Quality of Life in Patients With Head and Neck Cancer

Lessons Learned From 549 Prospectively Evaluated Patients

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Objectives: To summarize our quality-of-life (QOL) research findings for patients with head and neck cancer, to suggest areas for future productive QOL research, and to discuss how to undertake QOL studies in a cost-effective manner.

Design: Review of previously published analyses of advanced larynx cancer, advanced oropharynx cancer, and neck-dissection cases and current data from the complete set of patients.

Patients: From January 1, 1993, through December 31, 1998, data on 549 patients were entered in our head and neck database. Of these patients, 364 met additional criteria for histologic findings (squamous cell carcinoma) and the restriction of their cancer to 4 major anatomical sites (oral, oropharynx, hypopharynx, or larynx). Of these, 339 patients were more than 1 year beyond initial treatment. Complete baseline TNM staging and QOL data were obtained for 260 of these patients, of whom 210 presented with an untreated first primary tumor (index cases) to the University of Washington, Seattle.

Intervention: Pretreatment QOL was assessed with an interviewer-supervised self-administered questionnaire. Subsequent self-administered tests were completed at 3, 6, 12, 24, and 36 months. Other data collected on each patient included cancer site, stage, treatment, histologic findings, type of surgical reconstruction, and current disease and vital status.

Results/Conclusions: It is difficult to achieve “statistically significant” results in a single-institution setting. The “composite” QOL score may not be a sufficiently sensitive tool. Analysis of separate domains may be more effective.


Our quality-of-life (QOL) project was initiated in the late 1980s because we realized that while therapy was evolving in many ways, multi-institution trials had failed to demonstrate meaningful survival differences among various forms of treatment. This led to a consideration of measuring QOL as a way to compare treatment modalities with similar cure rates.

To undertake a QOL analysis of head and neck cancer, a disease-specific QOL tool, the University of Washington Quality-of-Life (UW-QOL) questionnaire, was created and validated. Since 1993, every new cancer patient presenting to the University of Washington Medical Center, Seattle, has been asked to participate in a prospective study. This article summarizes our experience and discusses what we have learned from studies of data within this set. We make suggestions about specific areas that may be fruitful for QOL research and consider how researchers may undertake QOL studies in a cost-efficient manner.

RESULTS

From January 1, 1993, through December 30, 1998, data obtained on 549 patients were entered in our head and neck database. From this group, 364 met additional criteria for histologic findings (squamous cell carcinoma) and restriction of their cancer to 4 major sites (oral, oropharynx, hypopharynx, or larynx). Of these 364 patients, 339 were more than 1 year beyond initial treatment. We obtained complete baseline TNM and QOL data on 260 of these patients, 50 of whom had recurrent or persistent disease at the time of presentation and were eliminated from this analysis. Two hun-
PATIENTS, MATERIALS, AND METHODS

The project began January 1, 1993, after approval by the Human Subjects Committee of the University of Washington. All new patients presenting to the University of Washington Medical Center with a diagnosis of head and neck cancer were asked to participate in a prospective analysis of QOL changes during and after treatment. Patients completed an interviewer-supervised self-administered pretreatment QOL questionnaire on the day of their initial workup. Subsequent self-administered questionnaires were completed at 3, 6, 12, 24, and 36 months. Other data obtained for each patient included site of treatment, cancer stage, type of treatment, histologic findings, surgical reconstruction, and current health status. A QOL registrar was responsible for patient follow-up and data collection and collation. All data were entered in the departmental relational database that was developed by one of the authors (M.D.C.).

DEFINITION OF TERMS AND DESCRIPTION OF THE UW-QOL QUESTIONNAIRE

Domain Score

The domain score reflects the QOL associated with different aspects of head and neck cancer treatment. Twelve domains were probed: (1) activity, (2) appearance, (3) chewing, (4) dry mouth, (5) employment, (6) pain, (7) recreation, (8) saliva, (9) shoulder function, (10) speech, (11) swallowing, and (12) taste. Responses ranging from 0 (worst) to 100 (best) were obtained with Likert scales. For example, the options for pain were scored as follows:

- I have no pain (score, 100).
- There is mild pain not requiring medication (score, 75).
- I have moderate pain, requires regular medication (codeine or nonnarcotic) (score, 50).
- I have severe pain controlled only by narcotics (score, 25).
- I have severe pain not controlled by narcotics (score, 0).

