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Trends in the 15D health-related quality of life over the first year following diagnosis of head and neck cancer

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Abstract Management of head and neck cancer influences both physical and mental wellbeing. Measuring the health-related quality of life (HRQoL) is important, as various treatment modalities are associated with significant morbidity and mortality. In this prospective cohort study, we tested the feasibility of the generic 15D HRQoL instrument in 214 head and neck cancer patients managed with surgery, definitive (chemo)radiotherapy, or with combined modality treatment. HRQoL was assessed at baseline and three times after treatment onset during 1 year, and compared with that of general population standardized for age and sex. At baseline, the patients' mean 15D score was significantly worse compared with general population. Overall HRQoL was at lowest at 3 months after treatment onset, it gradually improved towards 12 months but never reached baseline levels. The dimensions "vitality", "distress", "depression" and "sexual activity" showed marked deterioration at 3 months after the treatment onset, but improved gradually during 12 months. The 15D instrument seems useful for evaluation of HRQoL of head and neck cancer patients. Dimensions reflecting mental wellbeing improved gradually after 3 months, but they seldom reached baseline levels. The support for patients at the time of diagnosis, during treatment, and recovery is emphasized.

Keywords Head and neck cancer · Health-related quality of life · Surgery · Radiotherapy · Chemoradiotherapy

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Introduction

In Finland with a population of 5.5 M, in 2012 around 500 men and 260 women were diagnosed with head and neck cancer [1]. Surgery, oncological treatment, or combined modality treatment remain the curative treatment options for these patients. Treatment decisions are based on the location and TNM classification of the tumor, the treating institution's experience, comorbidities as well as patient preference.

Treatment of head and neck cancer may have a great impact on patients' physical and mental wellbeing and is associated with significant morbidity and mortality. The many consequences of diagnosis and treatment on patients' quality of life (QoL) can be unexpected and sometimes detrimental affecting the outcome of treatment. The World Health Organization has a definition for QoL, but the actual meaning of everyone's QoL is highly individual [2]. Information on the health-related QoL (HRQoL) of previously treated patients will help patients and their families

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to cope with the diagnosis and to understand the consequences of their cancer management [3]. Measuring HRQoL varies across different studies, and the content of self-administered questionnaires is variable. Disease-specific and generic HRQoL tools have been developed over the years [4–7]. An updated, preliminary European Organization for Research and Treatment of Cancer Quality of Life Questionnaire Head and Neck Module 43 (EORTC QLQ-H&N43) measures head and neck malignancies excluding eye and thyroid cancers. It contains additional questions to the previous version concerning problems with skin, neurological and shoulder problems [6]. Because there is no gold standard instrument currently available in the literature, it is difficult to choose a specific multi-domain questionnaire to outline head and neck cancer patient's QoL after treatment.

QoL is an interesting and important outcome in head and neck cancer treatment. Disease-specific QoL instruments alone may not give an appropriate view of this multidimensional disease. In this study, HRQoL was assessed using the self-administered generic 15D instrument. Its usefulness in head and neck cancer patients has been shown among a subgroup of patients after successful oncological treatment [8]. The aim of this prospective cohort study was to demonstrate the transitions in HRQoL for a larger head and neck cancer population using the 15D instrument over the first year after diagnosis.

Patients and methods

Altogether 296 patients entering treatment for a head and neck malignancy at our institution during the years 2007–2013 were given the 15D HRQoL questionnaire together with an informed consent form, and invited to participate by returning the questionnaire in a prepaid preaddressed envelope. All patients who responded to the baseline questionnaire were sent repeated questionnaires 3, 6 and 12 months after their first visit. Into the final analyses, we only included the 214 patients who had a follow-up time of at least 12 months and who had responded at least to the baseline and 12-month questionnaire resulting in a response rate of 72 %. Of the 296 patients, six were dead of disease and one was dead of other causes before the end of follow-up (Fig. 1).

