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Supportive Care Among Head and Neck Cancer Patients: Validation of the Dutch Version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer

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ABSTRACT

Objective: Oral mucositis is one of the most profound toxicities during (chemo)radiotherapy for head and neck cancer, impacting a patient's quality of life. To measure the effect of oral mucositis on one's quality of life, the use of patient-reported outcome measures is of utmost importance. Since Dutch-validated patient-reported outcome measures assessing the impact of oral mucositis are lacking, the aim of this study was to translate the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer into Dutch and to validate this version.

Methods: The Oral Mucositis Weekly Questionnaire—Head and Neck Cancer was translated according to the internationally described cross-cultural adaptation process. Thirty-five patients with head and neck cancer were asked to complete the Dutch version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer, together with the Functional Assessment of Cancer Therapy and the Swallowing Quality-of-Life Questionnaire for 5 times during the first 5 weeks of chemoradiotherapy. The Toxicity criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer was completed by the radiation oncologist at the same time points. Factor analysis was done for psychometric validation and reliability was tested using Cronbach's alpha. Convergent validity and discriminant validity were calculated and clinical validity was assessed.

Results: Ninety-one percent of the questionnaires were completed. Internal consistency was high, after removing items 1, 2, and 4F. Testretest reliability was high, and convergent validity and discriminant validity were demonstrated. The Dutch version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer can successfully detect differences in the impact of oral mucositis and is sensitive to detect changes in time.

Conclusion: The Dutch version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer is a valid and reliable instrument to assess the impact of oral mucositis in patients with head and neck cancer treated with chemoradiotherapy.

Keywords: Head and neck cancer, mucositis, patient-reported outcome measure, radiotherapy, supportive care, quality of life

Introduction

Radiotherapy is, along with surgery, the most frequently used treatment modality for patients with head and neck cancer (HNC). Unfortunately, radiotherapy in the head and neck area impacts the quality of life (QoL) of patients via acute and late toxicity.[1-3] Most common acute complications during radiotherapy are radiation dermatitis, oral mucositis (OM), xerostomia, loss of taste, fatigue, dysphagia, and dysphonia.[3-8] Oral mucositis refers to an inflammation/ulceration of the oral mucosa and is seen as the most impacting, dose-limiting, and dose-delaying toxicity during radiotherapy.[8-11] The severity and duration depend on the tumor site, the total radiotherapy dose and radiotherapy schedule, the use of concurrent

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chemotherapy, and patient-related factors, for example, age, oral hygiene, alcohol, and tobacco use.[5,12,13] Oral mucositis results in pain, bleeding, and infections, which can lead to dysphagia and nutritional intake impairment.[10,13] Since it has a significant impact on QoL,[3,14,15] it is of major importance to evaluate and assess this complication in patients with HNC.

A frequently used evaluation tool is the toxicity criteria of the Radiation Therapy Oncology Group (RTOG)/European Organization for Research and Treatment of Cancer (EORTC), which is completed by the radiation oncologist through clinical examination.[16] Although this clinician-based assessment is important in establishing a proper management plan for OM and allowing for follow-up, it does not provide information on the functional loss or impact on QoL. To represent treatment-specific functional consequences as well as the impact on QoL directly by the patient, patient-reported outcome measures (PROMs) can be used.[10,17]

Nevertheless, until now, there is no Dutch instrument available to assess patient-reported OM in the HNC population. The Oral Mucositis Weekly Questionnaire—Head and Neck Cancer (OMWQ-HN), however, is an English PROM assessing the impact of OM on patients' well-being and function with shown validity and reliability in HNC patients treated with radiotherapy.[9,13] Literature indicates that evidence of scalability, reproducibility, and construct validity of all language versions of PROMs, used in clinical trials, is needed.[18] Therefore, the aim of this multicenter, longitudinal study is the cross-cultural adaptation and validation of the Dutch version of the OMWQ-HN (D-OMWQ-HN) in order to provide a valid and reliable tool for assessing patients' perspectives of OM in Dutch-speaking countries.

Methods

This study was conducted at the University Hospitals in Antwerp and Ghent and included 2 phases: cross-cultural adaptation of the OMWQ-HN and the clinical study with data collection.

