Assessing Quality of Life in Patients With Head and Neck Cancer

Cross-validation of the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Head and Neck Module (QLQ-H&N35)

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Design: Cross-sectional study using questionnaire data and medical chart review.

Setting: Academic tertiary care otolaryngology clinic.

Participants: One hundred twenty ambulatory patients, including 30 patients with advanced head and neck cancer in each of the following stages of treatment: (1) prior to treatment, (2) during active treatment, (3) within 6 months of completing treatment, and (4) more than 6 months after completing treatment. In addition, (5) a comparison group of 40 patients without malignant disease was included (total sample, N = 160).

Main Outcome Measures: Scores on EORTC Quality of Life Core Questionnaire (QLQ-C30) and head and neck module (QLQ-H&N35), Profile of Mood States, and Impact of Events Scale.

Results: The QLQ-H&N35 demonstrated acceptable reliability (internal consistency). It successfully discriminated between cancer patients and the comparison group, and among subgroups of cancer patients at different phases of treatment (construct validity). The instrument was sensitive to the effects of radiation treatment and to site of disease. Its low-to-moderate correlations with the EORTC core questionnaire indicated that the QLQ-H&N35 provided unique information (discriminant validity). Scores were significantly associated with a number of demographic variables.

Conclusion: Results support the use of this disease-specific measure to assess quality of life among patients with advanced head and neck cancer.

PARTICIPANTS AND METHODS

Participants were a convenience sample of 160 ambulatory patients, aged 18 years or older, receiving care at the University of Arkansas for Medical Sciences Otolaryngology Clinic, Little Rock. The sample included 30 patients with head and neck cancer in each of the following phases of treatment: (1) prior to treatment, (2) during active treatment, (3) within 6 months of completing treatment, and (4) more than 6 months after completing treatment. In addition, (5) a comparison group of 40 patients receiving services for nonmalignant illnesses was included. Exclusion criteria included inability to speak and read English, dementia, or functional status sufficiently impaired to preclude completion of questionnaires (ie, Karnofsky score <60). Questionnaires from an additional 18 patients were eliminated from the analyses: 10 due to procedural error (a page was omitted from the packet) and 8 due to extensive missing data.

The mean (SD) age of participants was 57 (14.4) years. Demographic and medical characteristics are listed in Table 1. Consistent with referrals to a tertiary care clinic, most of the cancer patients had advanced disease, with approximately 73% diagnosed as having recurrent cancer or stage III or IV disease. Information concerning income and education was available for a subset of patients (51%), who had completed demographic forms prior to treatment. Among these patients, median household income was $27,500 (range, $1250 to $70,000), and most had a high school education (range, 6th grade to postgraduate degree).

DATA COLLECTION

Patients received the packet of questionnaires from the receptionist during routine clinic visits, and completed them while waiting to see the physician. Because these questionnaires are administered as part of standard clinical care to assist screening and treatment planning, this study was formally exempted from institutional review board approval; however, all participants were informed of the purpose of the questionnaires and apprised that a decision to decline would not affect their medical care. A trained clinical assistant was available to respond to any questions or concerns.

Participants completed a packet of questionnaires that included the EORTC measures, the Profile of Mood States (POMS),17 the Impact of Events Scale (IES),18 a demographic form, and questions about medical comorbidity and psychiatric history. The EORTC QLQ-C30 (version 2.0)9 is a 30-item measure of health-related quality of life. It yields 6 functional scales (Physical, Role, Emotional, Social, Cognitive, and Global quality of life), 3 symptom scales (Fatigue, Pain, and Nausea/Vomiting), and 6 single items (Dyspnea, Sleep disturbance, Appetite, Diarrhea, Constipation, and Financial difficulties). Participants respond to items in a yes/no format, a Likert scale, or a visual analog scale. The core instrument was used in tandem with the head and neck module (QLQ-H&N35), a 35-item questionnaire that assesses symptoms encountered specifically by patients with head and neck cancer.13,16 This measure generates 7 multiple-item scales (Pain, Swallowing, Senses, Speech, Social eating, Social contact, and Sexuality), in addition to 11 single items (eg, Opening mouth, Sticky saliva, Dry mouth, etc). To ensure content validity, items were developed in accord with EORTC standardized guidelines,14 which include review by panels of specialists and patients, followed by international field testing. All EORTC scales and single items were scored and linearly transformed to scales of 0 to 100.

