IJCRT.ORG ISSN : 2320-2882

INTERNATIONAL JOURNAL OF CREATIVE RESEARCH THOUGHTS (IJCRT)

An International Open Access, Peer-reviewed, Refereed Journal

An Assessment of Head and Neck Cancer Patients on Comparison of Quality Of Life in 12 Cities in Gujarat State, India.

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Abstract

The study was undertaken to obtain an overview of patterns of cancer in different part of Gujarat state. This study tests the validity and reliability of head and neck cancer module (QLQ-H&N) and the GORTC Core Questionnaire (QLQ) which was developed by the Gujarat Organization for Research and Treatment of Cancer (GORTC) and tested on 500 head and neck cancer patients from 12 cities. The patients completed the QLQ-C, the QLQ-H&N and a debriefing questionnaire before anti neoplastic treatment or at a follow-up. Two hundred thirty patients receiving treatment completed a second questionnaire after treatment. Problems were high and the questionnaire was well accepted by the patients. Multigrain scaling analysis confirmed the proposed scale structure of the QLQ-H&N. The QLQ-H&N was responsive between disease status, site and patients with recent performance status, and to changes over time. The new physical functioning scale with a four-point response format of the QLQ-C was shown to be more reliable than previous. The QLQ-H&N, in conjunction with the QLQ-C, shown to be reliable, valid and also applicable to broad multicultural samples of head and neck cancer patients.

Keywords: Head & Neck Cancer HNC; Quality of life QOL; Quality of life Questionnaire QLQQ; Quality of life Questionnaire Validity QLQV; IORTC Indian Organization for Research and Treatment of Cancer. National Cancer Institute NCI. Physical Functioning PF; Scale or Global Quality of Life S or GQOL; Score of Scales and Single Item SOSSI; Symptom Rating SR. Gujarat Organization for Research and Treatment of Cancer GORTC; Quality of life Questionnaire QLQ.

Introduction

Having head and neck (H&N) cancer may be shattering experience. These patients not only have to face a life threatening disease, but also have to deal with the impact of the disease and its treatment on appearance and on important function like eating, swallowing, breathing and communication. Treatment strategies are aimed not only at increasing the chances of cure but also to maintain health-related quality of life (HQOL), for example, preservation of speech. Measuring HQOL in these patients is therefore of great importance. The Indian Organization for Research and treatment of cancer (IORTC) Quality of life Group has developed a strategy for measuring HQOL in clinical trials. A tumor specific module, e.g. a lung cancer module, is used in conjunction with a general cancer questionnaire the QLQ-C. These modules are developed according to the guidelines of the IORC Quality of life group. A preliminary reliability and validity study of the module which started in 2018 included 500 patients with newly diagnosed disease in four centers in

Gujarat, and Gujarat cities. Following this study, a structure consisting of seven symptom scale (Pain, Swallowing, Senses, and Speech, Social eating, social Contact and sexuality), and six symptom items. (Problem with teeth, problem with opening mouth, dry mouth, sticky saliva, coughing and feeling ill) and five additional dichotomous items (related to the use of painkillers, nutritional supplements and feeding tube, and weight decrease) was proposed. The primary aim of this study was to test the postulated scale structure of the QLQ-H&N with regard to its reliability and validity in a large national sample of the patients, including patients with newly diagnosed disease, recurrent disease and disease-free patients. The secondary aim of the study was to test with a changed response format of the physical functioning scale in this patients group. The results from the preliminary validation study indicated that some of the scales (Senses and speech) performed better in some patient subgroups than in others. A few items (Trouble in eating and painful throat) could be included in more than one scale, and other items (Problems with teeth and the last five items) were patient characteristics for removal. This is the definitive report about the psychometric properties of the QLQ-H&N, and of the module is shown QLQ-H&NC.

Materials and Methods

Patients were eligible for the study if they had newly diagnosed or recurrent squamous cell carcinoma of the larynx, oral cavity, and Oro, Naso or hypo pharynx undergoing active treatment (Group I) or were disease-free 1-3 years after treatment (Group II). Group I was subdivided into five subgroups: newly diagnosed patients with laryngeal cancer receiving radiotherapy as first treatment (IA), or with caner of the oral cavity or pharynx receiving radiotherapy as first treatment, and patients with recurrent disease (Independent of site or previous treatment) receiving surgery as salvage treatment (ID) or radiotherapy (IE). Group II was subdivided into two subgroups, independent of previous treatment: disease-free patients with cancer of the larynx (IIA) or cancer of the oral cavity or pharynx (IIB).

Exclusion criteria were: expected survival less than three months; inability to understand the questionnaire; cognitive and/or mental impairment; brain metastases or intracranial extension of the tumor with cognitive impairment; other previous or concurrent malignancies; participation in another HQOL study interfering with the field study. There was no limit on age or performance status. Informed consent (Oral or written) was obtained from all patients and the study was approved by the national committee.