Composite QOL Score

The composite QOL score refers to the mean or numerical change, with scores ranging from 0 (worst QOL) to 100 (best QOL).

Global QOL Score

The global QOL score is a direct overall assessment of QOL. We asked patients about both health-related QOL and QOL related to all issues. For example, beginning in March 1993, all patients were asked the following: “Considering everything in your life that contributes to your personal well-being, rate your overall quality of life during the past 7 days.” Patient responses were scored as either outstanding, very good, good, fair, poor, or very poor.

Incremental QOL Change Score

The incremental QOL change score is an assessment by the patient of how his or her QOL has changed over a given period. For example, we asked, compared with 1 year prior to the diagnosis of a patient’s illness, if the patient would rate his or her health in general as much worse, somewhat worse, about the same, somewhat better, or much better.

Importance Score

The importance score (after 1995) was determined by asking each patient to indicate how important he or she considered each domain. For example, patients were asked to rank the importance of pain in their overall QOL as not important, a little bit important, somewhat important, quite important, or extremely important.

SUMMARY OF PREVIOUSLY PUBLISHED RESULTS

The results of analyses of 3 separate subsets of patients have been previously published.2-4 These studies were undertaken during the evolution of the project and therefore included a smaller group of patients.

The QOL of Disease-Free Survivors of Advanced (Stage III or IV) Oropharyngeal Cancer

Our first study, analyzing 13 consecutive patients with advanced oropharyngeal cancer who had been treated with statistically significant fashion (P<.001 by analysis of variance) (Figure 1). A similar distribution was noted when the index cases were stratified by T1 through T4 (Figure 2). Site of tumor (oral cavity, oropharynx, hypopharynx, or larynx) also affected composite QOL scores (Figure 3). Although the composite QOL scores were similar at baseline, the QOL curves had significantly different patterns by 3 months (P<.05 by analysis of variance), with laryngeal cases faring best and patients with oropharyngeal and hypopharyngeal tumors faring worst.

We were interested to determine whether differences in QOL emerged between treatment arms (surgery vs organ preservation) with this larger data set. Among advanced primary tumors (TNM stage III or IV) of the oropharynx and larynx, the composite scores did not appear to demonstrate clinically or statistically significant differences (Figure 4 and Figure 5). Similarly, we did not detect differences when global QOL or

<table>
<thead>
<tr>
<th>Cancer Stage</th>
<th>No. of Patients (%)</th>
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<tr>
<td>I</td>
<td>17 (8)</td>
</tr>
<tr>
<td>II</td>
<td>33 (16)</td>
</tr>
<tr>
<td>III</td>
<td>52 (25)</td>
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<tr>
<td>IV</td>
<td>108 (51)</td>
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An analysis of these 210 index cases revealed that TNM stage (I-IV) influenced composite QOL scores in a

<table>
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<th>No. of Patients</th>
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<tr>
<td>Enter in study</td>
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<tr>
<td>Squamous cell carcinoma at 4 major sites</td>
</tr>
<tr>
<td>&gt;1 year beyond initial treatment</td>
</tr>
<tr>
<td>Completed baseline QOL data</td>
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<td>Primary tumors at time of presentation</td>
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The distribution of these 210 patients by cancer stage demonstrates that our institutional experience is dominated by advanced-stage disease (stage III and IV, 76%).
either surgery and radiation or chemotherapy and radiation, was completed in 1995, and the results were published in 1997. All 13 patients were disease free 1 year post-treatment. The composite (total) QOL pretreatment and posttreatment scores were similar for the 2 groups. A subset analysis of the QOL domains demonstrated a worsening of chewing and swallowing in both groups after treatment. The surgical group showed a more frequent worsening of speech and appearance. Sixty-seven percent of the patients who received surgical treatment (n = 6) reported pain relief vs 29% of the nonsurgical group (n = 7).