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Contribute important, unique information concerning quality of life.7,10 A modular approach allows assessments to be tailored to specific patient groups (through use of disease-specific modules), while preserving comparability across studies (through use of the general measure). Such an approach is embedded in the European Organization for Research and Treatment of Cancer (EORTC) Quality of Life Questionnaire. The core instrument (QLQ-C30) has been validated in diverse samples of cancer patients (including those with head and neck cancer) across a number of studies in Western Europe and North America.9,11-14 The core instrument is intended to be used in conjunction with site- or disease-specific modules, to provide more comprehensive assessment of patients’ difficulties. Recently, a module was developed for use in patients with head and neck cancer.13,16 The module incorporates but is an extensive revision of one previously developed by Bjordal and Kaasa.11 Psychometric data from a large, international validation study are pending. Initial results from a study with Norwegian, Swedish, and Dutch patients were promising, indicating that the module is responsive to changes over the course of treatment, and sensitive to differences in disease site, stage, and performance status.16 Thus far, however, we are aware of no independent evaluations of this instrument, or examinations of its appropriateness for use in the United States. Further studies are clearly needed to establish its value. Moreover, few studies of quality of life in head and neck cancer patients have evaluated the potential influence of demographic factors (eg, age and socioeconomic status) or medical comorbidity. Yet results might be greatly affected by these variables.

The present study was intended to assess the reliability and validity of the new EORTC head and neck module (QLQ-H&N35) in a sample of patients with advanced disease, at diverse phases of treatment. A secondary aim was to provide additional information about the psychometric properties of the core questionnaire when used with an American sample. Specifically, we sought evidence of the instruments’ (1) reliability (internal consistency), (2) construct validity (sensitivity to group differences, convergent validity, discriminant validity), and (3) relationship with demographic factors and comorbid conditions. Construct validity was assessed by the ability of these instruments to differentiate between head and neck cancer patients vs a comparison group of otolaryngology patients with nonmalignant disease, and by their capacity to differentiate subgroups of cancer patients at different phases of treatment. Sensitivity to differences in type of treatment and site of disease was also examined. Convergent validity was as-
were reversed scored, so that higher scores indicate better functioning. Conversely, higher scores on the symptom scales and individual items indicate greater impairment. The EORTC questionnaires required approximately 8 minutes to complete. Of the 160 EORTC questionnaires included in the analysis, 22 contained missing values (13.8%); a total of 37 items were missing (0.4% of total items). The mean of the scale was used to substitute for missing values, provided at least half of the items on the scale had been completed.

The short form of the POMS was used to assess emotional functioning and fatigue. This 30-item questionnaire yields a Total Mood Disturbance score as well separate scores for each of 6 scales. Participants respond to each item on a 5-point Likert scale. The internal consistency and construct validity of the original instrument have been established across multiple studies with cancer patients. In this study, the Tension-anxiety, Depression, and Total Mood Disturbance scores were used to represent emotional functioning. The Fatigue scale was used to assess fatigue. Higher scores reflect greater distress. The IES was used to measure cancer-related stress. This 15-item instrument yields a total score as well as scores for 2 subscales, Intrusion and Avoidance symptoms. Patients respond to each item on a 4-point Likert scale. The instrument has demonstrated internal consistency and predictive validity in a sample of head and neck cancer patients and in a mixed sample of newly diagnosed cancer patients. Higher scores reflect greater stress-related symptoms associated with cancer.

Comorbid medical illnesses were assessed with the Health Conditions Questionnaire. This measure includes 15 items in a yes/no response format that inquire about current or prior major medical conditions. In addition, 4 items constructed by the investigators inquired about premorbid psychiatric and substance abuse history. A demographic form obtained information about marital status, income, education, ethnicity, and employment. Due to logistical considerations, the Health Conditions Questionnaire and demographic form were available only for patients assessed prior to treatment. Finally, the medical records of all cancer patients participating in this study were reviewed to obtain information about disease status and treatment (ie, tumor site, stage, recurrence, histologic findings, and dates and types of initial and adjuvant treatments received).