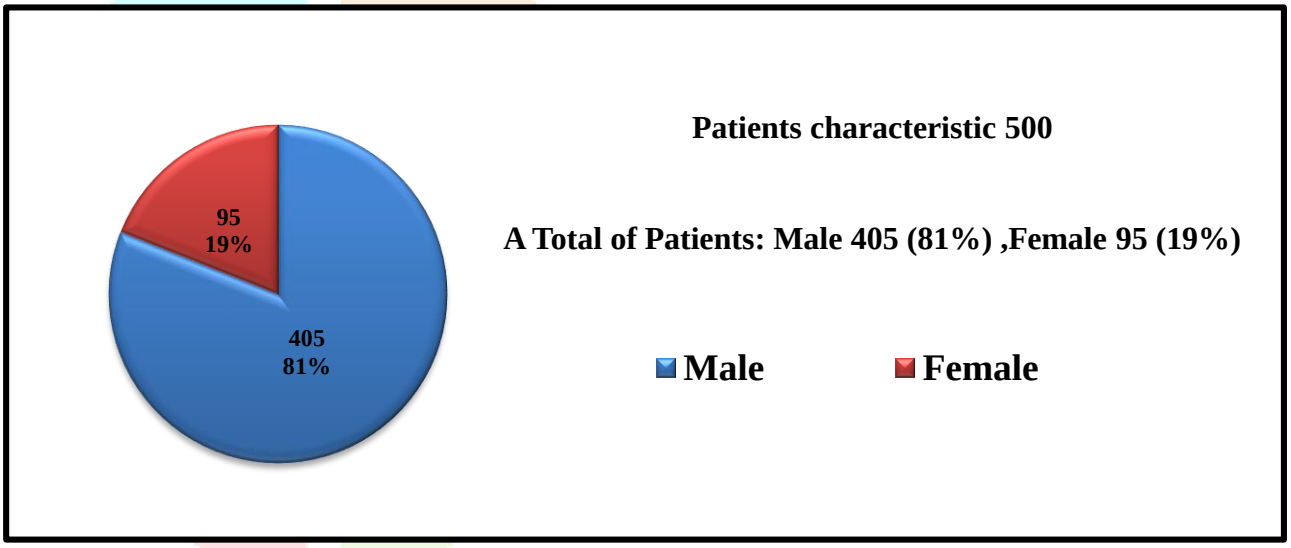
Questionnaires and data collection

Patients completed the IORTC QLQ-C, the IORTC QLQ-H&N and a debriefing questionnaire before the start of treatment (Group I) or at a regular follow-up visit 1-3.5 years after finishing active treatment (Group II). Patients from group I completed a second set of questionnaires within 7 days before or after completion of radiotherapy (Groups IA and IB), 3.5-5.5 weeks after surgery (Groups IC and ID), or up to 4 days before the third cycle of radiotherapy or at 6 weeks in case of weekly or continuous radiotherapy (Group IE). Patients were considered to be evaluable if they had completed at least one questionnaire. The IORTC QLQ-C is a cancer-specific questionnaire which has been used in H&N cancer patients. The current version differs in three respects from the first version: the role functioning and overall QOL scales have been changed and the dichotomous response format of the items of the physical functioning scale has been replaced by four-point Linker-type response categories. The IORTC QLQ-H&N is meant to be used in conjunction with the QLQ-C in patients with H&N cancer, irrespective of site, stage and treatment. It contains both single items and scales. The time frame which the module addresses is ‘During the last week’. The first 30 items are scored on a four-point Liker scale (‘not at all’, ‘a little’, ‘quite a bit’ and ‘very much’), whereas the last five items have a no/yes format. The scores of the QLQ-C and of the QLQ-H&N are transformed to a scale of 0-100, with a high score implying a high level of symptoms or problems (Both questionnaires), or a high level of functioning or global QOL. The debriefing questionnaire contained questions about the time required to complete both

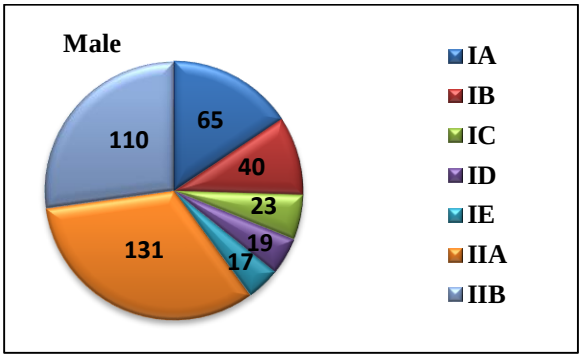
questionnaires, the need for assistance and the presence of questionnaire items which were confusing, difficult to answer or upsetting. The following socio demographic and clinical data were collected: Gender, Age, Marital status, cohabitation, education, employment, site of the tumor or relapse, stage, previous and/or subsequent treatment, Kar performance status, weight loss, selected symptoms/side-effects (Graded according to the National Cancer Institute (NCI) toxicity criteria, co-morbidity and use of pain medication.

