Patient-reported symptom questionnaires in laryngeal cancer: Voice, speech, and swallowing

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ABSTRACT

Objectives: To validate questionnaires on voice, speech, and swallowing among laryngeal cancer patients, to assess the need for and use of rehabilitation services, and to determine the association between voice, speech, and swallowing problems, and quality of life and distress.

Materials and methods: Laryngeal cancer patients at least three months post-treatment completed the VHI (voice), SHI (speech), SWAL-QOL (swallowing), EORTC QLQ-C30, QLQ-HN35, HADS, and study-specific questions on rehabilitation.

Results: Eighty-eight patients and 110 healthy controls participated. Cut off scores of 15, 6, and 14 were defined for the VHI, SHI, and SWAL-QOL (sensitivity > 90%; specificity > 80%). Based on these scores, 56% of the patients reported voice, 63% speech, and 54% swallowing problems. VHI, SHI, and SWAL-QOL scores were associated significantly with quality of life (EORTC QLQ-C30 global quality of life scale) (r = .43 (VHI and SHI) and r = .46 (SWAL-QOL)) and distress (r = .50 (VHI and SHI) and r = .58 (SWAL-QOL)). In retrospect, 32% of the patients indicated the need for rehabilitation at time of treatment, and 81% of these patients availed themselves of such services. Post-treatment, 8% of the patients expressed a need for rehabilitation, and 20% of these patients actually made use of such services.

Conclusion: Psychometric characteristics of the VHI, SHI, and SWAL-QOL in laryngeal cancer patients are good. The prevalence of voice, speech, and swallowing problems is high, and clearly related to quality of life and distress. Although higher during than after treatment, the perceived need for and use of rehabilitation services is limited.

Introduction

The past decades have shown an improvement in treatment options available to optimize functional outcomes in patients with laryngeal cancer. For instance, laser surgery has become a preferred treatment modality in selected cases of early glottic cancer, surgical voice restoration has become available for patients after laryngectomy, and organ-preservation treatment modalities such as chemoradiation are often the treatment of choice for patients with laryngeal cancer in an advanced stage.

Patient-reported voice, speech, and swallowing outcomes are often used in studies of patients after surgery or radiotherapy for early laryngeal cancer [1–7], as well as patients after laryngectomy, radiotherapy and/or chemotherapy for advanced laryngeal cancer [8–13]. These studies indicate that voice, speech, and swallowing problems occur frequently in laryngeal cancer patients, and appropriate referral to rehabilitation is often recommended. Starmer et al. argued that, despite medical/technical improvements, many laryngeal cancer patients still have swallowing, speech, and voice problems after treatment and require ongoing management by speech and swallowing pathologists [14]. Recent studies report that speech and swallowing rehabilitation may be beneficial to prevent or treat voice, speech and swallowing problems after treatment [15–18]. However, information on the patients’ perceived need for rehabilitation is scarce [19]. Furthermore, detailed information is scarce on important characteristics of voice, speech, and swallowing questionnaires, such as clinically relevant difference scores, overall discriminative abilities of these questionnaires, and sensitivity and specificity analyses. This information is valuable for purposes of group comparisons and to identify individual patients with clinically relevant voice, speech or swallowing problems. Previously, we provided this information for the Voice Handicap Index (VHI) among patients with early glottic cancer [7], and for the Speech Handicap Index (SHI) and the
Swallowing Questionnaire on Quality of Life (SWAL-QOL) among oral and oropharyngeal cancer patients [20,21].

The objectives of the present study are to validate the VHI, SHI, and SWAL-QOL in a population of laryngeal cancer patients and to establish clinically relevant differences scores, and cut-off scores. Furthermore, we investigate the prevalence of voice, speech, and swallowing problems and the perceived need for and use of rehabilitation services, and determine the association between voice, speech, and swallowing problems, and health-related quality of life (HRQOL) and psychological distress.

Materials and methods

Patients and controls

The study sample was composed of a series of patients who attended the outpatient clinic of the VU University Medical Center for a regular follow-up visit during a 3-month recruitment period in 2009. Patients had completed curative treatment for primary laryngeal cancer, at least 3 months to a maximum of 5 years earlier. Patients with serious cognitive problems or who lacked basic fluency in the Dutch language were excluded. The study also included a sample of healthy volunteers recruited from the circle of family and friends of the researchers, comparable for age and sex with the patient sample. Written informed consent was obtained from all study participants.

