

Effect of smoking, alcohol, and depression on the quality of life of head and neck cancer patients

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Abstract

This pilot study examined the relationship between smoking, alcohol intake, depressive symptoms and quality of life (QoL) in head and neck cancer patients. A questionnaire on smoking, alcohol, depressive symptoms and QoL was distributed to head and neck cancer patients ($N=81$). Over one-third (35%) of the respondents had smoked within the last 6 months, 46% had drunk alcohol within the last 6 months and 44% screened positive for significant depressive symptoms. About one-third (32%) of smokers were interested in smoking cessation services and 37% of patients with depressive symptoms were interested in depression services. However, only 9% of those who drank alcohol expressed interest in alcohol services. Smoking was negatively associated with five scales of the SF-36V including Physical Functioning, General Health, Vitality, Social Functioning, and Role-Emotional Health. Depressive symptoms were negatively associated with all eight scales on the SF-36V and all four scales of the Head and Neck Quality of Life instrument. Surprisingly, alcohol was not found to be associated with any of the QoL scales. While smoking, alcohol intake and depression may be episodically treated, standardized protocols and aggressive intervention strategies for systematically addressing these highly prevalent disorders are needed in this population. © 2002 Elsevier Science Inc. All rights reserved.

Keywords: Smoking; Alcohol; Depression; Cancer; Quality of Life

1. Introduction

Smoking, alcohol misuse and depression are among the most prevalent mental health conditions in the United States [1,2], and significantly decrease quality of life [3–7]. Head and neck cancer patients are more likely to smoke, drink alcohol and experience significant depressive symptoms and/or full depressive disorders than the general population. These patients are also more likely to experience poor quality of life. Previous research indicates that smoking and alcohol intake (the main risk factors for head and neck cancer) and depressive disorders often go undetected and untreated among these patients [8]. The purpose of this pilot study was to determine the relationship between smoking, drinking, depressive symptoms, related treatment needs and

quality of life of head and neck cancer patients. The specific aims of the study were to:

1. Determine baseline levels of smoking, alcohol intake, significant depressive symptoms and quality of life in head and neck cancer patients;
2. Determine whether head and neck cancer patients would be interested in interventions for smoking, alcohol intake and depression; and
3. Determine if there is a relationship between smoking, alcohol intake, depressive symptoms and the quality of life of head and neck cancer patients.

2. Significance and review of the literature

Multiple studies have shown that smoking, alcohol intake, and depressive symptoms and/or disorders are inter-related. People who smoke often consume alcohol and those

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with alcohol problems often have increased difficulty quitting smoking [9]. Finally, people who are depressed have both higher rates of smoking and alcohol misuse and greater difficulty quitting [10–13]. Unfortunately, smoking, alcohol intake and depressive symptoms are all highly prevalent among head and neck cancer patients [4,14,15].

Smoking and alcohol intake are independent risk factors for head and neck cancer and, when combined, have a synergistic rather than additive effect [16,17]. Moreover, continued smoking and alcohol intake after the first diagnosis of head and neck cancer significantly increases the likelihood of developing a second malignancy. It also adversely affects survival after the occurrence of a second cancer [18]. Yet patients with oral cancer are often unaware that smoking and alcohol can cause oral cancer [19]. Among head and neck cancer patients, 35–46% continued to smoke, including some laryngectomy patients [20,21]. Both smoking and alcohol intake have been individually associated with depression [10–13] which is, in turn, associated with increased mortality [22,23].

Approximately 25–40% of head and neck cancer patients experience depressive symptoms during the course of their treatment [24–28]. Psychological distress among head and neck cancer patients may be due to excessive use of alcohol, tobacco, other substances, low socioeconomic status, low educational levels and lack of social support [14] as well as physical effects caused by head and neck cancer and the side effects of treatment. For head and neck cancer patients, emotional status and mental health affect their global quality of life scores and disability status [4,29]. Adequate treatment of depression increases social functioning, patient productivity, and quality of life [30,31].

Quality of life and its assessment have become increasingly important in health services research, particularly in the field of oncology where quality of life is sometimes as important to a patient as quantity of life. Perhaps in no other group of oncology patients are quality of life factors as important as in head and neck cancer patients who suffer from debilitating speech, eating, and respiratory problems, as well as the psychological effects of loss of function and change in body image. In response to initiatives by the NIH and the FDA, clinical research on the effectiveness of new cancer therapies now routinely incorporates quality of life assessment in addition to traditional clinical endpoints such as disease-free interval, survival, or absence of morbidity.