Analysis: Reliability: The reliability internal consistency of the scales of the QLQ-C and QLQ-H&N was assessed using Cron alpha co efficient. A value of greater than 0.70 was considered to be adequate. Patients Characteristics: A total of 500 eligible and evaluable patients ware included in the study 164 patients with newly diagnosed disease (Group IA, IB & IC). In Group I Male Patients was 128 and Female Patients 36. In Group I patients with recurrent disease were 47 (Group ID & IE) out of which 36 male and 11 Female. In Group II 289 disease free patients (Group IIA & IIB). Of which 241 were Male and 48 were Female.

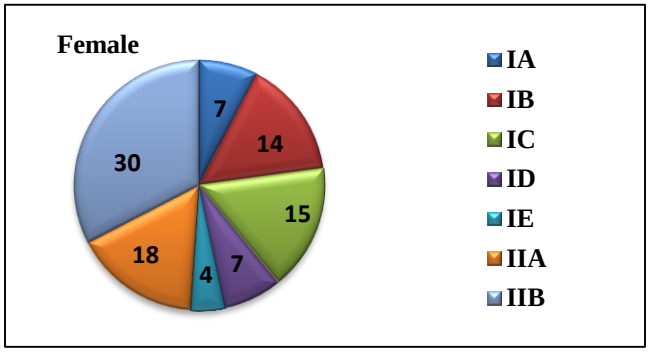
Figure 1 Pie Chart showing Number of Patients



Male

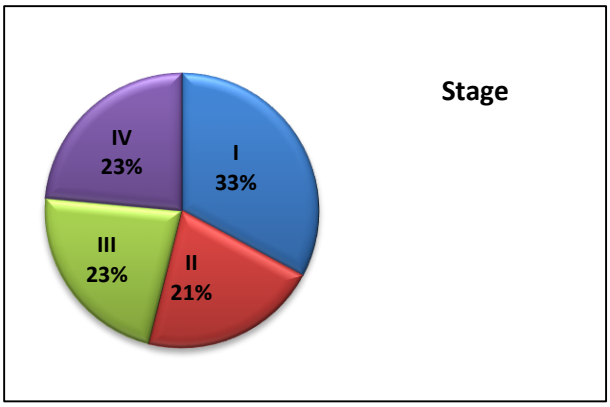


Female



Stage

Previous Treatment



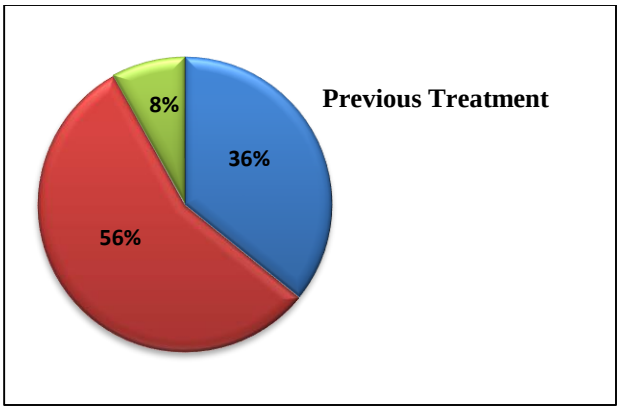


Table 1								
Patient characteristics (N=500)								
Patients Status	Active Treatment					Disease-free		
Diagnosed	Newly diagnosed			Recurrent				
Types of Sites	Larynx	Pharynx		All sites		Larynx	Pharynx	All
Types of Therapies	Radio	Radio	Surgery	Surgery	Chemo			
Types of Groups	IA	IB	IC	ID	IE	IIA	IIB	Total
Female Patients	7	14	15	7	4	18	30	95
Male Patients	65	40	23	19	17	131	110	405
Total Number	72	54	38	26	21	149	140	500