Patients

The mean age (SD, range) of the 214 patients was 63 years (10, 27–85). Sixty-six percent of them were men. The Charlson Comorbidity Index (CCI) was 0 for 63 %, 1–2 for 31 %, and ≥3 for 6 %. In this cohort, 36 % of the patients were current smokers, and 16 % were heavy drinkers. The
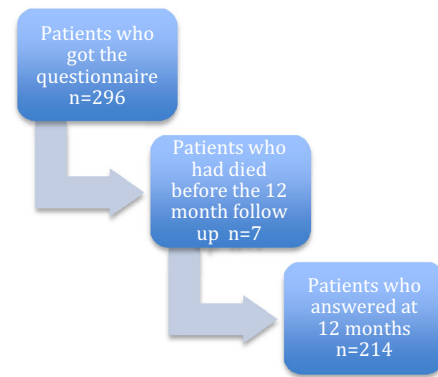
Fig. 1 Patient selection

most common tumor sites were oropharynx (37 %) and oral cavity (21 %). The most common histology was squamous cell carcinoma ($n = 182$; 85 %), followed by salivary gland malignancy ($n = 23$; 11 %), and additionally a few other histology types ($n = 9$; 4 %). Advanced stage disease (Stages III–IV) was diagnosed in 56 % of patients. Patient and tumor characteristics are listed in Table 1.

Treatment

All tumors were staged according to the seventh UICC TNM classification [9]. Most patients were treated with curative intent (99 %). For two patients, therapy was palliative due to advanced regional or distant disease at the time of diagnosis. Surgery was performed for 60 % of patients and 40 % of patients received postoperative adjuvant therapy. Eighty-six patients (40 %) received definitive oncological treatment. Treatment characteristics are listed in Tables 2 and 3.

15D

HRQoL was measured with a 15-dimensional standardized and self-administered generic HRQoL instrument that can be used as a profile and a single index utility score measure (The 15D© health-related quality of life instrument home page). The 15 dimensions of the instruments are: moving, seeing, hearing, breathing, sleeping, eating, speech, excretion, usual activities, mental function, discomfort and symptoms, depression, distress, vitality and sexual activity. For each dimension, the respondent chooses one of the five levels best describing his/her state of health at the moment (the best level = 1; the worst level = 5). The valuation system of the instrument is based on an application of the multi-attribute utility theory. A set of utility or preference weights, elicited from the general public through a 3-stage

Table 1 Patient and tumor characteristics

Characteristic	N = 214	%
Sex		
Female	73	34
Male	141	66
Age, years		
Mean	63	
Median	62	
Range	27–85	
Standard deviation	10	
Smoking		
No	46	21
Before, stopped	55	26
Yes	77	36
No data available	36	17
Alcohol		
No	33	15
Yes, reasonably	44	21
Yes, a lot	34	16
No data available	103	48
Charlson Comorbidity Index		
0	135	63
1	50	23
2	16	8
3–4	9	4
≥5	4	2
Tumor site		
Oral cavity	45	21
Nasopharynx	5	2
Oropharynx	79	37
Hypopharynx	8	4
Larynx	30	14
Parotid gland	12	6
Submandibular gland	5	2
Paranasal sinuses	12	6
Unknown primary	4	2
Skin	13	6
Mandible	1	0.5
Stage		
0	1	0.5
I	35	16
II	46	21
III	23	11
IV	96	45
Unknown primary	4	2
No data available	9	4
Histology		
Squamous cell carcinoma	182	85
Salivary gland carcinoma	23	11
Melanoma	2	1
Sarcoma	1	0.5
Other	6	3

Table 2 Treatment characteristics

Characteristic	N = 214	%
Surgery	43	20
Surgery + radiotherapy	55	26
Surgery + chemoradiotherapy	30	14
Radiotherapy	14	7
Chemoradiotherapy	72	34

Table 3 Surgical treatment

Type of surgery	N	%
Preoperative tracheotomy	56	26
Pre-treatment gastrostomy tube (PEG)	100	47
Total laryngectomy	8	4
Reconstructive surgery		
No	164	77
Pedicular flap	13	6
Microvascular flap	37	17
Bone reconstruction		
No	205	96
Titanium	2	1
Bone	7	3
Access mandibulotomy		
No	207	97
Yes	7	3
Neck dissection		
No	118	55
Selective neck dissection	65	30
Levels I–V	25	12
Radical neck dissection	6	3

valuation procedure, is used in an additive aggregation formula to generate the utility score, i.e., the 15D score (single index number) over all the dimensions. The maximum score of the 15D is 1 (no problems on any dimension), and the minimum score 0 (equivalent to being dead). The 15D compares favorably with other preference-based generic HRQoL instruments [10–14]. A change of ≥0.015 in the total 15D score is considered clinically or practically important, i.e., such a change that an individual can feel the difference [15]. The HRQoL of patients at baseline was compared to that of an age- and gender-standardized sample of the Finnish general population from the Finnish Health 2011 survey (n = 4835) [16].