The results of this study led us to observe that the total score of the UW-QOL questionnaire is derived from a variety of “domains” and that the functional changes created by various therapies demonstrate their effects in the domain scores. For example, patients who present with pain appear to have better relief by surgery than by radiation, and this domain score improves with surgery. In contrast, surgical treatment causes a decrease in the domain score for appearance, while both radiation and surgery create a transient worsening in chewing and swallowing. These various changes cause a “cancellation effect” (ie, while one score is rising, another is falling; therefore, the composite score does not change much). Because of this, the composite QOL score may be less sensitive to therapeutically induced change than individual domain scores.

Are Functional Disabilities Important in the Determination of QOL After Laryngectomy?

In another study, 25 patients with carcinoma of the larynx and hypopharynx occurring from 1993 through 1995 were identified. All patients were treated with surgery (total laryngectomy) and radiation therapy; some patients were also treated with induction or concomitant chemotherapy. (The study also assessed 10 patients who were alive without disease at 2-year follow-up.) We found that the postlaryngectomy QOL score and that 2 years after laryngectomy, the domain scores reflected a variety of functional disabilities. However, when patients were asked to judge the importance of these disabilities, there was no significant correlation. In all QOL domains, including speech and appearance, 50% or more of the patients reported having the same or better function at 20 years posttreatment. The majority of patients reported a good to excellent overall QOL, and most patients reported that their general health was the same as or better than it was 1 year prior to the diagnosis of cancer. We also found that although loss of speech was disabling and a laryngectomy disfiguring, only a minority of patients reported speech or appearance as being more than “somewhat important” to their overall QOL. They indicated that “activity” (ie, socialization) was the most important issue.

This adaptation effect has been noted by others. Given this natural tendency among survivors, it may be difficult to document a difference among treatments on the basis of QOL. A corollary to this conclusion is that, if a difference in total QOL score is demonstrated, it is probably real and probably significant. The addition of a global QOL question provided a valuable contrast to the disease-specific domains of the UW-QOL questionnaire.

The Impact of Neck Dissection on QOL

In a study by Kurtz and Weymuller, 149 consecutive patients who underwent neck dissection between June 1993 and March 1997 were evaluated. After patients with inadequate follow-up or compliance were excluded, 84 patients were included. We analyzed the QOL changes with respect to radical neck dissection, modified radical neck dissection (accessory nerve preserved), and selective neck dissection (levels II, III, and IV removed). Specific attention was directed at the domain that assessed shoulder function. Changes in this domain reflected the anticipated impact of the various forms of neck dissection. Shoulder domain scores for the radical neck group were lower than those of the selective neck dissection group at 6 and 12 months (P = .004). In addition, there was a trend toward decreased pain after treatment in the selective neck dissection and modified radical neck dissection groups.

The results of this study demonstrated that the shoulder domain question of the UW-QOL questionnaire was able to discriminate among selective neck dissection, modified radical neck dissection, and radical neck dissection. Similar analysis of other domains (speech, swallowing, etc) will be much more complex, since the surgical interventions, such as composite resection, are not as well defined as the variations of neck dissection.

health-related QOL was used as an outcome (data not shown).

However, incremental QOL change scores suggest that a difference was present. When patients with advanced oropharyngeal cancer were asked how their health had changed since prior to tumor identification, those who were treated with surgery perceived that their health was better, but those who were treated with chemoradiation perceived that their health was worse (Figure 6). The clinical difference is small, but we believe it is significant. The difference was found to be statistically significant at 1 year (P < .05, t-test), but diminishing sample size prevented the demonstration of statistical significance beyond 1 year.

Patients with laryngeal cancer showed the opposite effect (Figure 7). It appeared that patients with advanced laryngeal cancer who were treated with surgery perceived less improvement than those treated with an organ-sparing approach. Unfortunately, because of a small sample size (most laryngectomy cases at this institution present with recurrent disease and this analysis is limited to patients with previously untreated disease), statistical significance could not be reached, although the clinical difference was readily apparent.

QOL INFORMATION IN OUR DATABASE

Figure 2 provides the composite QOL score values over time for this cohort stratified by TNM stage. As hypothesized, QOL was best for patients with early disease and worst for those with advanced disease. Patients with advanced tumors also demonstrated the most precipitous decline in QOL, presumably associ-
ated with more aggressive therapy, and they did not return to their baseline QOL. These patterns are consistent with the clinical course we expect for various stages and treatments and are an indication of the validity and responsiveness of the UW-QOL questionnaire to clinical change.