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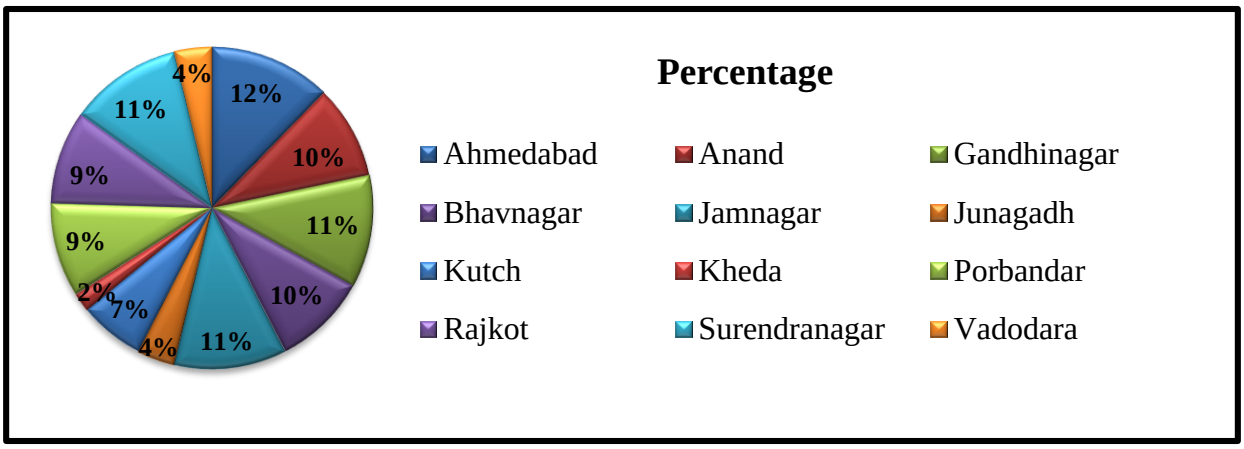
Table 1 shows total 500 eligible and evaluable patients ware included in the study out of which 164 patients with newly diagnosed disease (Group: IA=72, IB=54 & IC=38) were under active treatment. While in another Group 47 patients were with recurrent occurrence of disease (ID 26 & IE 21). In Group I Patients with active treatment were 211 and in Group II 289 Patients were disease free. In group I male patients was 164 and female patients was 47. In group II 289 disease free patients (IIA=149 & IIB=140) out of which male patients was 241 and female was 48. All patients in the study completed at least one questionnaire. Of the 211 patients of group I, only 11% failed to complete a second questionnaire, reason being the patients felt too ill to participate in study so they were withdrawn from the study.

Figure 2 Showing percentage of patients from different cities of Gujarat



In this study patient of 12 Cities of Gujarat was compared. In Ahmedabad 13%, Anand 10%, Bhavnagar 10%, Gandhinagar 12%, Jamnagar 12%, Junagadh 4%, Kutch 7%, Kheda 2%, Porbandar 10%, Rajkot 10%, Surendranagar 12% and Vadodara 4% patients were found. The percentage of items in both questionnaires was generally low < 3%, with the exception of some of QLQ-H&N. Problems with teeth 3% missing, sexuality 10% and 13%.and weight loss 3%. In the Ahmedabad Cities patients 95% completed both questionnaires within 15 min. For both questionnaires the distributions of scores were invariably skewed towards the positive range of responses. High values for functional scales and global QOL. QOL in Cancer and low values for symptom scales and single items. The means and standard deviation for both physical functioning scales happen to be similar in both studies. When differences between diseases according to status studied, high relative efficiency values of QOL.

Table 2: Differences in mean Scores (± S.D.) of Scale and single items of QLQ-C and the QLQ-H&N by disease status

Table 2	**Newly diagnosed**	**Recurrent**	**Disease-free**	**P Value**	**RE**
	(n=164)	**(n=47)**	**(n=289)**	**(n=500)**	
Physical functioning	67 ± 17.2	64 ± 17.1	68 ± 15.1	0.2	21
Role functioning	65 ± 24.3	51 ± 30.2	67 ± 20.1	<0.001	110
Emotional functioning	57 ± 20.3	55 ± 21.7	65 ± 18.3	<0.001	148
Cognitive functioning	66 ± 17.3	64 ± 20.8	71 ± 15.1	0.1	25
Social functioning	68 ± 17.3	57 ± 26.0	72 ± 15.1	<0.001	95

Fatigue	20 ± 19.9	29 ± 23.8	17 ± 18.9	<0.001	93
Nausea/ Vomiting	4 ± 9.6	5 ± 11.5	4 ± 10.7	0.6	6
Pain	16 ± 20.0	31 ± 26.3	12 ± 18.5	<0.001	208
Dyspnoea	16 ± 22.3	13 ± 20.3	16 ± 23.7	0.6	6
Insomnia	22 ± 25.4	27 ± 28.6	77 ± 15.1	0.006	57
Appetite loss	12 ± 22.6	30 ± 30.1	78 ± 15.1	<0.001	19
Constipation	10 ± 20.2	15 ± 25.9	9 ± 18.9	0.1	23
Diarrhea	4 ± 12.5	4 ± 11.1	4 ± 12.8	0.9	1
Financial problem	10 ± 18.2	14 ± 25.6	11 ± 22.2	0.8	3
General QOL	51 ± 19.2	45 ± 18.5	59 ± 17.4	<0.001	230
Pain	17 ± 18.1	28 ± 24.2	10 ± 14.5	<0.001	24
Swallowing	12 ± 18.3	26 ± 25.4	12 ± 17.8	<0.001	105
Senses	6 ± 14.8	21 ± 24.1	15 ± 23.2	<0.001	183
Speech	18 ± 20.6	25 ± 20.7	15 ± 18.8	<0.001	94
Social	10 ± 15.6	28 ± 26.3	13 ± 21.2	<0.001	165
Social contact	5 ± 9.6	15 ± 18.1	6 ± 13.6	<0.001	88
Sexuality	22 ± 27.3	37 ± 31.4	20 ± 26.6	<0.001	95
Teeth	14 ± 22.0	15 ± 27.0	15 ± 24.7	0.9	1
Opening mouth	9 ± 19.6	27 ± 32.3	11 ± 21.7	<0.001	118
Dry mouth	19 ± 22.8	34 ± 30.9	36 ± 30.7	<0.001	237
Sticky saliva	16 ± 21.5	36 ± 31.5	30 ± 29.9	<0.001	118
Coughing	22 ± 22.7	19 ± 24.9	19 ± 22.8	0.3	12
Feeling ill	14 ± 22.0	28 ± 28.7	10 ± 18.5	<0.001	170

