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Recording of morbidity

The Groningen Radiotherapy-Induced Xerostomia questionnaire: Development and validation of a new questionnaire

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ABSTRACT

Purpose: The purpose of this study was to develop and validate a questionnaire (Groningen Radiotherapy-Induced Xerostomia (GRIX) questionnaire) that has the ability to distinguish between patient-rated xerostomia during day and night and can be used to evaluate the impact of emerging radiation delivery techniques aiming at prevention of xerostomia in more detail.

Materials and methods: All questions in the GRIX were generated from an exhaustive list of relevant questions according to xerostomia as reported in the literature and reported by patients and health care providers. Finally the GRIX was reduced from 56 questions to a 14-item questionnaire, with four subscales; xerostomia during day and night and sticky saliva during day and night. 315 patients filled out 2936 questionnaires and the GRIX was evaluated by calculating Crohnbach's α for all subscales. Criterion validity was evaluated to compare the GRIX with patient-rated xerostomia scored with the EORTC QLQ-HN35 and physician-rated xerostomia, test–retest analysis and responsiveness were also tested.

Results: Crohnbach's α varied for all subscales between 0.88 and 0.94. The GRIX scored well for criterion-related validity on all subscales with high correlations with the EORTC QLQ-HN35 xerostomia and sticky saliva scale as well with physician-rated toxicity scoring. No significant differences were found between test and retest score and the GRIX showed good responsiveness with different time points for all subscales.

Conclusion: The GRIX is a validated questionnaire which can be used in future research focusing on patient-rated xerostomia and sticky saliva during day and night in relation with the impact of emerging radiation delivery techniques aiming at reduction of xerostomia.

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In patients with head and neck squamous cell carcinoma (HNSCC), radiotherapy as either primary or postoperative modality generally includes irradiation of at least some parts of the salivary glands. Irradiation of the salivary glands may result in salivary dysfunction and subsequent xerostomia, which is one of the most frequently reported side effects of radiation treatment in the head and neck area [1–6]. In addition, salivary dysfunction may lead to a sensation of dry mouth, altered taste, swallowing problems and speech problems and has a significant impact on the more general dimensions of health-related quality of life (HRQOL) [1,7–11]. From this point of view, xerostomia as reported by patients may provide important additional information in the assessment of radiation-induced salivary gland dysfunction.

The EORTC QLQ-C30 and the EORTC QLQ-H&N35 are the most commonly used validated questionnaires to determine HRQOL after irradiation of head and neck cancer in clinical trials [12–14]. The EORTC QLQ-H&N35 contains 35 questions concerning treatment-related symptoms and symptoms frequently present in head and neck cancer patients. This questionnaire is organized into seven multi-item scales and 11 single-item scales, including one xerostomia and one sticky saliva scale. All scales are rated on a four-point Likert-scale. As the EORTC QLQ-H&N35 only contains one question about xerostomia and one question about sticky saliva, the question arises as to whether this questionnaire is sufficiently sensitive to score more discrete changes of patient-rated xerostomia. In addition, this questionnaire does not allow for the assessment of different aspects of xerostomia at different time points. Some patients mainly suffer from xerostomia at night while others have complaints predominantly during the day [15]. Content and production of saliva may differ among different salivary glands and show a circadian rhythm [16,17], which may have various impacts on different aspects of symptoms related to salivary dysfunction.

Therefore, the purpose of this study was to develop and validate a questionnaire that enables scoring of different aspects

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of patient-rated xerostomia which can be used to evaluate the impact of emerging radiation delivery techniques aiming at prevention of xerostomia in more detail.

Materials and methods

Patients

Since March 2007, a prospective consecutive cohort of patients with HNSCC referred for radiotherapy was established at the Department of Radiation Oncology of the University Medical Center of Groningen. This prospective cohort was composed of 315 patients, who had to have head and neck cancer originating in the oral cavity, oropharynx, larynx, hypopharynx, or nasopharynx. All patients were treated with radiotherapy either alone or in combination with surgery, chemotherapy, and/or cetuximab. Understanding of the Dutch language was required to fill out the questionnaire. The study was approved by the Ethical Committee of the University Medical Center Groningen.