A large group of our patients is not addressed by these data. The decrease from 210 index patients at entry to 50 at 2 years posttreatment is the result of deaths (with or without disease), loss of contact, and exclusion of any patient with less than complete QOL data at any time. It is therefore important to note that we are reporting QOL scores, not survival.

IMPORTANCE SCORES

Since 1995, patients have been asked to rate the importance of each domain in the UW-QOL questionnaire on a scale from “not important” to “extremely important.”

Since QOL is such a subjective construct, we feel that assessing incremental QOL change is more representative of what we intend to measure when we examine QOL issues in head and neck cancer therapy.

The importance scores, however, have not improved the precision of our data.

In preliminary psychometric analyses, the concurrent validity of the UW-QOL questionnaire composite scores (compared with the global and incremental items) is worse when importance ratings are used in the calculations. We suspect this may be in part a result of the way importance ratings were obtained; our findings indicate that there appeared to be a tendency of patients to rate every item as “important,” which prevented us from identifying distinctions between the domains in terms of their relative importance. A proposed modification for obtaining this information will be presented separately.

INCREMENTAL QOL

Using the composite QOL score, we were unable to discern a difference between surgically and nonsurgically treated patients at either anatomical site where these treatment options exist (larynx or oropharynx). However, the technique of measuring incremental change did identify a statistically significant separation between treatments.6

Since QOL is such a subjective construct, we feel that assessing incremental QOL change is more representative of what we intend to measure when we examine QOL issues in head and neck cancer therapy. Quality of life is more (or less) than the sum of the domains of the UW-QOL questionnaire. As indicated by Calman:

The quality of life can only be described and measured in individual terms, and depends on present lifestyle, past experience, hopes for the future, dreams and ambitions. Quality of life must include all areas of life and experience and take into account the impact of illness and treatment.7

OPEN-ENDED TEXT

The availability of open-ended text provides yet another avenue of information regarding individual patients.
While collecting data with the UW-QOL questionnaire, we received a variety of written comments, some allowing us to recognize that there are health care problems in need of attention that would have otherwise escaped our attention. We also received a variety of humorous and tragic remarks, cartoons, photographs, etc. This material is more difficult to analyze statistically, but it can provide meaningful interaction with respect to an individual patient.

**RESOURCE CONSUMPTION**

Prospective collection of comprehensive QOL data is an expensive and time-consuming enterprise, requiring a full-time registrar to maintain data integrity. A conservative estimate of our cost that does not begin to address the sustained commitment by attending surgeons appears below.

Even when thorough data collection is accomplished, other realities can compromise the usefulness of the data in light of the unavoidable loss of patients as a result of cancer recurrence, death, and lack of sustained patient participation in long-term studies. For this reason, we have identified some actions that may reduce the costs of comparable studies that are conducted by single institutions.

**Eliminate Exhaustive Data Collection**

It is our recommendation that prospective longitudinal studies be limited to analysis of the most common types and sites of tumors at a particular institution.

**Obtain Long-term Funding**

The separation of QOL outcome in our laryngeal cases did not become apparent until the 2-year interval. When lon-
Prospective data collection does not guarantee meaningful information

Even in prospective studies with intense commitment from faculty and staff, data may be incomplete because patients (1) fail to keep appointments, (2) do not return questionnaires, and (3) fail to complete forms accurately. Furthermore, those patients whose QOL is poorest are least likely to respond to questionnaires or return for follow-up. Clearly, these issues will inject bias into the data.

Statistical power and single-institution studies

Even though our data set contains over 500 prospectively evaluated patients, analyses of patient subsets did not achieve statistical significance. There are 3 unavoidable issues in single-institution studies that must be recognized. First, randomization does not occur, and at the outset there is a selection bias for treatment decisions that is unavoidable. Second, when stratifying patients for cancer site, stage, and treatment, small populations do not allow for statistical comparisons of QOL, especially in advanced-stage tumors, because 40% to 50% of patients do not survive for 2-year comparisons. Third, if QOL is to be used as an end point for the comparison of 2 treatments, a multi-institution trial will generally be necessary to achieve numeric sufficiency. For single-institution projects, it is recommended that cross-sectional studies be considered. With the cross-sectional technique, a subset of surviving patients can be identified and studied using a single interaction based on a questionnaire. Of course, this format has its own limitations (ie, it does not address the QOL of those who fail to survive treatment).