R.E. Relative Efficiency; QLQ Quality Of Life. A high score for a functional scale Global QLQ; Kruskal-Wallis test.

Table 3

Differences in mean score (± S.D.) of scale and single items of the QLQ-H&N between sites (Baseline questionnaires only; patients undergoing active treatment and disease free patients combined) (n=500).

Table 3	**Oral cavity**	**Pharynx**	**Larynx**	**P value**	**RE**
	(n=154)	**(n=110)**	**(n=236)**		

Pain	6 ± 5.7	5 ± 4.6	4 ± 5.6	<0.001	180
Swallowing	5 ± 5.9	5 ± 4.9	4 ± 5.6	<0.001	147
Senses	3 ± 5.8	4 ± 5.4	5 ± 9.7	0.002	33
Speech	4 ± 5.3	3 ± 3.7	11 ± 10.2	<0.001	81
Social eating	5 ± 6.9	5 ± 5.3	4 ± 7.7	<0.001	132
Social contact	2 ± 4.5	2 ± 3.1	3 ± 6.8	0.6	3
Sexuality	7 ± 9.0	5 ± 6.1	10 ± 12.6	0.8	1
Teeth	5 ± 8.0	4 ± 6.0	5 ± 9.7	<0.001	38
Opening mouth	5 ± 8.1	4 ± 6.0	2 ± 6.2	<0.001	156
Dry mouth	9 ± 9.1	10 ± 7.0	12 ± 12.5	<0.001	79
Sticky saliva	8 ± 8.8	8 ± 7.2	10 ± 11.8	<0.001	44
Coughing	5 ± 7.1	5 ± 5.2	11 ± 10.6	<0.001	47
Feeling ill	4 ± 6.6	3 ± 5.1	5 ± 9.7	0.2	8

R.E, relative efficiency. A high score implies a high level of symptoms. 2 patients were unclassified. Kruskal-Wallis test

Table 4

Table 4	**KPS (A)**	**KPS (B)**	**KPS (C)**	**P Value**	**RE**
	(n=148)	**(n=145)**	**(n=207)**	**(n= 500)**	
Physical functioning	17 ± 5.8	20 ± 4.0	31 ± 4.1	<0.001	31
Role functioning	15 ± 8.6	19 ± 5.8	30 ± 6.4	<0.001	23
Emotional functioning	16 ± 6.7	19 ± 5.1	27 ± 7.1	<0.001	9
Cognitive functioning	18 ± 6.1	20 ± 4.4	30 ± 5.6	<0.001	12
Social functioning	18 ± 6.9	20 ± 5.3	30 ± 6.0	<0.001	11
Fatigue	9 ± 6.8	5 ± 5.3	5 ± 6.2	<0.001	23
Nausea/ Vomiting	2 ± 4.2	1 ± 2.7	1 ± 2.7	<0.001	10
Pain	7 ± 7.3	4 ± 5.2	4 ± 7.0	<0.001	19
Dyspnoea	8 ± 8.2	4 ± 6.0	4 ± 7.5	<0.001	14
Insomnia	8 ± 8.6	5 ± 7.0	7 ± 9.2	<0.001	6
Appetite loss	7 ± 8.7	3 ±5.2	3 ± 6.6	<0.001	16