All patients received scheduled routine protocol treatment and were asked to fill in the 15D questionnaire and to give a written informed consent. The study protocol was

approved by the Research Ethical Committee of the Helsinki and Uusimaa Hospital District (registration number 538/E0/02). The trial has been registered in the Helsinki and Uusimaa Hospital District Clinical Trials Register (http://www.hus.fi) with the unique trial number 75370.

Statistical analysis

Data were analyzed using the SPSS for Windows statistical software version 22.0 (SPSS, Inc., Chicago, IL, USA). The results are given as mean (standard deviation, SD, or confidence interval, CI), or as percentages. The statistical significance of the difference in the mean 15D score of the general population and study patients was tested by independent samples t test, and that in the means of continuous variables, including the 15D scores before and after treatment with paired samples t test. As some of the 15D variables were not normally distributed, also corresponding non-parametric tests were applied. Apart from minor differences in the level of statistical significance, the results of parametric and non-parametric tests were quite similar. Therefore, only results of parametric tests are reported. p values <0.05 were considered statistically significant.

Results

The mean 15D score (on a 0–1 scale) of the patients entering treatment was worse than that of the general population (0.872 vs. 0.911, $p < 0.001$). Furthermore, the patients were at baseline statistically significantly worse off than the general population on 9 of the 15 dimensions of the HRQoL instrument (Fig. 2).

The total 15D score showed a slight initial deterioration but then remained fairly constant during the rest of the 12-month follow-up as illustrated in Fig. 3. Compared with baseline, the mean 15D score was statistically significantly worse on all follow-up points. Patients reported the worst

mean 15D score of 0.839 (SD 0.114; $p < 0.001$—compared with baseline) at 3 months after which it gradually improved towards 12 months but never reached the baseline level (Fig. 3). Regarding the various dimensions, the most consistent impairment was seen on the dimensions of "hearing", "eating", "speech", "usual activities" and "distress". Compared with the baseline results of the study group, a statistically significant difference at 3 months was observed on the dimensions of "hearing" ($p < 0.01$), "eating" ($p < 0.001$), "speech" ($p < 0.001$), "usual activities" ($p < 0.001$), "discomfort and symptoms" ($p < 0.05$), "distress" ($p < 0.001$), "vitality" ($p < 0.001$), and "sexual activity" ($p < 0.001$) (Fig. 3).

At baseline, the dimension of "distress" was at its lowest (0.802) but improved quickly and exceeded the baseline level already at the 3-month follow-up point ($p < 0.001$). A similar trend was also seen on the dimension of "depression", but improvement was slower and evident first at the 6-month follow-up point ($p < 0.01$). The dimensions of "vitality" and "sexual activity" showed marked deterioration at 3 months after the treatment onset but then improved gradually during 12 months but never reached the baseline level ($p < 0.001$). Moreover, the score for "discomfort and symptoms" improved notably after 3 months ($p < 0.05$) (Fig. 3).