For the patient sample, tumour and treatment characteristics (subsite, stage, treatment modality, time since treatment) and comorbidity were recorded. Comorbidity was assessed with the Adult Comorbidity Evaluation 27 (ACE-27) [22]. The ACE-27 includes 27 co-morbid conditions, including cardiovascular, respiratory, gastro-intestinal, renal, endocrine, neurological, immunological, psychiatric and rheumatologic disorders, previous or synchronous malignancy, alcohol abuse, and excessive body weight. The ACE-27 was designed specifically for cancer patients and classifies patients into 4 grades of comorbidity (none, mild, moderate, severe). Patients were categorized in primary treatment groups (CO2-laser, radiotherapy, chemoradiation, and laryngectomy with or without radiotherapy).

Patient reported outcomes

Voice, speech, and swallowing outcomes were measured via the Voice Handicap Index (VHI), the Speech Handicap Index (SHI), and the Swallowing Questionnaire on Quality of Life (SWAL-QOL), respectively. We assessed HRQOL with the European Organisation for Research and Treatment of Cancer (EORTC) core questionnaire (the QLQ-C30) and the head and neck cancer module (the QLQ-H&N35). We assessed psychological distress with the Hospital Anxiety and Depression Scale (HADS). Patients also completed a study-specific questionnaire regarding the perceived need for and use of speech and swallowing rehabilitation at present and, retrospectively, at time of treatment.

The VHI is a validated voice-specific quality of life questionnaire consisting of 30-items focusing on voice-related problems in daily life [23]. Response categories range on a 5-point scale. The questionnaire also includes an overall voice quality item, with 4 response categories (“good”, “reasonable”, “poor”, and “severe”). A total VHI score is calculated by summing the scores on all 30 items, with a higher score indicating a higher level of voice-related problems. The VHI has been translated and validated for use with Dutch patients treated for early laryngeal cancer, and a cut-off score of 15 points (97% sensitivity and 86% specificity) has been established to identify patients with substantial voice problems in daily life [7].

The SHI is a validated, speech-specific quality of life questionnaire and consists of 30-items focusing on speech-related problems in daily life. Response categories range on a 5-point scale. The questionnaire also includes an overall speech quality item, with 4 response categories (“good”, “reasonable”, “poor”, and “severe”). A total SHI score is calculated by summing the scores on all 30 items, with a higher score indicating a higher level of speech-related problems. The SHI has been validated among oral and oropharyngeal cancer patients: a cut-off score of 6 (95% sensitivity and 90% specificity) has been established and a difference score of 12 points or more has been proposed as a criterion for clinically significant in group comparisons [20].

The SWAL-QOL is a swallowing-specific quality of life questionnaire and consists of 44-items assessing 10 quality of life domains: food selection; eating duration; eating desire; fear; burden; mental health; social functioning; communication; sleep; and fatigue. A symptom scale and a total SWAL-QOL score are calculated. All SWAL-QOL scales range from 0 to 100, with a higher score indicating more impairment. Finally, 3 separate questions are included regarding nutrition intake, liquid intake, and general health [24]. The SWAL-QOL has been translated and validated for use with Dutch oral and oropharyngeal cancer patients, and a cut-off score of 14 points (or higher) (94% sensitivity and 84% specificity) has been established for identifying patients with clinically relevant swallowing problems. A difference score of 12 points or more has been proposed for as a criterion for clinically significant group comparisons [21].

The EORTC QLQ-C30 is a cancer-specific questionnaire and comprises a global QOL scale (2 items), five functional scales, three symptom scales, and six single items [25]. The EORTC QLQ-H&N35 module covers specific HNC issues and comprises ten single items and seven subscales: swallowing, senses, speech, social eating, social contact and sexuality. The scores of the QLQ-C30 and of the QLQ-H&N35 are linearly transformed to a scale of 0–100, with a higher score indicating a better level of functioning or global QOL, or a worse level of symptoms or problems [26]. In the present study, the global QOL scale and the Swallowing subscale were used.

The HADS is a 14-item scale with 2 subscales, Anxiety and Depression. It has been translated and validated in Dutch [27]. The total HADS score ranges from 0 to 42, the subscales range from 0 to 21. Regarding the subscales anxiety and depression, possible or probable cases are defined as having a subscale score of 8–10 or above 10, respectively.

Statistical analyses

Descriptive statistics were generated for the outcome variables in the study. Psychometric analyses regarding the VHI, SHI, and SWAL-QOL scales included feasibility (percentages of missing questionnaire data), internal consistency (Cronbach’s coefficient alpha), known group validity (Student’s t-test testing patients vs. controls, and within patients: comorbidity (stage 0–1 vs. 2–3) and treatment modality (single (surgery or radiotherapy) vs. combined treatment (surgery and radiotherapy or chemoradiation)), and construct validity (Pearson correlations coefficients between the SWAL-QOL, SHI and VHI scales).