Constipation	4 ± 6.7	3 ± 6.0	3 ± 7.0	<0.001	8
Diarrhea	2 ± 4.5	1 ± 3.8	1 ± 4.1	0.1	3
Financial problem	5 ± 7.4	3 ± 5.8	3 ± 7.7	<0.001	4
General QOL	13 ± 5.2	17 ± 4.9	25 ± 7.3	<0.001	25
Pain	6 ± 5.9	4 ± 4.7	4 ± 5.5	<0.001	9
Swallowing	7 ± 6.7	4 ± 5.4	3 ± 5.5	<0.001	22
Senses	6 ± 7.7	3 ± 5.7	3 ± 6.9	<0.001	11
Speech	7 ± 6.5	5 ± 5.7	5 ± 7.1	<0.001	8
Social	7 ± 7.4	3 ± 5.3	3 ± 6.4	<0.001	22
Social contact	3 ± 5.1	2 ± 3.3	2 ± 4.1	<0.001	9
Sexuality	9 ± 9.3	7 ± 8.2	7 ± 9.4	<0.001	5
Teeth	6 ± 8.5	4 ± 6.3	5 ± 9.0	0.2	1
Opening mouth	4 ± 7.6	4 ± 6.6	4 ± 8.5	0.1	1
Dry mouth	10 ± 9.3	8 ± 8.2	12 ± 11.9	0.2	1
Sticky saliva	9 ± 7.7	7 ± 8.0	9 ± 11.2	<0.006	3
Coughing	8 ± 7.7	6 ± 6.4	7 ± 8.3	<0.001	7
Feeling ill	7 ± 8.1	3 ± 5.2	3 ± 6.3	<0.001	13

R.E. relative efficiency a high score for a functional scale or global QLQ Kruskal –Wallis test

Table 5

Mean (±S.D.) of score of scales and single item of the QLQ-H&N by symptom rating

QLQ-H&N	**Symptom Rating**					
QLQ-H&N	**0**	**1**	**2**	**3**	**4**	**P value**
Pain	10±14.9	23±20.9	40±27.7	43±30.3	79±5.9	<0.001
Swallowing	8±12.9	27±21.4	29±25.5	68±23.6	77±13.4	<0.001
Senses	7±16.7	29±27.4	52±27.8	71±29.7	7±16.7	<0.001
Speech	14±19.7	24±1.7	41±26.8	53±28.7	44±31.4	<0.001
Dry mouth	15±24.2	43±29.0	70±27.2	89±18.6	15±24.2	<0.001

For symptoms rating, NCI toxicity criteria are used (pain, dysphasia, altered test, speech and mouth dryness, respective) one –way ANOVA

Table 6

Change over time (before and after treatment) of mean score (±S.D.) Of scale and single items of the QLQ-C and the QLQ-H&N

QLQ-C	**Before**	**After**	**P value**	**SRM**
Physical functioning	84±20.6	74±24.6	<0.001	0.54
Role functioning	77±31.9	62±34.2	<0.001	0.45
Emotional functioning	71±25.7	72±24.8	0.7	0.03
Cognitive functioning	83±22.9	79±25.0	0.002	0.22
Social functioning	82±25.5	76±28.6	<0.001	0.25

Fatigue	28±25.9	43±28.6	<0.001	0.59
Nausea/ Vomiting	5±12.9	15±22.5	<0.001	0.44
Pain	24±27.8	33±30.3	<0.001	0.31
Dyspnoea	20±27.6	21±29.3	0.5	0.05
Insomnia	27±32.3	35±35.1	<0.001	0.23
Appetite loss	19±29.7	37±37.8	<0.001	0.43
Constipation	14±26.3	23±32.5	<0.001	0.31
Diarrhea	6±15.2	8±19.7	0.06	0.13
Financial problem	12±25.2	18±30.4	<0.001	0.23
General QOL	62±23.6	54±23.1	<0.001	0.32
QLQ-H&N				
Pain	22±25.2	32±27.3	<0.001	0.28
Swallowing	17±25.1	37±28.6	<0.001	0.61
Senses	12±23.1	30±29.6	<0.001	0.68
Speech	26±26.7	40±29.1	<0.001	0.56
Social	16±24.2	34±27.9	<0.001	0.65
Social contact	9±15.9	18±24.1	<0.001	0.4
Sexuality	31±35.7	41±38.7	<0.001	0.27
Teeth	17±29.2	22±32.4	0.06	0.13
Opening mouth	16±29.5	32±36.1	<0.001	0.48
Dry mouth	28±31.1	47±38.3	<0.001	0.54
Sticky saliva	28±31.3	48±36.6	<0.001	0.63
Coughing	26±28.4	34±29.7	<0.001	0.23
Feeling ill	22±30.1	30±32.6	<0.001	0.27

SRM, Standardized response means a high score for a functional scale or global QLQ implies a high level of functioning or global QLQ.

Discussion

The IORTC QLQ-H&N has been tested in two large series of patients. The first analysis was performed in a sample of 500 patients with newly diagnosed H&N cancer. The scale structure proposed in that first study has now been tested and validated in this larger and more diverse sample (including patients with recurrent disease and disease free patients) from 12 cites. This marks the IORTC QLQ-H&N one of the most widely tested disease specific HQOL modules in cancer patients. We have not yet explored cross cultural differences.