In the univariate analysis regarding surgical interventions, gastrostomy tube (PEG) affected the mean 15D score at 3 months ($p = 0.001$), tracheotomy tube ($p = 0.003$) and bone ($p = 0.048$) and soft tissue ($p = 0.002$) reconstruction affected the mean 15D score at 12 months. At baseline the mean 15D score was statistically significantly worse in the group of patients with a planned neck dissection (ND) in their treatment ($p = 0.029$). The dimensions of "eating" ($p < 0.01$), "usual activities" ($p < 0.05$), and "discomfort and symptoms" ($p < 0.01$) were affected. Other specific surgical interventions showed no statistically significant factors affecting the mean 15D score at different time points.
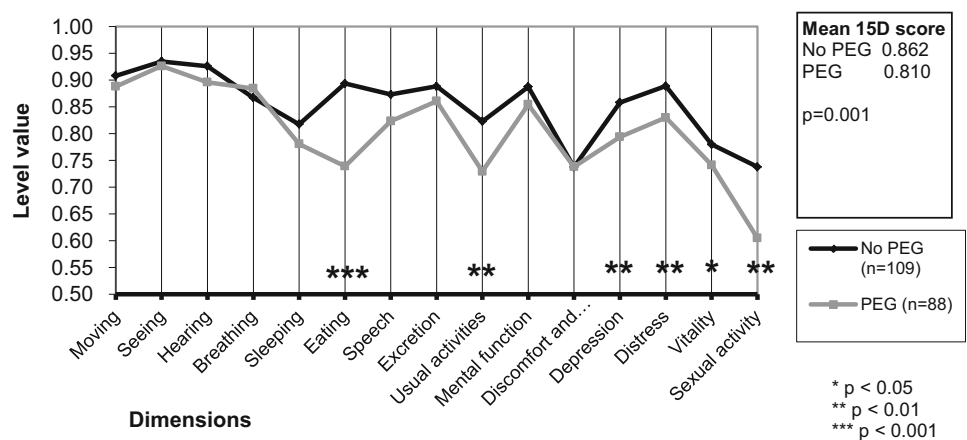
Fig. 2 15D profiles of 214 head and neck cancer patients (mean age 63 years, 66 % males) compared to general population standardized for age and sex
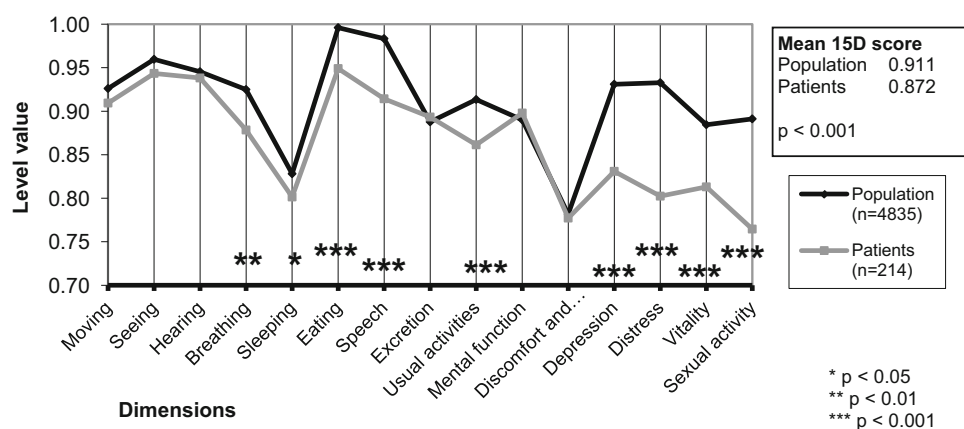
Fig. 3 15D profiles of 214 head and neck cancer patients (mean age 63 years, 66 % males) during 1-year follow-up. *mos* month
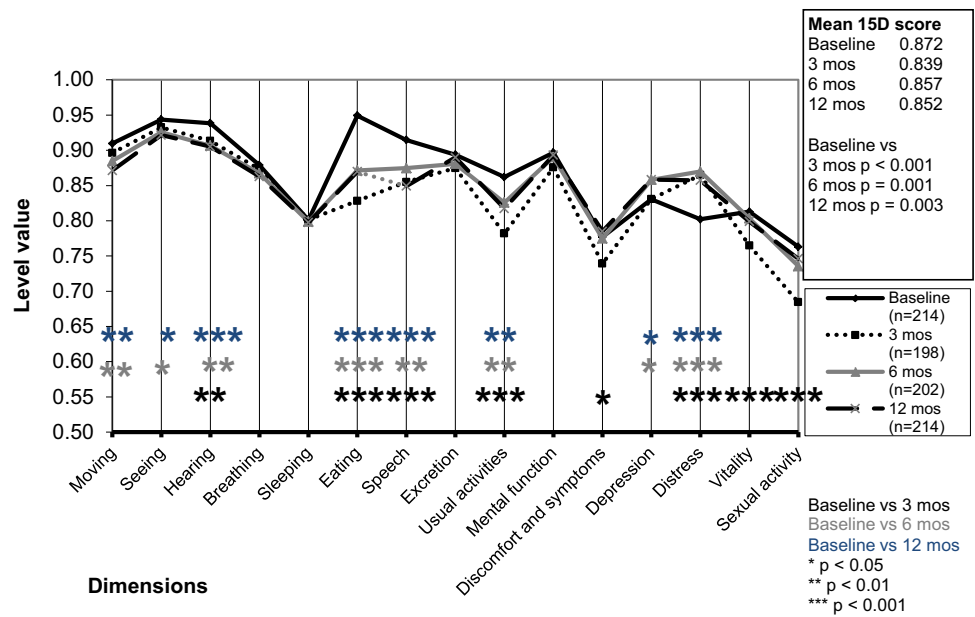
Fig. 4 15D profiles of PEG and non-PEG head and neck cancer patients at 3 months. *PEG* gastrostomy tube