The demographic and pre-treatment tumour characteristics of all patients who filled out the questionnaire are listed in Table 1. The majority of patients were male (69%). The mean age of the study population was 62 years, ranging from 19 to 90 years. The 315 patients filled out a total of 2936 questionnaires with a maximum of 2 years of follow-up and a mean and median follow-up of 12 months.

Assessment of radiation-induced toxicity

In April 2007, a standard follow-up program (SFP) was started at the Department of Radiation Oncology for all patients with head and neck cancer, who were treated with primary and/or postoperative (chemo) radiation. Acute and late radiation-induced side effects were assessed according to the Common Terminology Criteria of Adverse Events v3.0 (CTCAE v3.0). Baseline and acute side effects were assessed by the physician on a weekly basis during radiation treatment, while late side effects were assessed at 6 weeks after completion of treatment and every 6 months after treatment.

Table 1
Demographic and disease-related characteristics (n = 315).

Characteristics	No. of patients	Percent
Sex		
Male	218	69
Female	97	31
Age		
$\leqslant$65	189	60
$\geqslant$65	126	40
Treatment modalities		
Radiotherapy alone	182	58
Postoperative radiotherapy	133	42
Tumour classification		
T0	22	7
T1	58	18
T2	101	32
T3	45	14
T4	88	28
Tis	1	0.3
Node classification		
N0	136	43
N1	41	13
N2a	10	3
N2b	49	16
N2c	67	21
N3	12	4
Site		
Oropharynx	125	40
Sinuses and nasopharynx	16	5
Hypopharynx	19	6
Larynx	92	29
Salivary glands	22	7
Other	41	13

Assessment of patient-rated QoL

For the evaluation of the different aspects of patient-rated xerostomia, a new questionnaire was developed referred to as the Groningen Radiation-Induced Xerostomia (GRIX) questionnaire.

In the first phase, we composed an initial list of relevant questions related to xerostomia as reported in earlier studies [15,18–23] and as reported by patients and health care providers experienced in treating patients with head and neck cancer. This initial phase resulted in a questionnaire that contained 56 questions.

This initial list of 56 questions was reviewed by the investigators to delete questions that were closely related or in fact posed the same question in another way. In this phase, the questions were reconstructed in order to obtain the same response format as used in the aforementioned EORTC questionnaires, i.e., not at all, a little, quite a bit, and very much. This adjusted questionnaire was presented to three different health care providers and one patient. These observers were asked to indicate (1) for each question if this was considered relevant (varying from very much to not at all) and (2) for each question if the formulation was clear. Eventually, this resulted in a first version of the questionnaire that contained 16 questions, which after a first evaluation, was reduced to a 14-item questionnaire (see Appendix).

The GRIX version 1.0 was conceptualised as containing four subscales xerostomia and sticky saliva during day and night. This four subscales were chosen based on the physiological differences in content and production of saliva during day and during night [16,17]. Patients filled out the GRIX and the EORTC QLQ-H&N35 at baseline, weekly during radiation treatment, 6 weeks after treatment and every 6 months after completion of treatment until 24 months after treatment. All scores were linearly converted to a 0–100 scale, in which higher scores represent more xerostomia.

Statistics

The reliability of the scale of the GRIX was evaluated by examining the internal consistency of the scale by using Crohnbach's α, which refers to the extent to which the items within a scale are interrelated. Crohnbach's α were calculated for all questionnaires together and for each individual time point. Stability of the GRIX was evaluated by correlating test–retest scores using Pearson's correlation coefficients between pre-test, on the day of the first visit to the outpatient clinic and retest on the first day of radiation treatment. In general, the interval between these two time points was approximately 2 weeks and not any treatment was given during this period. For this test–retest analysis, patients referred for postoperative radiotherapy were excluded, to exclude any influence due to recovery of surgery on test–retest scores (n = 149).

Criterion validity of the GRIX was evaluated by comparing the questionnaire's score with the score on the two questions about xerostomia and sticky saliva in the EORTC QLQ-HN35 questionnaire and the physician-rated CTCAEv3.0 toxicity scoring system for xerostomia and salivary gland changes using Pearson's correlation coefficients. Criterion validity was also tested for all filled out questionnaires together as well for four different time points, baseline, 6 weeks after starting radiotherapy treatment and 6 months and 1 year after completion of treatment.

Responsiveness of the GRIX, which refers to the ability of a questionnaire to detect important changes over time, was evaluated by testing the scores of different subscales as a function of

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