To determine the relationship between smoking, alcohol intake, depressive symptoms and quality of life, patients with head and neck cancer were surveyed. The independent variables were: demographic and health information, smoking, alcohol and depression. The dependent variables were: patients' interest in receiving smoking, alcohol, and depression interventions during their regularly scheduled otolaryngology clinic appointments and quality of life scales.

3. Materials and methods

3.1. Design

A research assistant distributed a self-administered questionnaire on smoking, alcohol, depressive symptoms and quality of life to a convenience sample of head and neck cancer patients while they were waiting to be seen for their scheduled otolaryngology clinic appointment. The research assistant helped patients in completing the questionnaire as needed.

3.2. Sample

A total of 81 head and neck cancer patients were enrolled in the study during 1999. Of the 117 patients approached to participate in the study, 12 (10%) refused and 24 (21%) were ineligible because they had other cancers not included in this study. Inclusion criteria were patients with head and neck cancer who, from the time of diagnosis and any time thereafter, were: 1) not pregnant; 2) at least 18 years of age; 3) English speaking; 4) free from metastatic disease (non-terminal); and 5) free from severe unstable psychiatric/mental conditions such as suicidal ideation, acute psychosis, or dementia. The inclusion criteria were designed to target those head and neck cancer patients who have the potential to benefit from smoking, alcohol and depression interventions and to exclude those patients (such as terminal and medically or psychiatrically unstable patients) for whom an intervention might be insufficient or burdensome.

Respondents were recruited from both a VA and University hospital [32,33]. While patients from the University hospital may be more representative of the general population of head and neck cancer patients, VA patients are at greater risk for these problems [16,34,35]. Hence, inclusion of patients from both the VA and University hospital provided a diverse sample of head and neck cancer patients.

3.3. Measures

A self-administered health survey was constructed to collect data on demographics, health, smoking, alcohol intake and depressive symptoms, as well as interest in services for those problems, and quality of life information. When possible, previously validated questions and instruments (described below) were used. Tumor site and tumor stage were abstracted from the patient medical records.

3.3.1. Demographics and health measures

Demographic and health measures consisted of age, gender, race, marital status, education, employment, hospital type, miles traveled to hospital, tumor site and tumor stage. Since there were so few African American ($n=9$) and other race respondents ($n=2$) compared to Whites ($n=65$), race was classified into White and non-White. Due to the small number of college graduates ($n=3$) in this sample, educa-

tion was classified into high school or less vs. some college or more. Respondents were also asked whether they were employed before and after diagnosis. Based on previous studies of travel and use of VA facilities [36,37], the number of miles traveled was dichotomized into 25 or fewer miles vs. more than 25 miles traveled. Tumor sites were dichotomized into two groups based on other quality of life studies indicating laryngeal patients do best [38] (larynx vs. all others) and two stages based on severity (stage I and II vs. stage III and IV).

3.3.2. Smoking, alcohol and depression measures

The survey had questions about patients' smoking, alcohol intake and the presence of depressive symptoms. The survey incorporated several previously validated instruments, including the Fagerstrom Test for Nicotine Dependence (FTND) [39], the Alcohol Use Disorder Identification Test (AUDIT) [40], and the Geriatric Depression Scale–Short Form (GDS-SF) [41,42]. The six-question FTND is a low-cost, noninvasive way to rapidly assess nicotine dependence. Since smoking is the primary cause of head and neck cancer, anyone scoring 1 or more on the Fagerstrom was considered nicotine-dependent for this study. The AUDIT is a 10-item screen that assesses both level of alcohol intake and related problems including hazardous drinking, alcohol abuse and symptoms of dependence. A score of 8 or more on the AUDIT indicates a higher risk of alcohol-related disorders. The GDS-SF is a validated 5-item scale derived from the Center for Epidemiologic Studies/Depressed Mood Scale (CES-D). Scoring greater than 3 on the GDS-SF indicates patients have significant depressive symptoms. Based on past research, 17–40% of patients screening positive for significant depressive symptoms would be expected to meet criteria for major depressive disorder [30,42]. Questions requesting information on respondents' interest in services to quit smoking, quit drinking, or treat depression were also on the survey.