Treatment of head and neck cancer may cause swelling in the airway. Preoperative tracheotomy was performed for 26 % of patients ($n = 56$). The length of dependence on tracheotomy was not analyzed. At 12 months, patients with tracheotomy at the onset of treatment reported statistically significantly ($p = 0.003$) lower mean 15D scores than those without tracheotomy. The dimensions of "eating" and "speech" were affected in patients with tracheotomy throughout the follow-up but showed deterioration towards 12 months. The dimensions of "usual activities" ($p < 0.01$), "discomfort and symptoms" ($p < 0.05$), "depression" ($p < 0.01$), and "distress" ($p < 0.05$) were affected later in recovery at 12-month follow-up point.

In order to guarantee adequate nutrition during treatment, 47 % of patients ($n = 100$) in this cohort got PEG prior to treatment. The length of dependence on PEG was not analyzed in this cohort, but our patients typically have

it at least for the first 3 months during oncological treatment and recovery. The patients with PEG ($n = 88$ at 3 months) reported at 3 months statistically significantly lower mean 15D scores than those without it ($p = 0.001$) (Fig. 4). The statistically significantly affected dimensions were "eating" ($p < 0.001$), "usual activities" ($p < 0.01$), "depression" ($p < 0.01$), "distress" ($p < 0.01$), "vitality" ($p < 0.05$), and "sexual activity" ($p < 0.01$) (Fig. 4). At 12 months, the statistically significant difference of the mean 15D score between the groups, however, had disappeared ($p = 0.146$), probably due to the fact that PEG had already been removed during recovery.

Patients undergoing ND experienced problems with eating towards the end of the 12-month follow-up ($p < 0.01$), whereas the other dimensions improved. "Speech" was affected at the 3- and the 12-month follow-up points ($p < 0.01$). For patients with laryngectomy, the only