Phase 1: Cross-Cultural Adaptation

The original OMWQ-HN is a short and feasible tool to assess OM, specifically developed and validated in HNC patients receiving radiotherapy or chemoradiotherapy. It provides detailed information about patients' mouth and throat pain and soreness and consists of 7 items, in which a Likert-type response format is used to answer each item. The time frame to which the questions are addressed is "the past week." The first 2 questions evaluate global health and QoL using a 7-point scale (1: very poor, 7: excellent). The third question investigates the mouth and throat soreness using a 5-point scale (0: no soreness, 4: extreme soreness). If the answer to the third question is 0, the patient is instructed to stop the questionnaire. Otherwise, the patient continues with the remaining 4 questions. The fourth question, consisting of 6 items, assesses the impact of the mouth and throat soreness on sleeping, swallowing, drinking, eating, talking, and brushing teeth on a 5-point scale (0: not limited, 4: unable to do). The last 3 questions investigate the degree of mouth and throat pain and soreness on a 11-point scale (0: no pain or soreness, 10: the worst pain or soreness imaginable or possible).[9,13]

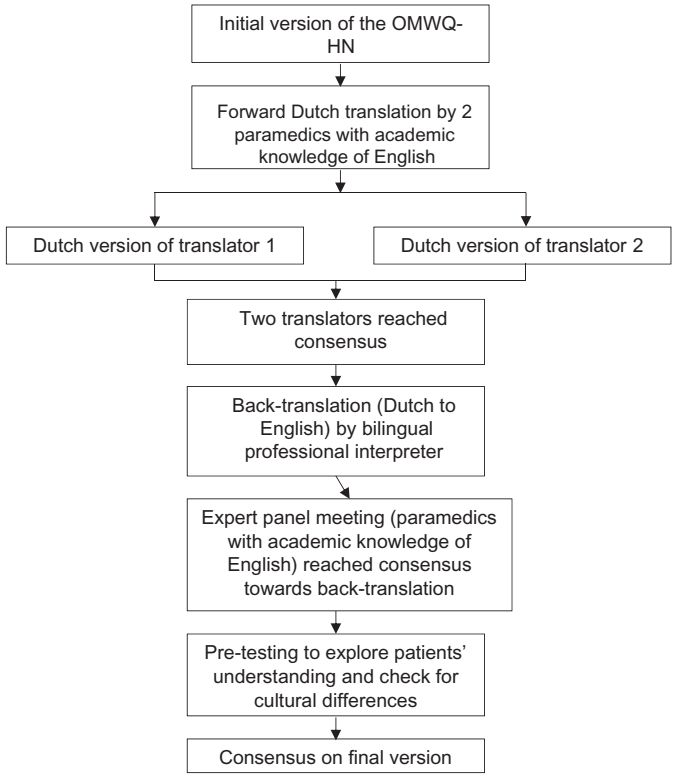

Figure 1. Flowchart of the process of cross-cultural adaptation.

This original version of the OMWQ-HN was translated into the Dutch language according to the cross-cultural adaptation process of translation and back-translation as described in international guidelines.[19-21] Figure 1 shows a flowchart of the cross-cultural adaptation process.

Phase 2: Clinical Study

Subject Recruitment

Thirty-five patients with newly diagnosed squamous cell carcinoma of the oral cavity, oropharynx, nasopharynx, hypopharynx, or larynx were included in this prospective multicenter study (University Hospitals of Antwerp and Ghent).

Ethical approval was obtained by the Ethical Committee of the Antwerp University Hospital and the University of Antwerp (Ethisch Comité van het Universitair Ziekenhuis Antwerpen en de Universiteit Antwerpen) (ref approval no. B300201318159 and B300201837097).

Main Points

- The Dutch Oral Mucositis Weekly Questionnaire—Head and Neck Cancer is a valid and reliable instrument to assess the impact of oral mucositis in patients with head and neck cancer treated with chemoradiotherapy.
- The Dutch version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer can detect differences in the impact of oral mucositis and is sensitive to detect changes in time.
- Clinicians and researchers can use the tool to assess and manage oral mucositis and to provide more patient-centered clinical care.