STATISTICAL ANALYSES

Data were analyzed using NCSS 2000 statistical analysis software (Jery Hintze, Kaysville, Utah). Internal consistency reliability was calculated by Cronbach coefficient α. Preliminary χ² tests (for categorical measures) and Mann-Whitney tests and Kruskal-Wallis 1-way analyses of variance (for continuous measures) were used to examine group differences on demographic and medical variables. Mann-Whitney tests were used to test for differences on the EORTC scores between cancer patients and comparison patients, and Kruskal-Wallis analyses of variance were used to examine differences between the subgroups of cancer patients. The sensitivity of EORTC scores to medical variables (ie, radiation treatment, disease site) was assessed using Mann-Whitney analyses. Spearman correlation coefficients were used to examine the intercorrelations between the EORTC scales (discriminant validity) and to assess the relationship of the EORTC scales with other psychosocial and demographic variables. All significance tests were 2-tailed, and P < .05 was considered significant.

RELIABILITY

The reliability coefficients (Cronbach α), means, and SDs for the QLQ-H&N35 scales are listed in Table 2. Reliability coefficients for most of the scales ranged from .75 to .93, indicating satisfactory internal consistency. The exception was the Senses scale (HNSE), which had a coefficient of .54. Reliability coefficients, means, and SDs for the EORTC core questionnaires (QLQ-C30) are listed in Table 3. Reliability coefficients for each of the scales equals or exceeds .72, except for the Cognitive functioning scale (.61).

SENSITIVITY TO GROUP DIFFERENCES

As a group, the cancer patients scored significantly higher (indicating greater difficulties) on most of the QLQ-
H&N35 scales than comparison patients. There were significant differences on each of the multiple-item scales: Pain (HNPA; \(P = .001\)), Swallowing (HNSW; \(P < .001\)), Senses (HNSE; \(P < .001\)), Speech (HNSP; \(P < .001\)), Social eating (HNSE; \(P < .001\)), Social contact (HNSC; \(P = .003\)), and Sexuality (HNSX; \(P < .001\)). On the 11 single-item measures, cancer patients reported significantly greater difficulties with the Opening mouth (HNOM; \(P < .001\)), Dry mouth (HNDM; \(P = .001\)), Sticky saliva (HNSS; \(P = .001\)), Felt ill (HNFI; \(P = .001\)), Feeding tube (HNFE; \(P = .005\)), and Weight loss (HNWL; \(P = .006\)) scales, and marginal differences on the Coughed scale (HNCO; \(P = .08\)). Results concerning Nutritional supplements became nonsignificant after adjusting for group differences in age. No differences emerged on the other 3 single-item scales: Teeth (HNTE), Painkillers (HNPK), and Weight gain (HNWG).

With respect to the core questionnaire (QLQ-C30), there were significant differences on the Physical functioning (\(P < .001\)), Role functioning (\(P < .001\)), Cognitive functioning (\(P < .001\)), Emotional functioning (\(P < .001\)), Social functioning (\(P < .001\)), Global quality of life (\(P < .001\)), Fatigue (\(P < .001\)), Pain (\(P < .001\)), Nausea/vomiting (\(P < .001\)), Dyspnea (\(P < .001\)), Appetite (\(P < .001\)), Constipation (\(P < .001\)), and Financial difficulties (\(P < .001\)) scales. On each of these scales, cancer patients reported poorer functioning than comparison patients. On the 6 single-item measures, cancer patients reported significantly greater difficulties with...
During Tx

Within 6 mos of

During Tx

>6 mos After Tx

>6 mos After Tx

Figure 1. Median scores on the European Organization for Research and Treatment of Cancer (EORTC) QLQ-H&N35 for patients with head and neck cancer at different phases of treatment (Tx). The scales are as follows: HNPA, Pain; HNSW, Swallowing; HNSE, Senses; HNSP, Speech; HNSO, Social eating; HNSC, Social contact; HNSX, Sexuality; OM, Opening mouth; DR, Dry mouth; SS, Sticky saliva; CO, Coughed; FI, Felt ill; PK, Painkillers; and WL, Weight loss. Higher scores indicate poorer functioning. Significance was determined by Kruskal-Wallis tests. (Scales are not displayed if the medians for all groups equal 0.)