Fig. 5 The mean 15D scores (with confidence intervals) at baseline and after 12 months according to primary treatment modality. *Sx* surgery, *Sx + RT* Sx + radiotherapy, *Sx + CRT* Sx + chemoradiotherapy, *RT* radiotherapy, *CRT* chemoradiotherapy, *n* number
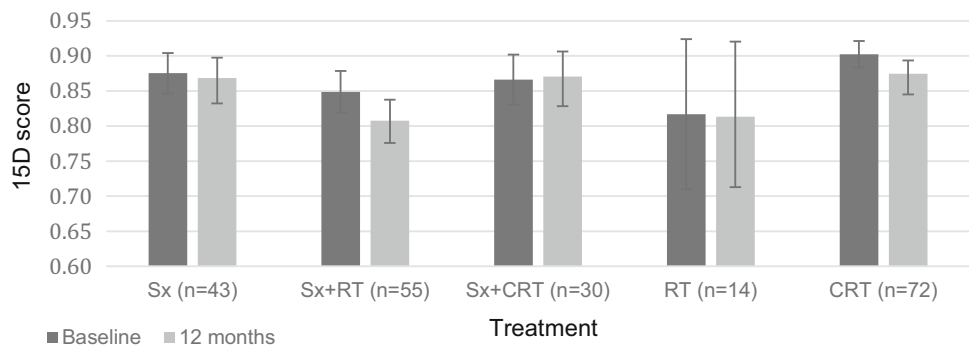
Fig. 6 Change in the mean 15D score (with confidence intervals) in 12 months according to primary treatment modality. Abbreviations are as in Fig. 5
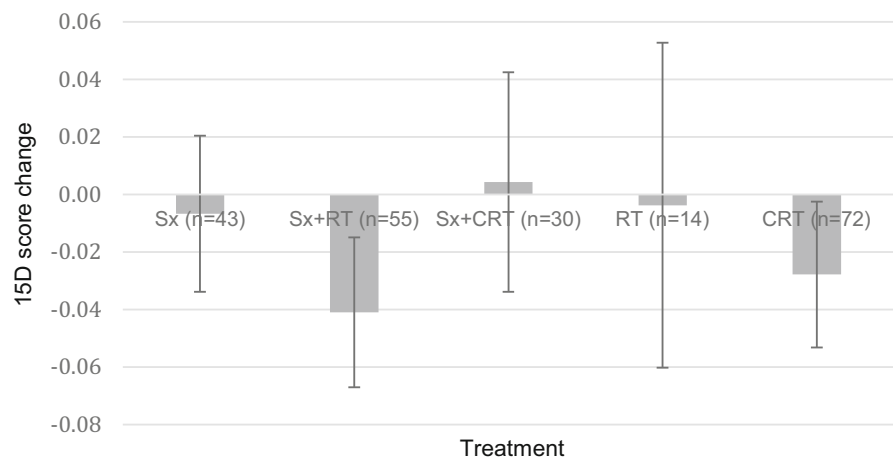
markedly affected dimension was "speech" which was statistically significantly worse than at baseline both at the 3- ($p = 0.050$) and 12-month ($p < 0.010$) follow-up points.

Patients with pedicular soft tissue reconstruction reported lower mean 15D scores compared with those patients with microvascular reconstruction or with no reconstruction. This was obvious throughout the follow-up but only at the 12-month follow-up this difference was statistically significant ($p = 0.002$).

The need for a bone reconstruction showed a clear effect on the dimensions concerning oral functions during the 12-month follow-up. Patients experienced difficulties in eating, which gradually worsened towards the end of the follow-up. The dimension "speech" improved during follow-up but remained affected.

Treatment results

Nine patients (4 %) had residual disease at 3 months after treatment onset. They all had Stages III–IV disease of paranasal sinuses, oral cavity, oropharynx, hypopharynx, and larynx. All but one were primarily treated with curative intent with definitive (chemo)radiotherapy [(C)RT], one

had surgery with adjuvant RT. A local or locoregional recurrence was observed in 37 patients (17 %) and distant metastasis in nine patients (4 %) during the 12-month follow-up. Nine percent ($n = 20$) of the patients died of disease during a follow-up of 1 year. None of the patients died of treatment-related causes. At 12 months, 87 % ($n = 187$) were alive without evidence of disease, 7 % were alive with disease. The status was not available for 6 % ($n = 12$) due to the fact that their follow-up was scheduled at other institutions.

The change in the mean 15D score according to primary treatment modality in the 12-month follow-up is shown in Figs. 5 and 6. The only group that showed a positive change was those patients treated with surgery and adjuvant postoperative CRT (0.0043, $p = 0.819$). Patients treated with surgery and adjuvant postoperative RT showed the biggest negative change in the mean 15D score (-0.410, $p = 0.003$).

The primary treatment modality was the most significant factor influencing QoL in this study. Patients treated with surgery and postoperative adjuvant CRT experienced a positive change in their mean 15D score during follow-up as opposed to other treatment modalities.

Discussion

We used the generic 15D assessment tool to investigate HRQoL of 214 patients treated for head and neck cancer. This instrument seems useful in evaluating HRQoL in this patient population. Dimensions reflecting mental wellbeing improved gradually after 3 months, but they seldom reached baseline levels.