Selection and use of QOL instruments

In the design of new QOL studies, it is important to construct a research question first and then analyze the various QOL instruments that are available. No single QOL instrument currently exists that is appropriate for all studies. Each QOL instrument should be carefully considered to ensure that the various domains address issues that are pertinent to the particular study being developed. We have learned that the composite QOL score (sum of domain scores) is a relatively insensitive measure because patients tend to adjust to their disabilities. Moreover, it is not likely that the composite QOL score will identify a difference between 2 forms of treatment. It is, however, true that if a difference is identified, it is probably quite meaningful.

The addition of global and incremental change scores brings balance to the analysis of the QOL of patients. A single global question is an appropriate addition to a disease-specific questionnaire and allows investigators to differentiate between disease-specific issues and the patient’s overall life satisfaction, which will be influenced by many psychological and social factors that may be totally unrelated to the disease-specific interventions under analysis. Additionally, incremental change variables may be more sensitive to clinical change. In our data, incremental variables suggested that differences between treatment arms existed, whereas the other QOL measures were unable to detect these differences.

It is evident to us that domain scores should be analyzed separately and that treatment-specific effects may become apparent through contrasting specific responses within the domains, as was noted in our analysis of neck dissection with respect to shoulder function.

Areas for single-institution studies

It is our impression that single-institution studies need sharp focus and are probably best done as (1) cross-sectional studies of survivors, (2) short-term studies in which QOL is the dominant or perhaps only issue (eg, palliative care analysis, alternative pain management strategies, and phase I and phase II analyses of the toxic effects of different chemoradiation or gene therapy regimens), or (3) study cohorts of patients that constitute your largest institutional experience.

Conclusions

1. Achieving statistically significant results in QOL studies of patients with head and neck cancer is challenging, especially in a single-institution setting while stratifying patients for cancer site, stage, and treatment and accounting for predictable attrition rates.

2. When QOL is a secondary end point (as in multi-institution studies comparing survival and local-regional control in radiation vs surgery), it will be difficult to demonstrate statistically significant differences in patient-oriented QOL, since survivors tend to accept and adjust to their disabilities. A corollary is that if a QOL difference is demonstrated, it is probably real and significant.

3. The composite QOL score (sum of the domain scores) is subject to an “internal cancellation” effect. It is therefore less sensitive to overall change when comparing treatment options.

4. Separate analysis of QOL domains provides a more accurate picture of the complex functional changes that occur during cancer therapy.
5. Global QOL and incremental change assessments provide important information and balance to QOL investigations. Compared with the composite QOL score, we feel that these measures more effectively portray this subjective construct. Assessing incremental change is more representative of what we intend to measure when we examine QOL issues in head and neck cancer therapy.

6. There are specific areas in which single-institution QOL research for head and neck cancer therapy is likely to be fruitful, especially in short-term studies in which QOL is the dominant end point, such as the examination of changes associated with surgery or chemotherapy during the first 6 months of treatment, pain management, and palliative care.

7. Comprehensive, prospective QOL data collection is expensive. Cost reduction in QOL studies may be accomplished through the use of cross-sectional studies and by addressing incremental change. Cost reduction may also be achieved by more aggressive utilization of computerized data collection.

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REFERENCES


Editorial Footnote

In this issue, Weymuller and coworkers1 describe their experience with the prospective evaluation of quality of life (QOL) in a large group of patients with head and neck cancer. The authors focus on the value of the information gained in attempting to measure QOL in all of their patients at the time of presentation, as well as at 5 intervals following treatment. This information was prospectively gathered in a relational database, which also included demographic, site, stage, treatment, histological, reconstructive, and current disease status data. Most of their patients (77%) presented with stages III and IV disease. Ninety-eight (40%) of 245 patients had a complete data set at 2 years. The chance of achieving a complete data set for an individual patient was strongly influenced by stage at the time of presentation, with 20 (95%) of 21 patients with stage I cancer fully characterized at 2 years, while just 41 (32%) of 129 patients with stage IV cancer are fully characterized at 2 years. The data reported for the fully characterized group of 98 patients includes mean QOL score over time by TNM stage (I-IV), T stage,2,4 and site. The authors also give 3 examples of QOL outcomes studies done by mining this rich database to evaluate QOL results achieved with specific treatment options.