Study Design

To assess the psychometric characteristics of the D-OMWQ-HN, all patients were asked to fill in the D-OMWQ-HN, together with the Functional Assessment of Cancer Therapy—Head and Neck (FACT-HN)[22] and the Dutch version of the Swallowing Quality-of-Life Questionnaire (D-SWAL-QOL).[23-25] The RTOG/EORTC was completed by the radiation oncologist. All used instruments are fully explained later. The patient questionnaires were administered prior to treatment (baseline) and during weeks 3, 4, and 5 of radiotherapy treatment. The radiation oncologist filled out the RTOG/EORTC at the same time points. During week 4, the D-OMWQ-HN was filled in twice within 24-48 hours for test–retest reliability evaluation. Opioid analgesic use was recorded throughout the study based on patient records. Table 1 shows an overview of all measurements at the different time points. Patients were asked to fill out the questionnaires while waiting in the hospital waiting rooms or at home. Data collected during week 5 were chosen to assess convergent and discriminant validity since it represents the time point on which OM will be strongly pronounced and the data quality and collection will still be very good.[26]

Instruments

Functional Assessment of Cancer Therapy—Head and Neck: The FACT-HN is a multidimensional QoL instrument developed specifically for the oncologic population and consists of the FACT-General (FACT-G) and an HNC-specific subscale.[22,27] The FACT-G includes 4 subscales, that is, a physical, functional, emotional, and social well-being subscale, with a total of 28 items. The HNC-specific subscale contains 11 items. A Likert-type response format is used for each item and consists of 5 levels ranging from "not at all" to "very much." The higher the score, the better the QoL. The FACT-HN has been translated into Dutch and has shown to be a valid and reliable scale.[28] The subscales "physical well-being" and "social well-being" were used to test the convergent and discriminant validity of the D-OMWQ-HN, respectively.

Swallowing Quality-of-Life Questionnaire: The Swallowing Quality of Life Questionnaire[23-25] is a dysphagia-specific PROM consisting of 44 items, grouped in different subscales: general burden, eating duration, eating desire, symptoms, food selection, communication, fear of eating, social functioning, mental health, sleep, and fatigue. The minimum and maximum scores refer to an extremely impaired QoL and no impairment in QoL, respectively. The subscale fear of eating of the validated D-SWAL-QOL was used to test the discriminant validity of the D-OMWQ-HN.[29]

Toxicity criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer: Acute Radiation Morbidity Scoring Criteria: The RTOG/EORTC[16] is a clinician-rated scale, scored by a radiation oncologist and based on clinical examination. It is an ordinal scale including 5 levels ranging from 0 (the absence of radiation effects) to 5 (the radiation effects led to death). The RTOG/EORTC consists of different subscales, of which the subscale "mucous membrane" was used to test the convergent and clinical validity of the D-OMWQ-HN.

Statistical Analysis

Statistical analyses were performed using Statistical Package for the Social Sciences Statistics version 27 (IBM, Armonk, NY, USA).

The Shapiro–Wilk test was used to test the normality of distribution of the D-OMWQ-HN, FACT-HN subscales, and D-SWAL-QOL subscales.

Table 1. Study Visits and Evaluations

		Study period				
Time Point	Enrollment	Baseline (Between Enrollment and Start RT)	Week 3 of RT	Week 4 of RT—Version 1	Week 4 of RT—Version 2	Week 5 of RT
Enrollment						
Eligibility screen	X					
Informed consent	X					
Assessments						
Patient, disease, and therapy characteristics	X					
D-OMWQ-HN		X	X	X	X	X
FACT-HN		X	X	X		X
D-SWAL-QOL		X	X	X		X
RTOG/EORTC		X	X	X		X
Opioid analgesic use		X	X	X		X

D-OMWQ-HN, Dutch Oral Mucositis Weekly Questionnaire—Head and Neck Cancer; D-SWAL-QOL, Dutch Swallowing Quality of Life Questionnaire; FACT-HN, Functional Assessment of Cancer Therapy—Head and Neck; RT, radiotherapy; RTOG/EORTC, Toxicity criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer.