To aid in defining a clinically relevant (difference) score for purposes of group comparisons, Cohen’s effect sizes (ES) were calculated. A clinically relevant difference score for the total VHI, SHI, and SWAL-QOL scales for use in group comparisons was defined as an effect size of 0.50 or greater. The effect size was calculated as the difference between the patient group mean minus the control group mean, divided by the standard deviation of the control group.
To assess the overall discriminative ability of the VHI, SHI, and SWAL-QOL and to define “caseness” (individual patients with clinically relevant voice, speech or swallowing problems) in this population of laryngeal cancer patients, Receiver Operating Characteristics (ROC) analyses were performed. Patients who rated their voice or speech as deviant on the extra voice or speech quality question of the VHI or SHI and patients who scored above 10 on the EORTC QLQ-H&N35 Swallowing subscale were compared with control subjects by ROC analyses. Sensitivity and specificity analyses were carried out to define cut-off scores for the total VHI, SHI, and SWAL-QOL scale.

For all statistical tests, significance was defined as a p-value less than or equal to .05.

**Results**

**Patient characteristics**

Eighty-eight of 105 eligible patients (83%) completed the questionnaires (Table 1). Median age of the patients was 66 years (range 43–91). Seventy-three patients were male (64%). No comorbidity was observed in 34 patients (39%), 35 patients had grade 1 (40%), 18 patients grade 2 (21%), and 1 patient grade 3 (1%) comorbidity. Primary tumour sublocalizations were glottic (n = 48), supraglottic (n = 31), and transglottic (n = 9). Overall tumour stages were I (n = 35), II (n = 20), III (n = 16) and IV (n = 17), which were categorized into stage I-II (n = 55) vs. III-IV (n = 33) for statistical analyses. Time since treatment ranged from 6 to 58 months (median 21 months). Ten patients were treated with CO2-laser only, 51 patients underwent radiation therapy, 6 underwent combined chemotherapy and radiation therapy, and 21 patients had a laryngectomy. In the group of laryngectomized patients, 1 patient was not irradiated, 8 patients underwent radiotherapy before receiving a laryngectomy, 10 patients underwent post-operative radiotherapy, and one patient had undergone previous chemoradiation.

**Psychometric properties of questionnaires**

Psychometric analyses focused on feasibility, internal consistency, known groups validity, and construct validity of the total VHI, SHI, and SWAL-QOL scales. Feasibility of the VHI, SHI, and SWAL-QOL was good: missing item responses on the single items ranged from 1% to 7% for the SWAL-QOL, from 2% to 5% for the SHI, and from 2% to 7% for the VHI. The scores could be calculated for 99% of the patients for the total SWAL-QOL scale, for 89% of the patients for the total SHI scale, and for 88% of the patients for the total VHI scale. Internal consistency (Cronbach’s alpha coefficient) of the VHI, SHI, and SWAL-QOL was high: 0.98, 0.98, and 0.97, respectively.

Regarding known groups validity, the SHI, and SWAL-QOL scales differentiated significantly between patients and controls (p < .01 for both measures). Within patients, the total VHI, SHI, and SWAL-QOL scales differentiated between patients grouped on the basis of comorbidity (p < .01, p < .05 and p < .01 for the VHI, SHI and SWAL-QOL, respectively) and treatment modality (p = .06, p < .05, and p = .05 for the VHI, SHI and SWAL-QOL, respectively) (Table 2).

Regarding construct validity, Pearson correlations between the scores on the total SWAL-QOL scale, and the total VHI and SHI scales were 0.58 and 0.59, respectively. The correlation between the scores on the total SHI scale and the total VHI scale was 0.98, indicating that the SHI and VHI total scores are very highly correlated and may not be assessing conceptually distinct constructs in this population of patients.

Clinically relevant VHI, SHI, and SWAL-QOL difference scores were based on effect sizes. Table 3 presents an overview of effect sizes for various group difference scores, with a standard deviation of 24.98 (VHI), 25.11 (SHI), and 21.07 (SWAL-QOL) (the standard deviations of the group of laryngeal cancer patients in the present study) and a power of 0.80. The results suggest that for all three outcome measures, a difference score of 12 points or more is clinically and statistically relevant in study designs comparing groups of patients after treatment for laryngeal cancer.

