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The psychometric and clinical validity of the SWAL-QOL questionnaire in evaluating swallowing problems experienced by patients with oral and oropharyngeal cancer

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SUMMARY

The aim of this study was to evaluate feasibility, reliability, validity of the SWAL-QOL (a questionnaire on swallowing problems in daily life), and to define sample size calculations and a clinically relevant cut-off score. One hundred and two patients were treated for cancer of the oral cavity or pharynx and 111 healthy subjects completed the SWAL-QOL and the EORTC H and N35 questionnaire. A randomly selected subset of patients ($n = 29$) completed the SWAL-QOL twice to assess test–retest stability. For the patient sample, data on tumor site (oral or oropharyngeal) and stage (I–IV), treatment modality (surgery, radiation, surgery + radiation, chemoradiation), and presence of a PEG tube were abstracted from medical records. Reliability of the SWAL-QOL was high with high internal consistency and test–retest stability. Feasibility was good, except for patients with tube feeding, of whom 38% did not complete the questionnaire (versus 9% of those with oral feeding). A cut-off score of 14 points (or higher) was defined regarding the total SWAL-QOL score to identify patients with swallowing problems with 94% sensitivity and 84% specificity. A difference score of 12 points or more is proposed to be used in study designs with multiple groups. It can be concluded that the SWAL-QOL is a feasible, reliable, and valid questionnaire to assess patients' swallowing impairment. It can be used in future comparative studies for oral and oropharyngeal cancer and in clinical practice to identify patients in need of further diagnostics and/or swallowing rehabilitation services.

Introduction

Annually, more than 640,000 patients worldwide are diagnosed with primary head and neck cancer and approximately 350,000 die of this disease.[1] Over the past decades, survival of patients with head and neck cancer only moderately increased and functional status and health-related quality of life (HRQoL) have become the key components of outcome. In head and neck cancer patients, swallowing and dysphagia are particularly important, with swallowing problems having a great impact on patients' lives.[2] Recent studies on swallowing among patients with head and neck cancer indicate that dysphagia is a common problem, despite medical and technical developments, such as microvascular reconstruction and organ preservation strategies.[3–6] Patients with larger tumors in the oral cavity or oropharynx frequently often report severe swallowing problems resulting from surgical treatment. Additionally, radiation-induced fibrosis and xerostomia can have a negative impact on swallowing function. Anatomical changes resulting from surgery and radiation-induced normal tissue damage may result in aspiration and pneumonia and need for long-term tube feeding to meet nutritional needs.[3,7–16]

Various methods have been used to evaluate the swallowing function including clinical swallowing examination and objective evaluation techniques.[17–22] Problems with swallowing are also addressed in most head and neck cancer-specific Quality of Life Questionnaires, such as the EORTC QLQ-H and N35,[23] the FACT-H and N,[24] and the University of Washington Quality of Life Questionnaire.[25] These instruments may be used as screening tools for swallowing dysfunction.[26] To obtain more insight in swallowing impairment, swallowing-specific Quality of Life Questionnaires have also been developed, including the Swallowing Quality of Life Questionnaire (SWAL-QOL)[27] and the MD Anderson Dysphagia Inventory (MDADI).[28] Interpretation of how patients cope with swallowing problems is difficult because no clear clinical cut-off scores are available and information on clinically relevant difference scores is scarce.

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The aims of the present study were to evaluate feasibility, reliability, and validity of the SWAL-QOL for use in patients with oral or oropharyngeal cancer, and to define sample size calculations and a clinically relevant cut-off score. These results can be used both for research investigations in which different groups of patients are compared or tracked over time, and to evaluate swallowing function of individual patients in the clinical setting.

Methods

Subjects

The study population was composed of a series of patients who had been treated with curative intent for oral or pharyngeal cancer who attended the outpatient department for a regular follow-up visit. Patients with serious cognitive problems or no understanding of Dutch language were excluded. The study also included a sample of healthy volunteers recruited from the circle of family and friends of the group of researchers.