Figure 2. Median scores on the European Organization for Research and Treatment of Cancer (EORTC) QLQ-C30 for patients with head and neck cancer at different phases of treatment (Tx). The scales are as follows: PF, Physical functioning; RF, Role functioning; CF, Cognitive functioning; EF, Emotional functioning; SF, Social functioning; QL, Global quality of life; F, Fatigue; P, Pain; N/V, Nausea/vomiting; Dys, Dyspnea; App, Appetite; Fin, Financial difficulties; and Sl, Sleep disturbance. For the top graph, higher scores reflect better functioning; for the bottom graph, higher scores indicate worse functioning. Significance was determined by Kruskal-Wallis tests. (Scales are not displayed if the medians for all groups equal 0.)

dyspnea (P = .01), appetite (P = .004), and finances (P = .01). After adjusting for group differences in age, results on the Emotional functioning scale became significant (P = .03), and those on the Fatigue scale became marginally significant (P = .10). The other scales on the core instrument did not distinguish between cancer patients and the comparison group.

Significant differences on the EORTC scales also emerged when we compared subgroups of cancer patients at different phases of treatment. On the QLQ-H&N35, there were significant group differences on the Pain (P = .003), Senses (P < .001), Speech (P = .003), Social eating (P = .03), and Social contact (P = .02) scales (Figure 1). On the single-item scales, group differences emerged on the Felt ill (P = .001), Painkillers (P = .008), Feeding tube (P = .009), and Weight loss (P = .001) scales, with marginal differences on the Sticky saliva scale (P = .08). Patients in the active treatment group scored higher than patients who had not yet received treatment (HNSE, HNSP, HNSO, HNSC, HNFI, HNPK, HNF, and HNW) or those who had completed treatment more than 6 months ago (HNPA, HNSE, HNSP, HNFI, HNPK, and HNW). In addition, patients who had recently completed treatment (within the past 6 months) scored higher than patients who had not yet began treatment (HNSP, HNSO, HNSC, HNFI, and HNW) or those who were further into recovery (HNPA, HNPK, and HNW). Findings on the Social contact scale were only marginally significant after adjusting for group differences in age (P = .06).

On the core questionnaire (QLQ-C30), significant group differences emerged on the Role functioning (P < .001), Social functioning (P = .007), Fatigue (P = .008), Nausea/vomiting (P = .006), and Appetite (P = .01) scales, with marginal differences on the Pain (P = .058), Sleep disturbance (P = .09), and Financial difficulties (P = .08) scales (Figure 2). In each case, patients receiving treatment reported greater difficulties than those in all of the other groups except patients who had completed treatment within the past 6 months. Patients who had recently completed treatment experienced poorer role and social functioning than patients who had not yet began treatment, and had greater difficulties with role functioning and fatigue than patients who had completed treatment more than 6 months ago.

To determine whether responses to the EORTC scales are influenced by type of treatment, patients who had received radiation treatment (n = 62) were compared with those who had not (n = 58). On the QLQ-
H&N35, patients who had received radiation treatment reported significantly greater difficulties with pain ($P = .005$), swallowing ($P = .004$), coughing ($P = .01$), dry mouth ($P = .03$), and weight loss ($P = .004$) than patients who had not received radiotherapy. On the EORTC core questionnaire, patients who received radiation treatment reported worse role functioning ($P = .03$) and more constipation ($P = .03$). Inspection of the means suggested greater distress for the radiation treatment patients on all the other EORTC scales, with the exception of the Appetite, Social contact, Opening mouth, and Felt ill scales.

To assess whether the QLQ-H&N35 is sensitive to differences in site of disease, patients with cancers of the oral cavity, oropharynx, hypopharynx, or larynx ($n = 62$) were compared with those with other disease sites ($n = 58$). As anticipated, patients with oral cavity, pharyngeal, or laryngeal cancer scored significantly higher on the Swallowing ($P = .005$) and Speech ($P = .03$) scales. They also reported significantly greater difficulties with pain ($P = .03$), sticky saliva ($P = .003$), coughing ($P = .01$), and use of feeding tubes ($P = .01$), relative to patients with other sites of disease. With respect to other relevant scales, means were in the expected directions for the Social eating and Social contact scales, but not for the Opening mouth scale.