By means of factor analysis using Pearson correlation coefficients (r_s) between items of the D-OMWQ-HN, identification and removal of items with a weak correlation was done to maximize internal consistency. Internal consistency was calculated using Cronbach's α coefficients. In order to avoid redundant items, we aimed for a correlation between 0.7 and 0.9. Based on these analyses, the final D-OMWQ-HN scale was created and the sum score of the new instrument was used in all subsequent analyses.

Test–retest reliability of the D-OMWQ-HN was measured by means of intraclass correlation coefficients (ICC), using the consecutive week 4 assessments. Convergent validity and discriminant validity were calculated using Spearman and Pearson correlation coefficients, by correlating D-OMWQ-HN sum scores with the RTOG/EORTC, D-SWAL-QOL, and FACT-HN. Confidence intervals were calculated for all scale variables. To demonstrate the sensitivity of the D-OMWQ-HN to detect different levels of impact on QoL (clinical validity), boxplots were made using the RTOG/EORTC scale. The lower bound of the boxplots (first quartile) was used as cut-off values to discriminate between none to light impact, moderate impact, or severe impact on QoL.

Linear mixed-effects models with post hoc pairwise testing and Bonferroni–Holm correction were used to assess the evolution of the D-OMWQ-HN scores through time. An independent samples *t*-test was performed to determine the difference in D-OMWQ-HN scores between patients who were using analgesic medication and patients who were not.

The statistical significance level was set at .05. For both ICC and Spearman/Pearson correlation, a precision of 0.13 (i.e., half width of the 95% CI) is expected for an anticipated correlation/ICC of 0.80 with a sample size of 35 people.

Results

Participants and Drop-Outs

Thirty-five participants were recruited for this study, of which 6 (17%) patients stopped the study earlier. One patient (3%) quit the study after baseline measurement due to pain caused by radiotherapy. The other 5 patients (14%) stopped during week 4 because of weakness due to radiotherapy treatment. The RTOG/EORTC data were still collected. Four hundred seventy-five of the 525 (91%) questionnaires were completed by the patients. Figure 2 shows a flowchart of the patients' selection and recruitment procedure. Patient and disease characteristics are presented in Table 2.

Factor Analysis

Factor analysis showed that the item concerning brushing teeth (4F) had a low (<0.5) item-total correlation relative to the other items (Table 3).[9]

Reliability

By deleting items 1 and 2, as proposed by Epstein et al.[9] internal consistency increased with 0.1, resulting in a high final consistency during week 5 (α = 0.784), pointing out a very good reliability. Test–retest reliability of the D-OMWQ-HN was very strong (ICC = 0.953, $P < .001$).

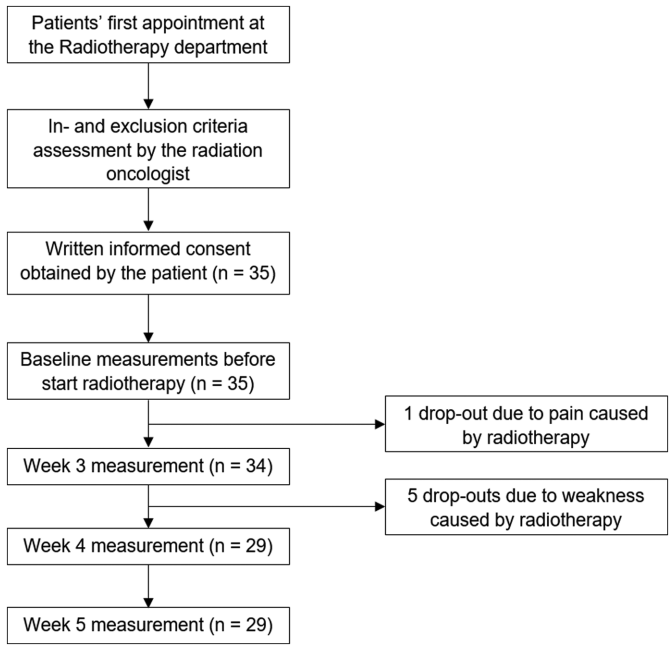

Figure 2. Flowchart of patient recruitment and follow-up.

Based on the results of factor analysis and reliability, item 1 (overall health), item 2 (overall QoL), and item 4F (limitations in brushing teeth) were excluded, resulting in the final scale consisting of 9 questions (Appendix 1). The total D-OMWQ-HN-score was calculated as the sum of all items. This score was used in all further analyses and is referred to as the D-OMWQ-HN score.