The patients included in this study were recruited from an unselected head and neck cancer patient cohort at an academic tertiary care hospital. This can be considered a strength of the study setting compared to, for example, controlled trials. Non-selection of patients can also ensure that the cohort represents a broad spectrum of head and neck cancer patients with various symptoms, comorbidities and tumors. The response rate was 72 %, which can be considered fairly high in this particular patient population. The fact that the group of non-respondents is not analyzed is a limitation of the study. However, only patients who responded at least to the baseline and 12-month questionnaire were included in the study so dropouts from the study do not influence the present results.

From a clinical and research point of view, a good HRQoL questionnaire is patient-reported, easy to interpret, comprehensive and applicable. For the patient, the questionnaire should be easy to interpret and short with only a few options to answer per question. The generic HRQoL instruments enable comparison between different patient populations and diseases and assessment of cost-effectiveness of treatment [12].

The usefulness of this 15D instrument has been tested in oncologically treated head and neck cancer patients [8] as well as among benign head and neck conditions (juvenile-onset recurrent respiratory papillomatosis, septoplasty, tonsillectomy) [17–19]. It enables comparisons between different health conditions as well as between general populations [12]. The mean 15D score in this study was in the same range as shown in patients with colorectal [20] and prostate cancer [21]. Previous studies on oncologically treated head and neck cancer patients show that a decline in HRQoL is usually seen during the first 3 months after treatment onset, but it then gradually improves towards 12 months [8, 22] and even 5 years after treatment patients are satisfied with their QoL [23]. This trend of improvement was also obvious in our study. At 3 months the mean 15D score was notably worst (0.839; $p < 0.001$) showing gradual improvement towards 12 months.

A tracheotomy tube was placed for 56 patients (26 %) before treatment. This group of patients experienced a notable decline in their mental wellbeing towards the end of follow-up. At the 3-month follow-up point, only the dimension "speech" was affected. Terrell et al. [24]

showed tracheotomy tube to be significant in relation to QoL. The affected domains were "speech" and emotional domains, but the change of these domains during recovery were not assessed. Another study evaluated the dependence on tracheotomy tube and showed that the average time of dependence was 11 months [25]. They did not measure QoL but speculated that tracheotomy tube may influence it.

Dependence of gastrostomy tube (PEG) during oncological treatment for oropharyngeal carcinoma is 81 % [26], but longer periods are uncommon [23]. This will positively affect QoL during the later recovery [24]. Thirty percent of hypopharyngeal cancer patients did not require PEG during treatment, but those who did, were still PEG dependent after a 12-month follow-up [27]. In our study, 47 % of patients got PEG prior to treatment and patients with PEG had lower mean 15D scores at the three-month follow-up point than patients without PEG ($p = 0.001$). Patients with PEG experience problems with activities of daily living and therefore its presence is predictive of impaired QoL [24]. Most patients who have a PEG placed, then become dependent on its use during definitive or postoperative oncological treatment. The continuation of normal oral intake during treatment will possibly enable the patient to maintain better swallowing function and thus reduces the time of gastrostomy tube dependence [26]. Prophylactic PEG placement may ensure better enteral nutrition during treatment and recovery and therefore improves QoL [28]. According to a recent study, the use of gabapentin during and after CRT may help to avoid dysphagia [29].

ND was performed for 96 patients (45 %). Among patients who were planned to have an ND, the dimensions of "eating", "usual activities", and "discomfort and symptoms" were affected. All but "eating" improved towards 12 months. The forthcoming ND worsened their mean 15D score statistically significantly ($p = 0.029$), thus possibly reflecting the negative impression of this treatment modality. Others have shown ND to have impact on QoL [24, 30–32]. Regarding physical functioning domain, ND has less impact on QoL than PEG but more than chemotherapy [24].

The study sample included eight patients with total laryngectomy. The only affected domain was "speech". Terrell et al. [24] showed that in addition to "speech", total laryngectomy affected social functioning domain. Still, tracheotomy and PEG affected both of these domains with greater magnitude. Speech problems often influence many patients with head and neck cancer. Furthermore, patients with laryngectomy are well adapted to their esophageal speech with the speech prosthesis.