### DISCRIMINANT VALIDITY

Correlations between the EORTC scales are displayed in Table 4. Within the QLQ-H&N35, correlations ($r_s$) between the scales were variable, ranging from 0.18 to 0.75. As might be expected, the strongest associations ($r_s > 0.60$) were among the Swallowing, Social eating, Speech, and Social contact scales. Within the core module, correlations between the scales ranged in magnitude from 0.19 to 0.75. The strongest relationships were found among the Global quality of life, Fatigue, Social functioning, and Role functioning scales. Correlations between the QLQ-H&N35 scales and those of the QLQ-C30 were low to moderate ($r_s = -0.14$ to $-0.67$), indicating that despite shared variance with the core questionnaire, the head and neck module offers unique information.

### ASSOCIATION WITH DEMOGRAPHIC VARIABLES

Both the EORTC QLQ-H&N35 and the QLQ-C30 were significantly associated with a number of demographic variables. On the QLQ-H&N35, older cancer patients reported greater difficulties with speech (HNSP; $r_s = -0.20$, $P = .03$) and social contact (HNSC; $r_s = -0.27$, $P = .003$) than younger patients. Patients with more extensive education reported less use of painkillers (HNPK; $r_s = -0.27$, $P = .04$) and less weight loss (HNWL; $r_s = -0.31$, $P = .02$) than less educated participants. Those with higher incomes reported less use of painkillers (HNPK; $r_s = -0.32$, $P = .02$) and feeding tubes (HNFE; $r_s = -0.30$, $P = .04$). Married patients had fewer problems with teeth (HNTE; $P = .05$) or feeling ill (HNFI; $P = .02$) but more problems with sex (HNSX; $P = .02$), relative to unmarried patients.

On the QLQ-C30, older patients reported better emotional functioning ($r_s = 0.23$, $P = .01$), less pain ($r = 0.24$, $P = .009$), less sleep disturbance ($r = 0.22$, $P = .02$), and fewer financial concerns ($r = -0.31$, $P < .001$) than younger individuals. Those with higher education obtained higher scores on the Cognitive functioning scale ($r_s = 0.27$, $P = .04$) and lower scores on the Pain scale ($r = -0.43$, $P < .001$) than less educated patients. Patients with higher income reported better emotional functioning ($r_s = 0.35$, $P = .01$), role functioning ($r_s = 0.29$, $P = .04$), and cognitive functioning ($r_s = 0.37$, $P = .007$), and less pain ($r = -0.38$, $P = .006$), fatigue ($r = -0.29$, $P = .04$), and dyspnea ($r = -0.36$, $P = .009$) than those with more modest income. Relative to unmarried patients, married participants had fewer difficulties with pain ($P = .03$), nausea and vomiting ($P = .048$), and dyspnea ($P = .03$). Scores on the QLQ-C30 and the QLQ-

### Table 4. Spearman Correlations Between the EORTC Scales*

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<thead>
<tr>
<th>EORTC Scales</th>
<th>PF</th>
<th>RF</th>
<th>CF</th>
<th>EF</th>
<th>SF</th>
<th>QL</th>
<th>F</th>
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<th>HNPA</th>
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<th>HNSE</th>
<th>HNSP</th>
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* Data are from 120 patients with head and neck cancer. EORTC indicates European Organization for Research and Treatment of Cancer.
H&N35 were not significantly affected by ethnicity, sex, or comorbidity.

**CONVERGENT VALIDITY**

The EORTC scales were significantly correlated with the other outcome measures used in this study (Table 5). There was a high correlation between the EORTC Fatigue scale and the POMS Fatigue scale. As anticipated, there were moderate-to-high negative correlations between the EORTC Emotional functioning scale and the mood scales from the POMS: Tension-anxiety, Depression, and Total Mood Disturbance ($r = 0.63$ to $0.72$). Associations between the EORTC Emotional functioning scale and the IES scores (Intrusion, Avoidance, Total score) were more modest, ranging from $r = -0.23$ to $-0.36$.