**Cut-off score to define “caseness”**

To compute a cut-off score for defining individual laryngeal cancer patients as having clinically relevant voice problems, patients who rated their voice as deviant on the extra voice quality question of the VHI (n = 32) were compared with control subjects (n = 101). ROC analysis revealed that the AUC was 0.94 (95% CI: 0.89–0.99) indicating high overall discriminative ability of the VHI. Sensitivity and specificity of the total VHI score in detecting patients using a range of cut-off points is shown in Table 4. A cut-off point of 15 (or higher) on the total VHI scale is proposed to identify patients with voice problems after treatment for laryngeal cancer, with 91% sensitivity and 83% specificity.

To compute a cut-off score for defining individual laryngeal cancer patients as having clinically relevant speech problems, patients who rated their voice as deviant on the extra voice quality question of the SHI (n = 31) were compared with control subjects (n = 101). ROC analysis revealed that the AUC was 0.90 (95% CI: 0.86–0.93) indicating high overall discriminative ability of the SHI. Sensitivity and specificity of the total SHI score in detecting patients using a range of cut-off points is shown in Table 4. A cut-off point of 15 (or higher) on the total SHI scale is proposed to identify patients with voice problems after treatment for laryngeal cancer, with 89% sensitivity and 88% specificity.

### Table 1

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<th>Overview of patient characteristics.</th>
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<td>Final primary treatment modality (n)</td>
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<td>CO2-laser</td>
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<td>Chemoradiation</td>
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<td>Co-morbidity as assessed with ACE-27 (n)</td>
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### Table 2

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<th>Known group comparisons of mean total VHI, SHI, and SWAL-QOL scores regarding known group differences: patients vs. controls and within patients: comorbidity (stage 0-1 vs. 2–3) and treatment modality (single vs. multimodal).</th>
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* p < .01.
** p < .05.
patients who rated their speech as deviant on the extra speech quality question of the SHI (n=34) were compared with control subjects (n=101). ROC analysis revealed high overall discriminative ability of the SHI (AUC was 0.99 (95% CI: 0.97–1.00). A cut-off point of 6 (or higher) on the SHI scale is proposed to identify patients with speech problems, with 97% sensitivity and 87% specificity (Table 4).

To compute a cut-off score for defining individual laryngeal cancer patients as having clinically relevant swallowing problems, patients who had a score >10 on the EORTC QLQ-H&N35 Swallowing subscale (n=23) were compared to controls (n=107). ROC analysis revealed that the AUC was 0.97 (95% CI: 0.94–1.00) indicating high overall discriminative ability of the SWAL-QOL. A cut-off point of 14 (or higher) on the SWAL-QOL scale is proposed to identify patients with swallowing problems, with 96% sensitivity and 83% specificity (Table 4).

Based on the defined cut-off scores, clinically relevant swallowing problems were present in 38 of 87 patients (44%), speech problems in 49 of 78 patients (63%), and voice problems in 43 of 77 patients (56%).

The impact of voice, speech and swallowing problems on HRQOL and distress

Pearson correlation coefficients were calculated between the total VHI, SHI and SWAL-QOL scores, and the EORTC QLQ-C30 global quality of life subscale and the HADS total score. VHI, SHI and SWAL-QOL scores were significantly associated with global quality of life (r=.43 (VHI and SHI) and r=.46 (SWAL-QOL)) and emotional distress (r=.50 (VHI and SHI) and r=.58 (SWAL-QOL)).

Perceived need for rehabilitation

Only 8% of all included patients expressed a need for speech and swallowing rehabilitation. Of these patients, only 20% had actually used rehabilitation services. Because of this unexpected low level of perceived need for care, no further statistical analyses were carried out to determine factors affecting perceived need. Of the patients 32% expressed, in retrospect, a need for rehabilitation at the time of treatment, and 81% of these patients reported having undergone rehabilitation at that time.

Discussion

There is growing interest in using patient-reported outcomes (PRO’s) to screen for physical and psychosocial problems and the need for supportive care in routine clinical practice and a recent review showed that using PRO’s in clinical practice facilitates communication about quality of life issues between doctors and patients, can lead to higher patient satisfaction and to improved symptom control [28]. In the present study, we used the SWAL-QOL, the VHI, and SHI to assess swallowing, voice, and speech problems in laryngeal cancer patients. Two main patient reported outcome measures regarding swallowing are the Swallowing Questionnaire on Quality of Life (SWAL-QOL) [24], and the MD Anderson Dysphagia Inventory (MDADI) [29]. In an earlier study, we translated and validated the SWAL-QOL and defined a cut-off score of 14 points regarding the total SWAL-QOL score to identify patients with swallowing problems after treatment for oral or oropharyngeal cancer [21]. This cut-off score was confirmed in the present study on laryngeal cancer patients.