Validity

Convergent Validity

To assess convergent validity, the subscale "mucous membrane" of the RTOG/EORTC and the subscale "physical

Table 2. Patient and Disease Characteristics

		Patients (n = 35) (%)
Age at diagnosis (year)	Mean	65
	Median	67
	Range	49-86
Sex	Male	27 (77)
	Female	8 (23)
Tumor site	Oral cavity	16 (46)
	Oropharynx	4 (11)
	Nasopharynx	1 (3)
	Hypopharynx	4 (11)
	Larynx	10 (29)
Treatment	Primary radiotherapy	12 (34)
	Surgery + adjuvant (chemo)radiotherapy	9 (26)
	Concomitant chemoradiotherapy	14 (40)

Table 3. Results of Factor Analysis Based on Pearson Correlation Coefficient

	D-OMWQ-HN		
	r_s	*P*	95% CI
Item 1	0.516	<.001	0.191–0.739
Item 2	0.518	<.001	0.194–0.740
Item 3	0.845	<.001	0.697–0.924
Item 4A	0.586	<.001	0.286–0.781
Item 4B	0.791	<.001	0.602–0.896
Item 4C	0.758	<.001	0.547–0.878
Item 4D	0.755	<.001	0.542–0.877
Item 4E	0.593	<.001	0.296–0.786
Item 4F	0.466	<.001	0.127–0.708
Item 5	0.870	<.001	0.742–0.937
Item 6	0.792	<.001	0.604–0.897
Item 7	0.841	<.001	0.690–0.922

D-OMWQ-HN, Dutch Oral Mucositis Weekly Questionnaire—Head and Neck Cancer; *P*, significance level; r_s, Pearson correlation coefficient.

well-being" of the FACT-HN were used. Spearman correlation between the D-OMWQ-HN score and RTOG/EORTC was moderate, while Pearson correlation between D-OMWQ-HN score and subscale "physical well-being" was high during week 5 (Table 4).

Discriminant Validity

To assess discriminant validity, the subscale "social well-being" of the FACT-HN and the subscale "fear of eating" of the D-SWAL-QOL were used. Poor correlations were observed during week 5 between D-OMWQ-HN scores and both subscales (Table 4).

Clinical Validity

To demonstrate the sensitivity of the D-OMWQ-HN to detect different levels of OM impact, boxplots were made based on the results of the RTOG/EORTC. Figure 3 shows that worse (i.e., higher) scores on RTOG/EORTC correlate with worse D-OMWQ-HN scores. None of the patients scored grade 4 on RTOG/EORTC. Based on the D-OMWQ-HN-values, corresponding with the first quartiles on the RTOG-subgroups, cut-off values can be determined by discriminating between none to light impact (D-OMWH-HN < 21), moderate impact (D-OMWQ-HN < 27), and severe impact (D-OMWQ-HN ≥ 27) of OM on QoL.

Table 4. Correlations (r_s) Between D-OMWQ-HN and RTOG/EORTC, FACT-HN, and D-SWAL-QOL During Week 5

	D-OMWQ-HN		
	r_s	*P*	95% CI
RTOG/EORTC mucous membrane	0.471	<.001	-
Physical well-being (FACT-HN)	0.739	<.001	0.516 to 0.868
Social well-being (FACT-HN)	0.071	.719	−0.297 to 0.421
Fear of eating (D-SWAL-QOL)	0.273	.145	−0.097 to 0.577

D-OMWQ-HN, Dutch Version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer; FACT-HN, Functional Assessment of Cancer Therapy—Head and Neck; *P*, significance level; r_s, Pearson correlation coefficient; RTOG/EORTC, Toxicity criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer.

Evolution of D-OMWQ-HN Scores Through Time

Figure 4 shows that D-OMWQ-HN scores deteriorate during radiotherapy treatment. Linear mixed-effects models showed significant differences in D-OMWQ-HN scores during treatment ($F_{3\text{-}125}$=14.719, P < .001). Post hoc analyses, adjusted by means of Bonferroni correction, showed significant effects between all weeks, except between weeks 4 and 5 (Table 5).