**COMMENT**

This investigation is one of the first to examine the reliability and validity of the new EORTC QLQ-H&N35 module for use with American patients with advanced head and neck cancer. Results indicate that the questionnaire performed well, and appears to be a useful, disease-specific instrument for assessing health-related quality of life in this population. All QLQ-H&N35 scales demonstrated high internal consistency, except for the Senses scale. The instrument was successful in discriminating among patient groups. All 7 multi-item scales and 7 of 11 single-item scales reliably distinguished between noncancer patients and those with head and neck cancer. Similarly, 5 multi-item scales (Pain, Senses, Speech, Social eating, and Social contact) and 4 single-item scales (Felt ill, Painkillers, Feeding tube, Weight loss) distinguished patients at different phases of treatment. Scores were also sensitive to the effects of radiation treatment and to differences in site of disease.

The small-to-moderate correlations between scales from the QLQ-H&N35 and those from the EORTC core instrument (QLQ-C30) indicate that the 2 modules tap relatively different dimensions of quality of life, as intended. Within the QLQ-H&N35 module, most correlations between scales were within the moderate range, indicating that each scale contributes distinctive information. However, there was considerable overlap between the Speech and Social eating scales, which should be monitored for redundancy in further research. Previous research among European patients has found greater independence for these 2 scales ($r = 0.32$-$0.45$).

A secondary goal of the present study was to provide additional information about the psychometric properties of the EORTC core questionnaire (QLQ-C30). As in most prior investigations, each of the scales of the core instrument demonstrated acceptable reliability, with the exception of the Cognitive functioning scale, which has been consistently problematic. In view of the small number of items in many of the scales, it is perhaps surprising that reliability is as good as it is. Five scales and 3 single-item measures within the core instrument were able to differentiate cancer patients from noncancer patients (ie, Physical, Role, and Social functioning, Global quality of life, Fatigue, Dyspnea, Appetite, and Financial difficulties). Four scales and 1 single-item measure distinguished cancer patients at different phases of treatment (ie, Role functioning, Social functioning, Fatigue, Nausea/vomiting, and Appetite); 3 additional scales were marginally effective (ie, Pain, Sleep disturbance, and Financial difficulties). Correlations among the scales varied, indicating a good deal of overlap among different dimensions of quality of life, but most of the associations were moderate. Some of the scales from the core instrument and the head and neck module were influenced by patient characteristics such as age, education, income, and marital status. The impact of these variables should be carefully assessed in future studies. Overall, these results provide supportive evidence for the validity of the EORTC modules among patients with advanced head and neck cancer.

As anticipated, correlations with other measures of psychosocial adjustment were moderately high. The EORTC Fatigue scale was strongly associated with another measure of Fatigue (POMS), and the Emotional functioning scale was significantly associated with other measures of emotional well-being (POMS Depression, Anxiety, Total Mood Disturbance; IES Intrusion, Avoidance, Total score). We are not aware of other studies that have compared these particular instruments. However, other investigators have reported strong correlations between the EORTC Emotional functioning scale and other measures of emotional adjustment (ie, General Health Questionnaire–20, Emotion scale from the Functional Living Index–Cancer) in Norwegian and Australian samples of cancer patients, some of which included patients with head and neck cancer. The EORTC Fatigue scale has never been compared with other established measures of fatigue, to our knowledge. Nevertheless, this scale has been shown to be sensitive to extent of disease, performance status, and treatment efficacy in other studies. Our results provide further evidence for the convergent validity of these scales.

How does the EORTC QLQ-H&N35 compare with other self-report quality-of-life measures that have been

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**Table 5. Spearman Correlations Between EORTC Scales and Measures of Fatigue and Mood**

<table>
<thead>
<tr>
<th>Measure</th>
<th>Correlation</th>
</tr>
</thead>
<tbody>
<tr>
<td>EORTC Fatigue</td>
<td>0.78</td>
</tr>
<tr>
<td>POMS Fatigue</td>
<td>0.78</td>
</tr>
<tr>
<td>POMS TMD</td>
<td>-0.72</td>
</tr>
<tr>
<td>POMS Depression</td>
<td>-0.63</td>
</tr>
<tr>
<td>POMS Tension-anxiety</td>
<td>-0.69</td>
</tr>
<tr>
<td>IES Total</td>
<td>-0.30</td>
</tr>
<tr>
<td>IES Intrusion</td>
<td>-0.36</td>
</tr>
<tr>
<td>IES Avoidance</td>
<td>-0.23</td>
</tr>
</tbody>
</table>