3.3.3. Quality of life measures

Quality of life was assessed using the SF-36V [43]. The SF-36, a general health status measure, is well validated and commonly used to measure physical, social, role, and emotional functioning. Low scores on the eight subscales of the SF-36 indicate a poorer quality of life. Since the majority of the population was veterans, the SF-36V, a modification of the SF-36 tailored for and validated in veteran populations, was used [44]. In the SF-36V, two of the eight subscales are altered as follows: the original yes/no response set is replaced by a 5-point rating scale ranging from No, None of the Time to Yes, All of the Time. These modifications to the SF36 are not substantial enough to preclude use of the SF-36V on non-VA patients and in fact increase precision of the instrument.

In addition to the SF-36V, which measures overall quality of life, disease specific instruments are often used to capture compromises in quality of life brought about by

specific conditions. Terrell et al [8] developed the first multiple-domain, disease-specific quality of life instrument for head and neck cancer patients. It is a concise, reliable and comprehensive instrument for the assessment of head and neck cancer-specific quality of life. The Head and Neck Quality of Life (HNQoL) instrument includes 20 items scored on a five-point rating scale covering four domains: 1) eating and swallowing; 2) communication; 3) head and neck pain; and 4) emotional well-being [8].

3.4. Data analysis

Descriptive statistics (means and frequencies) were conducted on all demographic and health characteristics, smoking, alcohol, depressive symptoms, interest in services for smoking, alcohol and depression and quality of life scores. Tests were computed to determine associations between the variables including demographic, health, smoking, alcohol, presence of significant depressive symptoms and patients' interest in smoking, alcohol and depression services. χ^2 tests were used for categorical variables, Student's *t* tests and Pearson correlation coefficients were used for interval level variables. Controlling for age, tumor site and tumor stage (the independent variables thought to be most influential on quality of life) [4,21,38], linear regression tests were conducted to determine the influence of smoking, alcohol and depressive symptoms on quality of life scores on the SF-36V and HNQoL instruments. For the regression analyses, tumor site and stage were dichotomized as described previously in the health measures section.

The data were double entered into a Microsoft Access database. The data were analyzed using SAS. Since all of the respondents did not answer all of the questions, the sample size may vary for different results. Values for $P < .05$ are reported.

4. Results

4.1. Demographic and health characteristics

The demographic and health characteristics of the sample are summarized in Table 1. The mean age was 61.9 years and the majority (83%) were male. Most (86%) were White while 14% were non-White (9 African Americans and 2 of other race). There were no females seen at the VA hospital, and there were no non-White patients at the University hospital. Only 35% were married while 42% were divorced/separated, 15% were widowed, and 8% had never married. Over half (57%) had a high school diploma or less. Of 35 respondents who were working prior to diagnosis, 63% were disabled after diagnosis.

The majority of patients were from the VA hospital (73%) and the rest were from the University hospital (27%). The mean number of miles traveled one-way to the hospital was 86. Only 11% of patients lived within 25 miles of the

Table 1
Demographics and health characteristics of head and neck cancer patients

	Mean	Range
Age (N = 78)	61.9 years	40–84 years
Miles Traveled to Hospital	85.6 miles	3–218 miles
	n	Percent
Sex (N = 78)		
Male	65	83%
Female	13	17%
Race (N = 76)		
White	65	86%
African American	9	12%
Other	2	3%
Marital Status (N = 79)		
Married	28	35%
Divorced/separated	33	42%
Widowed	12	15%
Never married	6	8%
Educational Level (N = 79)		
Less than high school	15	19%
High school	30	38%
Less than 4 years of college	31	39%
Bachelors degree or more	3	4%
Hospital Setting (N = 81)		
VA	59	73%
University	22	27%
Tumor Site (N = 78)		
Larynx	36	46%
Hypopharynx	14	18%
Oropharynx	7	9%
Oral Cavity	11	14%
Other	10	13%
Tumor Stage (N = 68)		
I	17	25%
II	12	18%
III	13	19%
IV	26	38%
Working prior to diagnosis of HNCA	38	49%
Of those working prior to diagnosis, how many disabled by disease? (N = 35)	22	63%

hospital. Cancers of the larynx accounted for 46% of the cancers while cancers of the oral cavity, oropharynx, hypopharynx and other accounted for the remaining 54%. Stage I and II tumors accounted for 43% of the head and neck cancers and the rest were stage III and IV.