Patient reported outcomes that specifically relate to voice production include: the Voice Handicap Index (VHI) [23], the Voice Related Quality of life questionnaire (VRQOL) [30], the Voice Activity and Participation Profile (VAPP) [31], a 5-item list for screening purposes [32], and the S-Secel [33]. Of these, the VHI is the most widely used questionnaire and comparable throughout various European translated versions [34,35]. In an earlier study we validated the VHI and defined a cut-off score of 15 points to identify patients treated for benign voice disorders and early glottic cancer [7]. This was confirmed in the present study of laryngeal cancer patients, including patients with early and advanced staged laryngeal cancer who underwent varied treatments. A limitation of the present study is that no comparisons were made with objective measures. Future studies are required to anchor the patient reported outcomes and to define caseness.

Regarding patient reported speech outcome, the Speech Handicap Index (SHI) was developed on a cohort of patients with oral or
oropharyngeal cancer [20]. Similar to the Voice Handicap Index, the SHI consists of 30-items on speech problems in daily life. The SHI was validated and a cut-off score was defined of 6 on the total SHI scale to identify patients with speech problems in daily life after treatment for oral or oropharyngeal cancer. This was confirmed in the present study of laryngeal cancer patients. A very strong correlation was found between the total VHI and SHI scores, suggesting that, in this population of patients, the VHI and SHI questionnaires do not assess conceptually distinct features of oral communication.

The defined cut-off scores on laryngeal cancer patients in the present study are the same as those established in earlier studies of patients with benign voice disorders and early glottic cancer (VHI) [7], and patients with oral or oropharyngeal cancer (SHI and SWAL-QOL) [20,21]. Based on these cut-off scores, in the present study, many laryngeal cancer patients reported clinically relevant voice problems (56%), speech problems (63%), and swallowing problems (54%) after completion of treatment. These results confirm results from earlier studies [1–18]. Also, as reported in earlier studies [36–38], voice, speech, and swallowing problems were found to be significantly associated with global quality of life and emotional distress.

In light of this high prevalence of voice, speech, and swallowing problems and the impact on quality of life and emotional functioning, it is striking that only 8% of the patients expressed a need for speech and swallowing rehabilitation after treatment. Of these patients, only 20% actually underwent rehabilitation. A larger but still relatively low percentage of patients (32%) reported, in retrospect, that they had experienced a need for rehabilitation at the time of treatment, and 81% of those patients also indicated that they had received such care. These results confirm those reported in an earlier study of patients with voice problems after treatment for early glottic cancer, of whom 50% indicated wanting voice therapy [39]. The reasons for these limited needs for rehabilitation in patients with complaints remain unclear; more studies are needed into the patient’s attitude of patients towards rehabilitation. Chen et al. [40] reported that information needs and need for supportive care targeting anxiety, fears, and sleeping problems are at the top of (unmet) needs for patients with oral cancer. Health literacy, the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health care decisions, may also play a role. In a study of patients who underwent a total laryngectomy, patients with limited health literacy were more likely to become “lost” in the health care system [41].

In a recent review paper, it is argued that care coordination improves supportive care delivery in head and neck cancer patients [42]. At the time the current study was carried out, care navigators were not yet available. Based on our findings, a care navigator was recently appointed. Also, we implemented the SWAL-QOL and SHI (but not the VHI, because of its overlap with the SHI)) in OncoQuest, a touch screen computer system designed to monitor speech and swallowing functioning in relation to quality of life and emotional distress in routine clinical practice for the total group of head and neck cancer patients, including laryngeal cancer patients [43]. We expect that OncoQuest will improve communication between the professional care navigator, physicians and patients, and may facilitate supportive care delivery. Future studies will provide insight into the feasibility of this approach in other centers as well.

Conclusions

Psychometric characteristics of the VHI, SHI, and SWAL-QOL in laryngeal cancer patients are good, with cut-off values equivalent to those established for oral or oropharyngeal patients. In laryngeal cancer patients, VHI and SHI appear to assess the same construct. The prevalence of voice, speech, and swallowing problems in post-treatment laryngeal cancer patients is high, and is clearly related to quality of life and emotional distress. The perceived need for post-treatment rehabilitation is limited, and is much lower than at the time of treatment. Further prospective studies are needed to better understand the course of voice, speech, and swallowing outcomes, and the perceived need, use and effectiveness of (early) voice, speech, and swallowing rehabilitation.

Conflict of interest statement

All authors disclose any actual or potential conflict of interest including any financial, personal or other relationships with other people or organizations within that could inappropriately influence this work.

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