Use of Analgesic Medication

Independent samples *T*-test showed that patients who are using analgesic medication show significantly worse D-OMWQ-HN scores than patients who are not (t(127) = −3.576, P < .001).

Discussion

In general, the implementation of PROMs in both clinical practice and research is increasing.[30,31] They are used to assist clinicians to select the best treatment, to enrich the understanding of patients' experiences, and for assessing the quality of health care. In clinical trials, they are increasingly considered as valuable instruments to collect patient-centered data since they provide unique information about the patients' perspective toward a medical condition and its treatment.[30,31] Translation and validation of all new language versions of PROMs are therefore needed.[18] Since OM is one of the most common complications in HNC patients during radiotherapy treatment, with a major impact on QoL, we conducted this study to develop the D-OMWQ-HN. Our study showed the impact of OM on the patient's well-being and demonstrated again the importance of assessing patient-reported outcomes to learn about their experiences during a burdensome period of RT treatment. The results of this study indicate that the D-OMWQ-HN is a reliable and valid PROM to measure the impact of OM in patients treated with (adjuvant) (chemo)radiotherapy for HNC.

By performing factor analysis and calculating internal consistency, items 1, 2, and 4F of the original D-OMWQ-HN were removed, resulting in the final scale with high internal consistency, including 9 questions. These results are consistent with the original study by Epstein et al.[9] The low correlations of item 1 (overall health) and item 2 (QoL) with the questions related to OM can be explained by the fact that overall health and QoL can be influenced by other factors, for example, psychosocial factors.[32,33] It is also expected that changes in specific symptoms (e.g., OM) do not always reflect changes in overall health or QoL.[9] Item 4F (concerning brushing teeth) was also poorly correlated with the other items. The reason for this result is probably due to the high number of missing data on this question. There was no control for patients having dental prosthesis or for patients being edentate.

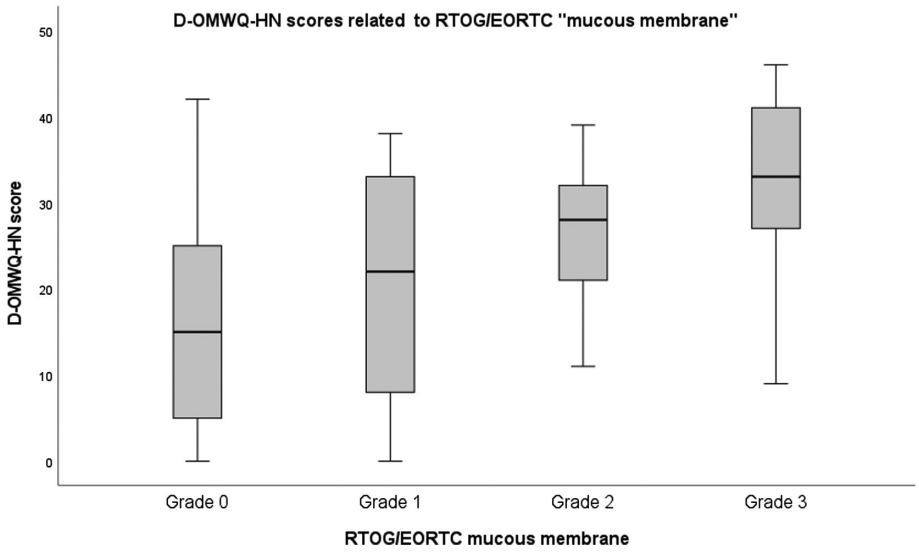

Figure 3. D-OMWQ-HN score related to RTOG/EORTC "mucous membrane" subscale. D-OMWQ-HN, Dutch Version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer; RTOG/EORTC, Toxicity criteria of the Radiation Therapy Oncology Group/European Organization for Research and Treatment of Cancer.

