 to 3.51)	0.641
Advanced Stage (vs. Early)	0.94 (0.46 to 1.91)	0.861
Treatment (vs. Surgery alone)		
Surgery + aRT	0.74 (0.26 to 2.06)	0.564
Surgery + aCRT	0.50 (0.21 to 1.21)	0.124
RT or Chemotherapy alone	0.27 (0.06 to 1.31)	0.105
Chemoradiation therapy	0.67 (0.29 to 1.50)	0.326
Number of Treatment Modalities (relative to 1)		
2	0.82 (0.41 to 1.67)	0.589
3	0.60 (0.25 to 1.41)	0.240

Table 3: HRQOL Outcomes in Patients with and without Self-reported Financial Burden

Questionnaire	Patients with Financial burden mean (SD)	Patients without Financial burden mean (SD)	Mean difference (95% CI)	p-value
FACT GP Total	77.9 (15.2)	83.3 (16.7)	-4.85 (-10.05 to 0.35)	0.067
FACT GP Physical	22.0 (4.9)	23.2 (5.0)	-1.03 (-2.61 to 0.55)	0.201
FACT GP Social	20.7 (5.4)	21.1 (5.7)	-0.40 (-2.17 to 1.37)	0.654
FACT GP Emotional	18.8 (4.5)	19.7 (4.7)	-0.98 (-2.44 to 0.48)	0.189
FACT GP Functional	16.4 (7.1)	18.9 (7.3)	-2.44 (-4.72 to -0.16)	**0.036**
PROMIS Physical	45.1 (8.0)	49.3 (9.0)	-4.24 (-7.01 to -1.46)	**0.003**
PROMIS Mental	49.2 (8.0)	53.5 (9.0)	-4.31 (-7.09 to -1.52)	**0.003**