4.2. Smoking, alcohol and depression

The smoking and alcohol characteristics and the depression screener scores of the respondents are shown in Table 2. Almost one-quarter (23%) of head and neck cancer patients were currently smoking and over one-third (35%) had smoked within the last 6 months. On the FTND, 36% scored 1 or more for nicotine dependence. Moreover, not quite half (46%) of the sample drank alcohol within the last 6 months. Of those who drank (or quit drinking) within the last year, 62% drank 2 or more times per week. On a typical day drinking, 61% drank 3 or more drinks. Of 77 respondents,

Table 2
Smoking, Alcohol use, and depression of head and neck cancer patients

	n	Percentage
Smoking Status (N = 77)		
Never smoked	5	6%
Quit over 1 year ago	39	51%
Quit within last 1 year	6	8%
Quit within last 6 months	7	9%
Quit within last 1 month	2	3%
Currently smoking	18	23%
Cigarettes per day of persons who have smoked within last year (N = 26)		
Smoke < ½ pack per day	10	38%
Smoke ½–1 pack per day	9	35%
Smoke 1–1½ pack per day	5	19%
Smoke >1½ pack per day	2	8%
Nicotine Dependence Score (FTND) (N = 74)		
Non-smoker (0)	47	64%
Very Low (1–2)	5	7%
Low (3–4)	8	11%
Medium (5)	2	3%
High (6–7)	10	14%
Very High (8–10)	2	3%
Alcohol Use Patterns (N = 76)		
Never drank alcohol	5	7%
Quit over a year ago	34	45%
Quit within 1 year	2	3%
Quit within 6 months	3	4%
Quit within last month	1	1%
Currently drink alcohol	31	41%
Frequency of alcohol intake of persons who drank within last year (N = 34)		
Monthly or less	4	12%
2–4 times/months	9	26%
2–3 times/week	11	32%
4 or more times/week	10	29%
Number of drinks on typical day when drink (N = 36)		
1–2 drinks	14	39%
3–4 drinks	12	33%
5–6 drinks	7	19%
7–9 drinks	0	0%
10 or more drinks	3	8%
Alcohol Use Disorder (AUDIT) Score (N = 77)		
0–7	63	82%
8 or higher	14	18%
Depression Score (GDS-SF) (N = 77)		
0–4	43	56%
4–15	34	44%
Interest in interventions for:		
Smoking (N = 25)	8	32%
Alcohol problems (N = 333)	3	9%
Depression (N = 29)	11	38%

18% had AUDIT scores greater than 7 putting them at risk for alcohol-related disorders. Finally, using a cut-off of greater than 3 on the GDS-SF, 44% screened positive for significant depressive symptoms. Of 80 respondents, 76% scored positive for one or more of these problems/disorders of smoking, at-risk alcohol intake and significant depressive symptoms.

Thirty-two percent ($n=8$) of the 25 current or recent smokers said they were interested in smoking cessation

Table 3

Significant coefficients for regressions of smoking, alcohol, and depression on quality of life scales controlling for age, tumor site, and tumor stage*

Dependent Variables	Independent Variables**					
	Age (in Decades)	Tumor Site (Larynx vs. All Others)	Tumor Stage (III & IV vs. I & II)	Nicotine Problem (FTND Score of >0 vs. 0)	Alcohol Problem (AUDIT Score of ≥ 8 vs. <8)	Depressive Symptoms (GDS-SF Score of >3 vs. ≤ 3)
SF-36V Scales***						
Physical Functioning				-20.1 [†]		-26.6 ^{††}
Role-Physical						-38.4 ^{††}
Pain Index			14.4 [†]			-30.0 ^{††}
General Health Perceptions	-6.0 [†]			-17.4 ^{††}		-27.7 ^{††}
Vitality				-12.1 [†]		-28.7 ^{††}
Social Functioning				-13.8 [†]		-47.5 ^{††}
Role-Emotional			19.4 [†]	-18.1 [†]		-36.1 ^{††}
Mental Health Index						-35.3 ^{††}
HNQoL Scales***						
Eating		19.2 ^{††}				-18.2 [†]
Speech						-29.8 ^{††}
Emotion		12.0 [†]				-33.3 ^{††}
Pain			16.1 [†]			-27.6 ^{††}

* All the SF-36V and HNQoL scales are based on a scale of 0–100. For all scales, the higher the scores, the better the subject's health in that domain; ** All independent variables except age are coded as dummy variables (1, 0); *** All twelve regression models were significant at $P < .001$; † Indicates significance of predictor at $P < .05$; †† Indicates significance of predictor at $P < .01$.

services. Thirty-eight percent ($n=11$) of the 29 patients with significant depressive symptoms who also answered questions about services were interested in depression services. Only 9% ($n=3$) of the 33 patients drinking alcohol were interested in alcohol cessation services. Overall, 21% of respondents were interested in at least one of these services and 4% were interested in all three of these services.