Study measures and procedures

The Swallowing Quality of Life Questionnaire (SWAL-QOL) consists of 44-items that assess 10 quality of life domains, including: food selection (two items); eating duration (2); eating desire (3); fear (4); burden (2); mental health (5); social functioning (5); communication (2); sleep (2); and fatigue (3). After completing the questionnaire, a symptom scale (14 items), and a total SWAL-QOL score (23 items, including the items of the first seven scales listed above) can be calculated. All SWAL-QOL scales range from 0 to 100, a higher score indicating more impairment. Finally, three questions are included regarding nutrition intake (normal, soft, pureed, liquids only, mostly tube feeding, and tube feeding only), liquids intake (all liquids, thick liquids, very thick liquids, thickened liquids, and no liquids), and general health (poor, moderate, good, very good, and excellent).[27] The SWAL-QOL was translated into Dutch in a consensus process involving a speech and language pathologist (SLP), a psychologist/SLP and an otolaryngologist/SLP. The resulting translation was translated back into English by an independent translating agency specialized in medical terminology. A second consensus process resulted in subsequent minor changes in some items.

The EORTC QLQ-H and N35 questionnaire[23] consists of 35 items 25 of which are organized into seven multi-item subscales: pain (four items), swallowing (5), senses (2), speech (3), social eating (4), social contact (5) and sexuality (2). The remaining 10 single items address problems with teeth, dry mouth, sticky saliva, cough, opening mouth, weight loss, weight gain, use of nutritional supplements, feeding tubes, and pain medication. The swallowing subscale, with scores ranging from 0 (no swallowing problems) to 100 (severe swallowing problems) was used to evaluate the construct validity of the SWAL-QOL.

Patients and controls were asked to complete the SWAL-QOL and the EORTC QLQ-H and N35 at home. One question was added for the controls to determine whether they had any problems with swallowing (response categories "yes" or "no"). To investigate test–retest stability, a subset of patients completed the questionnaire on a second occasion. Written informed consent was obtained from all subjects.

Age and gender were recorded for both patients and controls. For the patient group, data on tumor site (oral or oropharyngeal), stage (I–IV), treatment modality (surgery, radiation, surgery followed by radiation, chemoradiation), and presence of a PEG tube were abstracted from medical records. Comorbidity was assessed with the Adult Comorbidity Evaluation 27 (ACE-27).[29] The ACE-27 was designed specifically for cancer patients and classifies patients into 1 of 4 grades of comorbidity (none, mild, moderate, and severe).

Statistical analysis

Descriptive statistics were generated for the outcome variables in the study. Percentages of missing questionnaire data were calculated to assess feasibility. Student's *t*-tests (age) and chi-square tests (gender, comorbidity, tumor site and stage, treatment modality, and presence of a PEG tube) were performed to test for differences between those who did and did not complete the questionnaires. Scale reliability was assessed by calculating the internal consistency (Cronbach's alpha) and test–retest stability (Spearman's rho). Construct validity was assessed by correlating the SWAL-QOL scales with the EORTC QLQ-H and N35 swallowing and social eating subscales (Spearman's rho). Student's *t*-test and analysis of variance with post-hoc Tukey tests were used to examine the known group validity of the SWAL-QOL. To aid in defining a clinically relevant (difference) score for purposes of group comparisons, Cohen's[29] effect sizes (ES) were calculated. A clinically relevant difference score for the total SWAL-QOL scale for use in group comparisons was defined as an effect size of 0.50 or greater. The effect size is defined as the difference between the experimental group mean minus the control group mean, divided by the standard deviation of the control group. The association between the total SWAL-QOL score and the EORTC H and N35 swallowing scale was examined with Receiver Operating Characteristics (ROCs) analyses. Sensitivity analyses were carried out to examine various cut-off scores for the SWAL-QOL. All statistical comparisons were two-sided. A p-value <0.01 was considered statistically significant.

Results

Subjects

One hundred sixteen patients were asked to participate in the study, of whom 102 agreed (response rate: 88%). There were no significant differences between responders and non-responders regarding age, gender, comorbidity, tumor site and stage, treatment modality, and presence of a PEG tube. Mean age of the patients was 62 years (range 36–90) and 56% was male. The pretreatment characteristics are summarized in Table 1.

Two hundred eighty-seven control subjects were invited to participate, of whom 111 agreed (response 39%). Mean age of the control group was 56 years (range 31–83), and 44% was male.

Feasibility

Regarding the various single items, missing item responses ranged from 1% to 8% for the patients and from 0% to 4% for the controls. The various SWAL-QOL subscales could be calculated for 93–99% of the patients and for 96–99% of the controls. Regarding completion of the questionnaire, gender, age, comorbidity, tumor site and stage, and treatment modality were not associated with questionnaire completion rate. However, the presence of a PEG did have a significant impact: 38% of patients with a PEG did not complete the questionnaire versus 9% of patients without a PEG ($p < 0.01$).