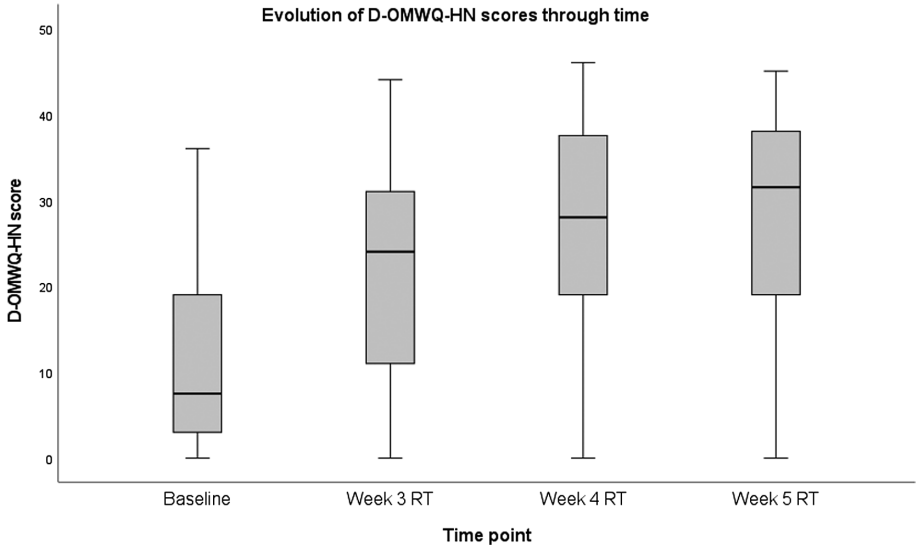

Figure 4. Evolution of D-OMWQ-HN scores during radiotherapy treatment. D-OMWQ-HN, Dutch Version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer.

Table 5. Post Hoc Analyses with Bonferroni Correction for the Evolution of D-OMWQ-HN Scores Through Time

		D-OMWQ-HN	
		P	**95% CI**
Baseline	Week 3	<.001	−15.380 to −8.029
	Week 4	<.001	−20.167 to −12.742
	Week 5	<.001	−22.372 to −14.787
Week 3	Week 4	.026	−8.474 to −1.026
	Week 5	.002	−10.679 to −3.072
Week 4	Week 5	.275	−5.966 to 1.716

D-OMWQ-HN, Dutch Version of the Oral Mucositis Weekly Questionnaire—Head and Neck Cancer; *P*, significance level.

Convergent validity was assessed by using the subscale "mucous membrane" of the RTOG/EORTC and the subscale "physical well-being" of the FACT-HN. In general, convergent validity shows that 2 measures, which are supposed to measure the same construct, are in fact related. The correlation was assumed on these 2 subscales since, first, "mucous membrane" assesses the severity of damage to the oral mucosa clinician-based, and second, "physical well-being" contains questions related to pain and soreness due to cancer treatment.[16,22,34-36] Coefficients were moderate to high, suggesting that the D-OMWQ-HN measures the same construct as the subscales used. However, the correlation coefficients with the RTOG were moderate, indicating that the instruments are not redundant. To test discriminant validity, it was assumed that the D-OMWQ-HN would not correlate with "fear of eating" (subscale of D-SWAL-QOL) and "social well-being" (subscale

of FACT-HN).[22-25,35] In general, discriminant validity shows a lack of correlation between the 2 measures that should theoretically be unrelated. Based on the shown low correlations between the D-OMWQ-HN and "fear of eating" and "social well-being", discriminant validity was demonstrated.

The D-OMWQ-HN can successfully detect differences in OM impact (based on RTOG/EORTC comparison) and cut-off scores to define these different impact levels were determined. We hypothesize that by using these cut-offs, patients could be better counseled and treated with correctly chosen and dosed analgesics. Moreover, in this study, patients taking analgesics scored worse on the D-OMWQ-HN, demonstrating that despite their use, the impact of OM still remains high. It is, however, possible that patients using analgesics are more aware of the OM and its consequences on daily (quality of) life.

A significant deterioration in D-OMWQ-HN scores during radiotherapy treatment was found, showing its sensitivity to detect changes through time. Scores were worst during week 5, which strengthens the choice to assess validity based on these results. Our findings are consistent with the literature, describing the occurrence of mucosal erythema in the first week of daily fractionated RT programs, with a peak of patchy/confluent mucositis during the fourth to fifth week.[26,37]

The high rate of compliance to fill in the questionnaire demonstrates the feasibility of this new instrument. The limited number of questions in the D-OMWQ-HN contributes to this success, which is in concordance with previous studies concluding that PROMs consisting of >30 questions impose a higher burden on the patient.[38]

This study is, however, not without limitations. To detect differences in the impact of OM, we made conclusions based on RTOG/EORTC scale. However, in our study, there were no patients who were given a grade 4 score on this instrument, which raises questions about the practicality of the levels of impact. Future research with a larger study population should examine whether our impact levels are valid.