The questionnaire was well accepted by the patients and the compliance was high. The number of missing items was generally very low. As in other modules, the sexuality items were problematic. Nevertheless, approximately 90% of patients answered both questions and few

indicated that these questions were inappropriate or upsetting. The main reason that patients did not answer these questions was because they were sexually inactive. The time needed for completing both questionnaires (< 20 min 95% of patients) is very acceptable and marks it feasible to use them in clinical studies.

Approximately one – quarter (26%) of the patients needed help, often consisting of help to read the question because the patients did not have reading glasses. In our opinion, this does not mean that the QLQ-H&N is inappropriate or unacceptable. Patients who were unable to understand the questionnaire (because they were senile /demented, had severe cognitive impairment, or were illiterate) were excluded from the study. Measurement of HQOL by proxy might be considered for these patients, but this has not yet been approved as an acceptable alternative.

Scaling analysis showed the scale structure to perform very well, indicating a high level of construct validity. Few scaling errors were observed. The main problem was the item about painful throat. From a clinical perspective, it is understandable that this item had a higher correlation with the swallowing scale. However, since this item represents a specific type of pain which is relevant for H&N cancer patients, in particular those with pharyngeal cancer, it was decided for clinical reasons to the QOL-C both contain a pain scale and a social functioning scale; the correlation between the corresponding scale was moderately high.

In addition, taking into account the wording of the items, the pain and social contacts scale of the QLQ-H&N seem to add a specific H&N dimension to the use of the pain and social functioning scale of the QLQ-C. In the study to the preliminary analysis some items (Problems with teeth and the last five items) were patients for removal. With regard to the teeth item, from a clinical point of view this is regarded as an important item in patients with oral and oropharyngeal cancer. There were clear differences between sites.

Therefore, for reasons of content validity, it was decided to keep this item in the questionnaire. With regard to the last five items, those can be considered optional. They can be omitted in studies, in which these data can be reliably collected by other means. However, it should be realized that clinicians may not always be aware of the use of pain killers and nutritional supplements (in particular those which can be bought without prescription) and therefore, we have still included them in the questionnaire. The reliability as assessed by cronbach's alpha coefficient was excellent. A test-retest procedure was not performed in this study. Test –retest data are available from an analysis of 120 Gujarat patients 3 years after primary treatment of head and neck cancer. In that study, the intraclass correlation ranged from 0.76 (Senses) to 0.94 (social eating) for scales and from 0.65 (Feeling ill) to 0.86 (Dry mouth) for the single items of the QLQ-H&N. Thus, the –retest reliability seems to be comparable with that of the QLQ-C.

There were very clear–cut difference in the scores of almost all scales and single items of the QLQ-H&N between disease states, site and patients with different Karnofsky performance status. The differences between different disease states clearly reflect differences between tumor-related symptoms (Patients with newly diagnosed disease), long-term complications of treatment (Disease-free patients) and the combination of recurrence and treatment-related symptoms (patients with recurrent disease). For example, pain was most prominent in patients with newly diagnosed or recurrent disease, whereas dry mouth and sticky saliva (a long-term complication of radiotherapy to the region of the salivary glands) were most prominent in disease-free patients and patients with recurrent disease. Differences between sites also reflected site-specific differences in symptoms (e.g. high level of speech problems in laryngeal cancer; high level of swallowing problems in oral and pharyngeal cancer; only small differences in social contact and sexuality problems between sites). Both the QLQ-C and the QLQ-H&N showed a strong correlation between the scores of scales or single items and the Karnofsky performance status.

The only area where the QLQ-H&N failed to show a consistent correlation pattern was in disease stage. The expected correlation between more advanced stages and higher levels of symptoms in patients with newly diagnosed disease was not found for the group as a whole or for specific sites. The lack of this correlation may be due to the low patients with newly diagnosed disease in this sample, even in advanced stages, and to the fact that patients requiring a primary laryngectomy (reflecting very advanced disease) were not included in this study. The QLQ-H&N was able to detect significant deterioration of symptoms after treatment. The differences were in the order of 10-20; for the QLQ-C this has been shown to indicate a clinically significant effect. The QLQ-C was also able to detect significant difference between disease status, sites and patients with different Karnofsky performance status; although for disease status and site the differences were less pronounced than those found with the QLQ-H&N.

This demonstrates the validity of the QLQ-C in H&N cancer patients, as was shown before, but it also illustrates the need for an H&N cancer-specific module to increase the possibility of detecting differences in H&N cancer-specific HQOL.

The specificity of the QLQ-H&N was also illustrated by its sensitivity as measured by the relative efficiency. When differences between disease status and sites were studied, higher relative efficiency values were seen for the physical symptom scales and items of the QLQ-H&N compared with the scales and items of the QLQ-C.

The QLQ-C differs from the previous version with regard to the response format of the physical functioning scale. It was to be expected that the scale with the four-point scale would have better reliability than the version scale, and the values of Kronbach's alpha coefficient and the item scale correlations confirm this. Similarly, we confirmed that the new scale was more strongly associated with Karnofsky performance status scores.