Reliability

Internal consistency reliability (Cronbach's alpha coefficient) of the total SWAL-QOL score and the symptom scale was 0.97 and

Table 1
Overview of patients characteristics (n = 102).

Tumor site		
	Oral	44
	Oropharyngeal	58
Tumor stage		
	I	28
	II	13
	III	19
	IV	42
Primary treatment		
	Surgery	30
	Radiotherapy	16
	Surgery with radiotherapy	51
	Chemoradiation	5
Radiotherapy		
	Yes	72
	No	30
Tube feeding		
	Yes	13
	No	89
Comorbidiy		
	None	41
	Grade 1	21
	Grade 2	33
	Grade 3	7

0.91, respectively. Internal consistency of the other SWAL-QOL subscales was also high, ranging from 0.81 to 0.96.

Twenty-nine patients with no signs of locoregional recurrence and no additional treatment completed the SWAL-QOL twice. The second assessment took place on average 13 weeks following the initial administration. The test–retest reliability (Spearman's rho) of the total SWAL-QOL score and the symptom scale was 0.87 and 0.88, respectively. Test–retest reliability of the other scales was above the 0.70 level, with the exception of the communication scale (Spearman's rho = 0.59).

Construct validity

Correlation (Spearman's rho) between the total SWAL-QOL score, and the swallowing and social eating subscales of the EORTC QLQ-H and N35 was 0.81 and 0.71, respectively. Correlation between the SWAL-QOL symptom scale and these scales was 0.80 and 0.57. The correlations between the other SWAL-QOL subscales and the swallowing subscales of the EORTC QLQ-H and N35 ranged from 0.37 to 0.79. Levels of significance for all correlation coefficients were <.01.

Known groups validity

All SWAL-QOL scales differentiated clearly between patients and controls (Table 2) except for the sleep scale. No differences were observed as a function of age or gender. Patients treated for advanced tumors (stages III–IV) had significantly worse scores compared to patients with stages I–II tumors ($p < .01$) on all SWAL-QOL subscales, except for the fatigue subscale (Table 3).

Patients with grade 3 co-morbidity scored worse compared to patients with grade 0 on the total SWAL-QOL scale, symptom scale, and mental health subscale; grade 3 patients scored worse compared to all other graded patients (0–2) on the subscale social functioning.

Because of small numbers in several of the individual categories of the item assessing nutritional intake, the categories tube feeding + soft food, liquids only, and tube feeding only were combined into one category. Patients with normal food intake scored significantly better compared to patients who were only capable to take soft diet (on four scales), and compared to patients on pureed food (on nine scales) and compared to patients on tube feeding (on eight scales).

Table 2
Mean scores on the SWAL-QOL scales for patients versus healthy controls.

	Patients (n)	Controls (n)
Total	32.6 (99)*	6.0 (107)
Symptom scale	32.5 (97)*	10.1 (110)
General burden	38.8 (100)*	5.2 (107)
Food selection	36.3 (95)*	5.6 (109)
Eating duration	45.8 (96)*	6.7 (109)
Eating desire	32.8 (99)*	8.3 (109)
Fear of eating	28.5 (98)*	10.4 (109)
Sleep	40.5 (99)	33.5 (110)
Fatigue	39.9 (99)*	26.2 (110)
Communication	39.2 (101)*	5.2 (109)
Mental health	29.7 (98)*	5.2 (109)
Social functioning	28.1 (99)*	3.7 (107)

* Indicates $p < 0.01$.

Table 3
Comparison of mean scores on the SWAL-QOL scales between patients with stage I/II disease versus stage III/IV disease.

	Stages I and II (n)	Stages III and IV (n)
Total	18.4 (40)*	42.3 (59)
Symptom scale	20.1 (40)*	41.1 (57)
General burden	19.2 (40)*	51.8 (60)
Food selection	21.3 (40)*	47.2 (55)
Eating duration	29.6 (40)*	57.3 (56)
Eating desire	19.1 (40)*	42.1 (59)
Fear of eating	17.2 (40)*	36.3 (58)
Sleep	29.6 (40)*	47.8 (59)
Fatigue	34.4 (40)	43.7 (59)
Communication	20.7 (40)*	51.4 (61)
Mental health	16.3 (40)*	39.0 (58)
Social functioning	14.9 (40)*	37.0 (59)

* Indicates $p < 0.01$.