*Data are from 120 patients with head and neck cancer. EORTC indicates European Organization for Research and Treatment of Cancer; POMS, Profile of Mood States; TMD, Total Mood Disturbance; and IES, Impact of Events Scale. P < .01 for all correlations.
used with head and neck cancer patients? The Functional Assessment of Chronic Illness Therapy—Head and Neck Cancer (FACIT-H&N),3 the University of Washington Quality of Life Scale,30 the Head and Neck Quality of Life Questionnaire (HMQOL),31 and the Head & Neck Survey10 are validated instruments that provide important disease-specific information from the patient’s perspective. When combined with a general quality-of-life measure (eg, FACIT-G, SF-36 [Medical Outcomes Study 36-Item Short-Form Health Survey]32), each assesses multiple dimensions of health-related quality of life. As yet, limited data are available concerning the psychometric properties of these questionnaires. Relative to the other disease-specific instruments, the EORTC QLQ-H&N35 represents one of the most comprehensive measures. It captures many though not all of the difficulties included in other questionnaires. A second advantage of the EORTC QLQ-H&N35 is that, like the HMQOL and the Head & Neck Survey, it provides subscale scores for different domains of functioning (eg, speech, pain, eating). The other instruments generate only a total score, which may obscure findings in particular problem areas. The EORTC QLQ-H&N35 and FACIT-H&N were both designed to be used in conjunction with their respective general modules; the consistency of response format within one series of modular questionnaires may be somewhat easier for patients to use than 2 separate questionnaires with different formats. A final advantage of the EORTC QLQ modules is that they were specifically developed for use in international trials; a large database will soon be available to facilitate comparisons across studies, and there is some assurance of cross-cultural suitability.

Among its disadvantages, on the other hand, the EORTC QLQ-H&N35 is a lengthier questionnaire than its counterparts, raising questions about patient burden. In our experience, the length of the questionnaire has not been problematic, but when combined with several other psychosocial measures or used repeatedly over time this becomes more of a concern. From a psychometric perspective, one might question the reliance on single-item scales in both the core and head and neck modules; multiple-item scales usually offer greater reliability.33,34 Unlike the HMQOL, whose subscales were generated through factor analysis, the factor structure of the EORTC QLQ-H&N35 has yet to be explored. Finally, despite its breadth the instrument does not assess a few of the difficulties included in other questionnaires (eg, shoulder disability, self-esteem changes associated with facial disfigurement). Different needs or goals may dictate use of different quality-of-life measures (eg, brevity vs comprehensiveness). In addition, studies that directly compare the performance of these instruments would be helpful, particularly because the validation process for each of them remains in its early stages.

In sum, the present study supports the value of the EORTC modules for use with patients with advanced head and neck cancer. These findings extend the results of previous research with Northern European patients.18 Although the performance of these instruments was promising, the reliability of the Senses and Cognitive functioning scales was poor. Among the limitations of this study, the sample size was small, most participants were white, and most had advanced disease. Further work is needed to determine the psychometric properties of the QLQ-H&N35 module in other cultural and minority groups in the United States, and in patients with earlier-stage disease. Longitudinal research among European patients has demonstrated that the QLQ-H&N35 is sensitive to changes over the course of treatment—3—an important consideration for quality-of-life instruments. Comparable longitudinal studies in the United States would contribute to the cross-validation of the measure. Additional research should focus on whether the QLQ-H&N35 is sensitive to chemotherapy or radiation toxicities, extent of surgery, and presence of tracheoesophageal punctures or tracheotomies. Data concerning test-retest reliability (ie, the stability of scores over brief periods of time) would be helpful. Finally, further research should examine the relationship between the QLQ-H&N35 module and other measures of performance status (eg, Performance Status Scale for Head and Neck Cancer)4 and disease-specific quality of life (eg, the FACIT-H&N3). Current findings are encouraging.

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