The means and standard deviation for both physical functioning scales happen to be similar in both studies, but this may well be due to chance in these two studies; the new scale was not designed with this specifically in mind. Thus, the anticipated improvements in the new

scale were confirmed, and we conclude that the QLQ-C.

The QLQ-H&N has now proven its value in the assessment of HQOL in H&N cancer patients having been tested more extensively than other instruments. The Functional Assessment of Cancer Therapy-H&N scale is used in the same way.

However, the data on reliability and validity of the FACT – H&N are limited. Other instruments have been tested less extensively and/ or are aimed at specific subgroups, e.g. patients receiving radiotherapy. Moreover, the QLQ-H&N has been tested in 12 cites of The Gujarat State, in The India. Thus, the IORTC QLQ-H&N, in conjunction with the QLQ- C, can be regarded as a standard instrument to measure HQOL in H&N C and validity of the FACT. For Patients Copies of the questionnaire and scoring instructions can be obtained from the Quality of Life Unit of the IORTC Data.

References

- Aaronson NH, A S, Bergman B, et al. The INDIAN Organization for Research and Treatment of Cancer QLQ-C,, a quality-of-life instrument for use in international clinical trials in oncology. J Natl Cancer 1993, 85, 165.
- Aaronson NH, Cull A, S, et al. The Indian Organization of Research and Treatment of Cancer modular approach to quality of life assessment in oncology,, and update. In Sr B, ed. Quality of Life in Clinical Zvialz 2nd ed., Raven Press, 1996, 179−189.
- B GP, Levine MN, Hodn DI, et al. The H N C radiotherapy question,, Assessment of H&N Patients and QLQ of Life before, after and between a morbidity quality-of-life instrument for clinical trials of radiation therapy in locally advanced head and neck cancer. J Clin Oncol 1993, 11,
- B.H, Has S. Psychometric validation of the IORTC Core Quality of Life Questionnaire, 30-item version and a diagnosis specific module for head and neck cancer patients. Act Oncol 1992, 31, 311−321.
- Be B, Aaronson NH, Ahmedzai S, Haasa S, Sullivan M. The IORTC QLQ-LC13,, a modular supplement to the IORTC core quality of life questionnaire (QLQ-C) for use in lung cancer clinical trials. Euv J Cancer 1994, D, 572.
- Bj H, E, Ar Elmvist M, et al. Indian HN Patients of Quality of life in head and neck cancer patients,, validation of the IORTC QLQ-H&N35. J Clin Oncol 1999, 17, 1008−1019.
- Bjo H, H S. Psychological problem with stress in head and neck cancer patient 7−11 years after care treatment. Bv J Cancer 1995, 71, 592−597.

- Cancer Care QOL Questionnaire. J Clin Oncol 1998, 16, 1178−1199.
- Cohen J. Statistical Power Analysis for the Behavioral Sciences. Hillsdale, NJ, Lawrence Erlbaum, 1988.
- Cull A, Sprangers MAG, Bjordal H, et al. IORZC Quality of Life Organization for Research and Treatment of Cancer, 1998.
- D al. A prospective study on quality of life of patients with laryngeal cancer treated with radiotherapy. Head Neck 1999, 21, 231−236.
- D. Dtonio LL, Zimmerman GJ, Cella DF, Long SA. Quality of life and full status measures in patients with head and neck cancer. Avch Otoavyn gol Head Neck Suvg 1996, 122, 482−487.
- Degr R A, de Le JRJ, Ros UJG, Hodijk GJ, Biham GH, Uinubst JAM Di. A post operative cancer study on quality of life of patients with cancer of the oral cavity or oropharynx treated.
- Fayers P, Machin D. Quality of Life,, Assessment, Analysis and Interpretation. Chichester, John Uiley Mac, 2000, 66−71.
- Glikch R, Goldsmith TA, Funk GF. A head and neck spe.
- H EA. Assessment with quality of life in head and neck cancer patients. Head Neck 1993, 15, 485−496.
- Hais RD, Hayashi T, Carson S, et al. Jzev'z Guide for the Multi rait Analyze Program (WAP). Santa Monica, CA, Radiation Cooperation, 1988.
- Hame E, Mercke C, Sullivan M, Uest T. A prost quality of life study of patients with oral or pharyngeal carcinoma treated with beam irradiation with or without brachy therapy. Oval Oncol
- The Department of Veteran ARairs Laryngeal Cancer Study Group. Induction chemotherapy plus radiation joined with surgery and radiation in patients with first laryngeal cancer. N Engl J Wed 1991, 324...
- Terrell JE, Nanavati HA, Esclamado RM, Bishop JH, Bradford C, Uolf GT. Head and neck-specific quality of life. Lifestyle effect with Head and Neck cancer.