Cut-off score to define "caseness"

The sensitivity and specificity of the total SWAL-QOL score in detecting patients with clinically relevant swallowing problems as defined by a score >10 on the EORTC QLQ-H and N35 swallowing scale were evaluated using a range of cut-off points as shown in Table 4. The AUC was 0.97, indicating high overall discriminative

Table 4
Overview of the sensitivity and specificity of the total SWAL-QOL scale at various cut-off points.

Cut-off score	Sensitivity	Specificity
4.5	1	0.679
6	1	0.698
7.5	0.98	0.736
8.5	0.98	0.745
9.5	0.98	0.764
10.5	0.98	0.792
12	0.939	0.802
13.5	0.939	0.83
14.5	0.939	0.84
15.5	0.898	0.84
17	0.878	0.84
19.5	0.878	0.849
21.5	0.878	0.858
22.5	0.878	0.868
24	0.878	0.877

Table 5
Overview of effect sizes based on various group mean difference scores for the total SWAL-QOL scale.[a]

Mean group difference	Effect size
18	0.86
17	0.81
16	0.76
15	0.71
14	0.67
13	0.62
12	0.57
11	0.52

[a] Assuming a power of 0. 80 and a standard deviation of 21.0.

ability of the SWAL-QOL. A cut-off score of >14 on the total SWAL-QOL scale yielded 94% sensitivity and 84% specificity.

Clinically relevant SWAL-QOL scores for group comparisons

Table 5 presents an overview of effect sizes for various group difference scores, with a standard deviation of 21.0 (the standard deviation of the group of patients with swallowing problems in the present study) and a power of 0.80. The results suggest that a difference score of 12 points or more is clinically and statistically relevant in comparing groups of patients after treatment for oral or oropharyngeal cancer.

Discussion

Swallowing and communication are important outcome factors that should be included in the evaluation of treatment among patients with head and neck cancer. Both speech and swallowing problems have a significant impact on the more general dimensions of HRQoL2. In the last decade, major progress has been made in the development of questionnaires aiming at evaluating swallowing problems from the patients' perspective.[27,28] We evaluated feasibility, reliability, and validity of the SWAL-QOL questionnaire in oral cavity and oropharyngeal cancer. In addition, we were able to define cut-off scores that can be used to identify patients with clinically relevant swallowing dysfunction. Moreover, at the group level, clinically relevant scale differences were defined as well.

In this population of patients, the feasibility regarding the completion of the SWAL-QOL was excellent. The vast majority of patients completed all items except for the subset of patients with tube feeding, who had significantly higher levels of missing items. This might be due to the fact that some items refer directly to oral feeding which may be not relevant to patients that require tube feeding, in particular when oral intake is completely impossible. This is consistent with the observations made in the study of McHorney et al.[27] where one patient wrote: "You should ask more questions about how people live on a G tube". These observations prove the need for an additional questionnaire focusing specifically on patients with tube feeding.[30]

The SWAL-QOL exhibited high levels of reliability, and the pattern of results from the known groups validity exercise supported the ability of the questionnaire to distinguish not only between patients and healthy controls, but also between subgroups of patients formed on the basis of various clinical characteristics. Additional evidence of the validity of the SWAL-QOL was provided by the high correlations observed with relevant subscales of the EORTC H and N35.

The SWAL-QOL provides detailed information about swallowing complaints in daily life of patients with oral and pharyngeal cancer and is a useful tool in future prospective studies to obtain insight in the incidence and prevalence of swallowing problems after various treatment modalities such as organ sparing (chemo) radiation or new radiation delivery techniques aiming at sparing of anatomical structures that are correlated with swallowing function. Including a control group in the analysis provided a useful anchor for the interpretation of the patient scores on the various SWAL-QOL scales. To facilitate using this questionnaire in clinical practice, we calculated a cut-off score of 14 on the total SWAL-QOL score for defining caseness. This yielded high levels of sensitivity and specificity. Using this cut-off, the SWAL-QOL may be useful in identifying patients for whom further swallowing assessment such as videofluoroscopy may be indicated, and in identifying patients who may benefit from swallowing rehabilitation programs such as exercising before and during radiotherapy. However, prospective randomized trials are needed to provide evidence-based effectiveness of swallowing rehabilitation.

Conclusion

The SWAL-QOL is a feasible, reliable and valid questionnaire for assessing swallowing problems in patients with oral cavity and oropharyngeal cancer. This questionnaire can be used in future clinical trials and is also useful to assess swallowing problems of the individual patient in daily clinical practice. An adapted version of the questionnaire may be needed for patients with tube feeding.

Conflict of Interest Statement

None declared.

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