4.3. Associations between independent variables

A few relationships among the independent variables consistent with population trends were noted. Men scored higher than women for alcohol problems on the AUDIT (4.8 vs. 1.2; $t=3.5$; $df=71.2$; $P<.001$). Furthermore, smoking and alcohol problems were positively associated ($\chi^2=8.82$; $df=1$; $P<.01$) as were smoking and significant depressive symptoms ($\chi^2=3.84$; $df=1$; $P<.05$). However, there was no association between alcohol and screening positive for significant depressive symptoms.

In comparison to Whites, non-Whites (primarily African Americans) were more likely to be interested in smoking cessation services (44% vs. 8%; $\chi^2=9.32$; $df=1$; $P<.01$) and drinking cessation services (22% vs. 2%; $\chi^2=6.76$; $df=1$; $P<.01$). Interest in services for depression did not differ by race or other demographic characteristics. However, distance traveled to the hospital was associated with interest in services for smoking, alcohol, and depression. Half (50%, $n=4$) of those within 25 miles were interested in at least one of the services compared to 17% ($n=11$) of those living farther away ($\chi^2=4.77$; $df=1$; $P<.05$).

4.4. Influence of smoking, alcohol and depression on quality of life controlling for age, tumor site and tumor stage

Twelve regression analyses were conducted using the eight SF-36V and four HNQoL scales as the dependent variables. Smoking, alcohol and significant depressive symptoms were the predictor variables while age, tumor site and tumor stage (the three independent variables thought to have the greatest impact on quality of life) were the control variables (see Table 3). All twelve models were significant ($P<.001$). Age was found to be negatively associated with General Health on the SF-36V. Tumor site was found to be associated with the Eating and Emotion scales of the HNQoL. Tumor stage was found to be associated with the Bodily Pain scale and Role Emotional scale of the SF-36V and the Pain scale of the HNQoL. Smoking was found to have a negative association on five scales of the SF-36V including Physical Functioning, General Health, Vitality, Social Functioning and Role-Emotional Health. Surprisingly, alcohol was not associated with any of the quality of life scales. Finally, screening positive for significant depressive symptoms was found to have a negative and strong association on all eight scales of the SF-36V and all four scales of the HNQoL instrument.

5. Discussion

Almost half of the respondents in this study screened positive for significant depressive symptoms. Of all the

predictors, depressive symptoms had the strongest association with patients' quality of life. The prevalence of depressive symptoms and the impact of positive screens for significant depressive symptoms on all scales of the SF-36V and HNQoL scores suggest that this is a severe problem for head and neck cancer patients. For example, significant depressive symptoms predicted a 38 point lower score on the Role Physical and a 47 point lower score on the Social Functioning domain of the SF-36V (range=0–100), indicating a marked decrease in physical status and social well-being [45].

Inadequate coping has been shown to affect the immune system [46] and even survival [22,23]. Yet depressive symptoms and disorders are often undetected in cancer patients [47] perhaps because it is a low priority for providers who are preoccupied with managing the physiological problems associated with head and neck cancer. Moreover, depressive symptoms are difficult to assess because symptoms of the head and neck cancer can obscure the diagnosis. For example, poor appetite and sleeplessness can be related to depression and/or to the diagnosis of head and neck cancer [48]. To address psychiatric issues in head and neck cancer patients, liaison psychiatry services, behavioral team approaches, and increased training programs for providers have been suggested in the literature [49,50].

Despite the known risk of continued smoking in patients with head and neck cancer [18,51], over one-quarter of the head and neck cancer patients continued to smoke; most of them smoked more than ½ a pack per day. Smoking negatively influenced five of the eight SF-36V quality of life scores in the regression analysis. Thus, smoking cessation services may increase the quality of life of head and neck cancer patients who have continued to smoke.

In addition, almost half of the respondents continued to drink alcohol; the majority drank more than two times a week, and most drank more than two drinks per day. Surprisingly, alcohol intake was not associated with quality of life in this pilot study. Drinkers have been shown to have worse quality of life and mortality outcomes than nondrinkers [7]. Despite these results, referrals to alcohol treatment programs may benefit selected head and neck cancer patients. Alcohol intake is a major risk factor for increased smoking and relapse to smoking [52].