The diagnosis of an unknown primary causes anxiety for the patients since they are unable to specifically

characterize or name their cancer in such cases. Also the treatment in these cases cannot be planned according to a specific site. Durmus et al. [22] studied QoL after the diagnosis of carcinoma of unknown primary in patients undergoing transoral robotic surgery (TORS). They showed that QoL scores immediately after TORS were significantly better than after adjuvant therapy but no difference was observed after 12 months. This is partly attributed to head and neck irradiation after TORS, which further deteriorates eating function and slows down recovery. The detection of an occult primary improves treatment outcome and may bring relief to the patient. If the primary is detected, the treatment can be focused and outlined to the specific site. Resection of the detected primary with clear margins could enable avoidance of chemotherapy and reduction of radiation dose therefore influencing the degree of dysphagia. In our cohort, TORS was not performed for the four patients with unknown primaries, but after this study it became part of the diagnostic and treatment regimen at our institution.

The impact of human papilloma virus (HPV) on the HRQoL of head and neck cancer patients varies. Maxwell et al. [33] showed that p16-positive head and neck squamous cell carcinoma patients have better QoL scores at baseline irrespective of the treatment modality compared with the p16-negative counterparts. The HPV-positive patients had worse salivary function in the early stage of recovery than HPV-negative counterparts. This was probably partly attributable to the site of the HPV-positive tumor in the oropharynx affecting treatment modality. In their study, patients were recruited even after one completed survey at any point of treatment and therefore no knowledge of change in QoL during treatment was shown. On the other hand, Durmus et al. [22] showed HPV status to be insignificant in relation to QoL. In our study, the HPV/p16 status was not available for all patients with oropharyngeal cancer. The incidence of oropharyngeal squamous cell carcinoma was distributed evenly across ages. Most cases at this site ($n = 43$; 54 %) were treated with definitive CRT, which is usually the standard treatment modality in HPV-positive cases at our institution. This treatment modality was used at this site more often than for tumors at other sites ($n = 29$; 14 %). By reviewing these other studies, the HPV/p16 status might not affect QoL in our patient cohort.

Dental-related issues are important in the treatment of head and neck cancer. After treatment, patients may experience difficulties in chewing, dry mouth, oral hygiene, appearance and self-esteem. Patients with significant chewing problems report worse overall QoL [34]. Patients with an advanced clinical stage disease, free flap surgery or RT experience more chewing problems highlighting also the need for regular dental follow-up [34]. In our cohort,

for patients with a free flap or pedicular reconstruction, the most affected dimensions were "speech", "eating", and "usual activities". Patients with bone reconstruction showed similar deterioration in these dimensions during follow-up without improvement. These results show major long-term influence of treatment to patient's oral functions and esthetics. Dental rehabilitation usually takes place after 12-month follow-up and probably positively influences QoL later in recovery.

Patients' perceptions of their symptoms may differ from that of a physician. Various attempts to reduce radiation toxicity regarding mucosal appears to provide little improvement in patient-reported symptoms, which sometimes differs from the clinician's judgment on symptom relief [35]. In a group of patients undergoing septoplasty, the mean 15D score worsened 6 months after surgery [18]. Surprisingly, in the present cohort, only patients treated with surgery and postoperative CRT showed a positive change in their mean 15D score during the 12-month follow-up. These results highlight the fact that not all clinically and medically relevant interventions will improve patients' QoL and neither do they always meet various expectations of the patient. Patients undergoing surgery and postoperative adjuvant CRT are usually well prepared for their treatment and this might have a positive influence on certain QoL domains during recovery.

Since treatment of head and neck cancer has functional, emotional, social and esthetic consequences, early supportive measures are warranted to guarantee a better QoL through treatment and follow-up.

Conclusion

The present study gives an overview of the HRQoL in head and neck cancer patients during the first year after treatment. It is noteworthy, that the overall HRQoL score remained fairly constant despite of intensive treatment. Furthermore, certain domains reflecting psychological wellbeing tended to improve after treatment indicating that the initial anguish related to the diagnosis of a malignant disease can be attenuated during treatment. More importantly, this result highlights the value of patient support throughout diagnostic, treatment, rehabilitation and follow-up process. The 15D instrument seems useful for evaluation of HRQoL of head and neck cancer patients treated surgically, oncologically or with combined modality.

Compliance with ethical standards

Conflict of interest The authors claim no conflict of interest.

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