The University of Washington (Seattle, Wa) Head and Neck QOL Questionnaire is a well-designed, validated, diseasespecific QOL assessment instrument. The investigators involved in this work have played a leadership role in promoting high-quality clinical research techniques in head and neck oncology. The creation of this large relational database required a major commitment by the leadership of the Department of Otolaryngology; the physicians, nurses, and registrars who worked with the patients; and the patients themselves who completed the assessment instrument on multiple occasions. Has it been worth it? Probably so, but there are many challenges and there is much yet to learn. The study reviewed here sheds more light on these challenges and the current status of QOL research analysis than on any specific clinical question of interest to physicians and patients.

The use of measured patient perceptions of outcome as data points in a clinical research study was initially viewed with considerable skepticism by the academic medical community. At that time, physicians were trained to prefer more objective data. Later, the concept was embraced with considerable enthusiasm as part of a broader interest in outcomes research. Proponents predicted widespread benefits, including better information for patients and physicians, valid guidelines for medical practice, and better decisions by health care purchasers. Arnold Relman, the highly respected past editor of the New England Journal of Medicine, called the growing interest in outcomes measurement “the third revolution in medical care.”2 More recently, some skepticism seems to have resurfaced, related to concerns about the quality of the measurement, analysis, and interpretation of this data. A thoughtful review of the challenges involved with using QOL data in the highly charged world of new oncology drug approval was recently presented in The Cancer Letter3; that review focuses on the need to continuously improve the rigor of QOL outcomes research.

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Investigators who are interested in adding QOL outcomes to their clinical research face a number of challenges. First, there has been little standardization of the way in which QOL data are analyzed and presented. There is, if you will, no Kaplan-Meier standard for the presentation of QOL data as there is for survival data. Weymuller and colleagues present their data as mean total QOL scores for a fully characterized group of patients over time. This gives a clear picture of the group as a whole, but the outlook for individuals within the group is less clear, and many patients are excluded by the lack of a complete data set. Requiring a complete 2-year data set for inclusion in the data analysis excludes those patients who die early of their disease, as well as those who may be less motivated for recommended follow-up, and may introduce bias. In addition, Weymuller et al point out that analysis of data using total QOL scores obtained with the University of Washington instrument may obscure the efficacy of a treatment through cancellation, which occurs when the patient improves in 1 or more domains but also experiences an equal decline in other domains. For example, laryngectomy may relieve pain and improve swallowing, but it may worsen communication. Analysis by individual domains (eg, pain, communication, eating, shoulder function) minimizes the chance of a cancellation effect, but complicates the presentation of the data. The University of Washington Head and Neck QOL Questionnaire includes information about 12 separate domains. Requesting a global QOL assessment from the patient and asking the patient to rate the importance of each domain began later in the study, and both were helpful in avoiding the cancellation effect. Finally, there are a number of different validated instruments to choose from, and investigators are only now gaining experience with the strengths and weaknesses of each. As discussed by the authors, no single instrument is appropriate for all studies.

Another challenge experienced by investigators using QOL outcomes is in the actual conduct of a study. Despite a great deal of commitment and a high-quality team effort, Weymuller and colleagues were able to obtain a complete data set in only a minority of their patients. In addition, this type of work currently consumes a great deal of time and resources, especially if one attempts to maintain a complete relational database on all patients within the institution. Automation of data entry may minimize this issue in time, but for now the expense is prohibitive for many groups. The ability to implement these studies in a cost-effective manner is an important issue.

As today’s multidisciplinary treatment teams investigate the value of specific therapeutic options, it is important to have effective methods for measuring the impact of treatment on QOL, in addition to more effectively measuring objective outcomes, such as the chance of survival and the incidence of complications. Survival remains the most important single issue for most patients with head and neck cancer, but QOL issues are next in significance. The lessons learned from the large experience of the group at the University of Washington are a welcome addition to the growing body of knowledge in this field.

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