While respondents seemed to be most interested in smoking and depression services, few were interested in services to decrease alcohol intake. The respondents' interest in smoking and depression services implies respondent discomfort with these problems, while alcohol intake may serve as a more acceptable form of coping for head and neck cancer patients. Although the sample size is too small to draw any firm conclusions, non-Whites (primarily African Americans) had a greater interest in smoking and depression services than did Whites. The decreased interest in services by those traveling more than 25 miles one-way suggests that distance may be a barrier to receiving services and that innovative intervention strategies need to be developed to

reach vulnerable head and neck cancer patients in their own communities.

Having a tumor site of larynx vs. all others (oral, oropharynx, hypopharynx or other) and having a higher tumor stage (III & IV) predicted increased quality of life related to Pain, Emotional Status, and Eating. Although these findings may seem counterintuitive, the most likely explanation for this finding is related to the relatively large percentage of patients with laryngeal cancers and/or advanced stage (III and IV) cancers who, at our institutions, are frequently successfully treated with organ-preservation therapies and are thereby spared from the morbidity of surgical therapies. Patients with laryngeal cancers and/or advanced tumor stages are often spared the surgical morbidity (pain) associated with shoulder dysfunction after neck dissection, and often are spared the cosmetic/emotional morbidity related to laryngectomy status, facial disfigurement, speech, or swallowing problems that accompany surgery in many cases [21].

Since educational status has been shown to influence smoking, alcohol intake and depression and over half of the sample had a high school education or less, the respondents in the sample were vulnerable to smoking, alcohol intake and depression. Veterans, which comprise the majority of the respondents, are particularly at risk for smoking, alcohol intake, and depression [16,53,54]. While almost half of the respondents were working prior to diagnosis of head and neck cancer, over half of those working were no longer employed after diagnosis reflecting the physical, psychological, social and financial costs of the disease.

The mean age of the respondents was similar to other populations of head and neck cancer [55,56] and the racial and gender composition of the sample was similar to that of the institutions from which the respondents were recruited. Given that marital status has been shown to be a marker of social support [57] and survival [58] and over half of the sample was not married, the respondents were at risk for poor social support making them more vulnerable to smoking, alcohol intake, depression, and poor quality of life. Head and neck cancer patients tend to become even more socially isolated after treatment [59,60].

5.1. Limitations of the study

This pilot study consisted of a convenience sample of head and neck cancer patients from a VA and a University hospital. The sample size was small, but nonetheless produced some powerful results related to the association of smoking, alcohol, and depressive symptoms with the quality of life of head and neck cancer patients. Due to the small sample size, we were unable to include in the regression analysis a number of other control variables (e.g., race, gender, educational level, marital status, and hospital site) that may also influence quality of life scores. Furthermore, we did not follow up positive depression screens with semi-structured interviews that would have allowed us to deter-

mine the diagnostic status of these patients. We also did not collect information on comorbidities and treatment modalities (surgery, chemotherapy and radiation) that may influence quality of life scales. The results of this study served as pilot data to conduct a larger study (now in progress) designed to further explore the relationship between smoking, alcohol intake, and depression on the quality of life of head and neck cancer patients.

6. Conclusion

Head and neck cancer patients are at risk for smoking, alcohol intake and significant depressive symptoms. Patients with these problems have significantly lower quality of life than those without these problems. While smoking, alcohol intake and depression may be episodically treated, standardized protocols for systematically assessing and treating these highly prevalent behaviors/conditions may be needed in this population. Aggressive intervention strategies (such as informational, preventative, and relapse-prevention interventions) for one or more of these comorbid problems are needed for head and neck cancer patients who smoke, drink alcohol, or experience significant depressive symptoms.

Acknowledgment

The authors thank the Department of Veterans Affairs, the Oncology Nursing Society and Sigma Theta Tau (both the International and Lambda Chapter) for partial funding of the study. In addition, the authors thank the clinic personnel at the VA Ann Arbor Healthcare System and the University of Michigan Medical Center, otolaryngology clinics for their cooperation in the study. Moreover, the authors thank the patients who participated in this study for their time and cooperation. Finally, the authors express their appreciation to research associates Christine Kowalski, M.P.H., Allison Mitchinson, M.S., research assistants Shara Kilarski, Claire Hansen, Karen Dobias, and Terrance Craion, and nurse practitioner Lynn Gregory for their participation in data collection and management.

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