This validation study is of major importance since OM is one of the most impacting and dose-limiting toxicities for HNC patients during radiotherapy and Dutch-validated PROMs assessing the impact of OM are lacking. The D-OMWQ-HN gives detailed information about patients' mouth and throat pain and soreness and its functional limitations. It can be used to compare the effects of mucositis interventions during radiotherapy treatment and also in clinical practice to assess patients' experiences.[9] Since it is a short questionnaire, feasible to be completed without the supervision of a health-care provider, the questionnaire can be used to optimize consultations with the radiation oncologist. The D-OMWQ-HN can also be a useful tool to gain insight into the prevalence and incidence of OM in trials assessing new treatment techniques for patients with HNC. By using and analyzing the D-OMWQ-HN, caregivers can provide more patient-centered clinical care.

In summary, it can be concluded that the D-OMWQ-HN is a valid, reliable, and feasible tool to assess patient-reported OM in patients with HNC treated with (adjuvant) (chemo)radiotherapy. The instrument allows the impact of OM on a patient's QoL to be measured in a standardized way.

Ethics Committee Approval: This study was approved by Ethics committee of the Antwerp University Hospital and the University of Antwerp (Ethisch Comité van het Universitair Ziekenhuis Antwerpen en de Universiteit Antwerpen), (Approval No: B300201318159 and B300201837097, Date: 19/08/2013 and 30/07/2018).

Informed Consent: Written informed consent was obtained from the participants who agreed to take part in the study.

Peer-review: Externally peer-reviewed.

Author Contributions: Concept – G.V.N, L.V.D.S.; Design – G.V.N, L.V.D.S.; Supervision – G.V.N, L.V.D.S., F.D., M.D.B., O.V.; Funding – G.V.N, L.V.D.S.; Materials – M.B., G.V.N., L.V.D.S.; Data Collection and/or Processing – M.B., G.V.N., L.V.D.S., S.W.; Analysis and/or Interpretation – M.B., G.V.N., L.V.D.S., S.W.; Literature Review – M.B., G.V.N., L.V.D.S., S.W.; Writing – M.B., S.W.; Critical Review – G.V.N., L.V.D.S., F.D., O.V., M.D.B.

Declaration of Interests: The authors have no conflict of interest to declare.

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Appendix 1

NEDERLANDSTALIGE ORAL MUCOSITIS WEEKLY QUESTIONNAIRE – HOOFD- EN HALSKANKER

Naam: Geboortedatum:

Datum afname:

Hoeveel last in mond en keel ervaarde u de afgelopen week?

0	1	2	3	4
Geen last				Zeer veel last

Indien u 0 (geen last) aanduidde, dient u de verdere vragen niet in te vullen.
Indien u 1, 2, 3 of 4 aanduidde, dient u de verdere vragen wel in te vullen.

In welke mate heeft de last in mond en keel u de afgelopen week belemmerd bij volgende activiteiten?

	Geen belemmering				Onmogelijk te doen
Slapen	0	1	2	3	4
Slikken	0	1	2	3	4
Drinken	0	1	2	3	4
Eten	0	1	2	3	4
Praten	0	1	2	3	4

Hoe zou u uw algemene last in mond en keel tijdens de afgelopen week beoordelen op een schaal van 0 tot 10?

0	1	2	3	4	5	6	7	8	9	10
Geen last										De ergst denkbare last

Welk getal van 0 tot 10 beschrijft het best hoeveel pijn u de afgelopen week in uw mond had?

0	1	2	3	4	5	6	7	8	9	10
Geen pijn										De ergst denkbare pijn

Welk getal van 0 tot 10 beschrijft het best hoeveel pijn u de afgelopen week in uw keel had?

0	1	2	3	4	5	6	7	8	9	10
Geen pijn										De ergst denkbare pijn