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Brief Communication

Quality of life in patients of nasopharyngeal carcinoma: Validation of the Taiwan Chinese version of the EORTC QLQ-C30 and the EORTC QLQ-H&N35

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Abstract

The authors followed the guidelines of translation and pilot testing of the EORTC QLQ-C30 and EORTC-QLQ-H&N35 questionnaires. The questionnaires were given to 50 nasopharyngeal carcinoma patients under active treatment and 50 under follow-up at our institution from November 2000 to June 2001. A retest was conducted 2 weeks after the first interview/form completion for the follow-up group. The intraclass correlation coefficients of the two questionnaires were moderate to high in the follow-up group. Cronbach's α coefficients of all scales of the two questionnaires were $\geqslant 0.70$ except that of cognitive functioning. Correlation of scales measuring similar dimensions of the QLQ-C30 and the SF-36 were moderate to high, while that of the QLQ-H&N35 and the QLQ-C30 and the SF-36 were moderate to low. Patients in the active treatment group had more serious acute problems due to disease and chemotherapy. Patients in the follow-up group had more serious chronic problems due to radiation therapy. We concluded that the Taiwan Chinese version of the EORTC QLQ-C30 and the EORTC QLQ-H&N35 had moderate to high test–retest reliability, high internal consistency in most scales, and could show the expected differences between patients in active treatment and follow-up group.

Key words: The EORTC QLQ-H&N35, The EORTC QLQ-C30, Nasopharyngeal carcinoma, Quality of life

Introduction

Nasopharyngeal carcinoma (NPC) is a special type of head and neck cancer very common to south-east Asian and southern Chinese populations [1]. According to the Cancer Registry, the age-adjusted incidence of NPC in Taiwan in 1997 was 7.90 per 100,000 population in men and 2.96 per 100,000 population in women. The 5-year survival of early-stage disease with radiotherapy is around 70% and that of advanced stage with combination of chemotherapy and radiotherapy is approaching 50% [2, 3]. The relatively high cure rate and long survival implied that health-related quality of life should be an important issue in the treatment and follow-up of this disease.

The European Organization for Research and Treatment of Cancer (EORTC) developed both cancer specific and site-specific questionnaires for the measurement of quality of life of cancer patients. The EORTC QLQ-C30 contains 30 questions belonging to five functional scales, nine symptom scales, financial difficulty, and one global health status (quality of life) scale. Previous studies showed good reliability and validity for different cancer diagnoses [4–8]. The EORTC QLQ-H&N35 was designed as a supplement to the EORTC QLQ-C30 for the use in head and neck cancer clinical trials. Previous studies also showed good reliability and validity among patients with head and neck cancers in different countries [9–11]. However, NPC was not studied separately from

other head and neck cancers [9, 11], and only 21 NPC patients were included in the 12-country study [10].

The EORTC version 3 has not been translated to Chinese. The only available Chinese version of the EORTC QLQ-C30 before this study was the Cantonese translation of version 2 in Hong Kong [12], which was different from the language in Taiwan. Though the EORTC QLQ-H&N35 has been validated in Europe, its translation has not been validated on patients speaking non-European languages, nor on NPC which is highly region-specific.

The aims of this study were to translate the EORTC QLQ-C30 version 3 and H&N35 to a language commonly used in Taiwan (Traditional Chinese) and conduct a cross-validation of on NPC patients.

Patients and methods

Translation and pilot testing of the QLQ-C30 and the QLQ-H&N35

We followed the guidelines for translation and pilot testing of the EORTC [13]. Although there are three major sub-linguistic groups in Taiwan, the questionnaires were translated to Mandarin because only Mandarin has a unified written form. The translation of the QLQ-C30 and the QLQ-H&N were performed in July and January 1998, and approved by the EORTC in August 1999 and May 1999. Compared with the symptoms and treatment side effects of NPC [3], the questionnaires cover most of the problems of NPC patients except some nasal, ear and cranial nerve symptoms (that usually do not affect the QoL of patients).

Questionnaire used as a comparison instrument

The Taiwan Standard version 1.0 [14] of the SF-36 [15] was used as a generic comparison instrument, which has been proved to have good reliability and validity [16–19].

Patients and questionnaire completion/interview

The full program for NPC treatment included 13 weeks of treatment and follow-ups once every 3 months in the first 3 years, once every 6 months in the fourth and the fifth years, and once a year thereafter. Each NPC patient enrolled in the treatment plan received mitomycin, epirubicin, and cisplatin on weeks 1 and 4, 5-fluorouracil/leucovorin on weeks 2 and 8, and radiation therapy from week 7 to week 13, with cisplatin on weeks 7, 10, 13 as a part of concurrent chemoradiotherapy. We defined patients receiving active treatment (on week 5) and being followed-up at the Department of Oncology of National Taiwan University Hospital as two known groups. The choice of groups was based on the hypothesis that patients in the active treatment group could have more symptoms and acute side effects of chemotherapy, while patients in the follow-up group could have more chronic side effects of radiotherapy. All patients in the two categories were approached separately between November 2000 and June 2001. Patients whose clinic appointment was outside the assistants' working time (scheduled by clinic computer and unrelated to QoL) or refused (about 10%) were excluded. The recruitment stopped when the patient numbers for both groups reached 50. A written introduction of the study was sent to, and a written consent was obtained from each patient.

Data collection

Patients filled out the questionnaires primarily by themselves. One author (C.C. Lai) and one trained assistant helped those who had difficulties in reading and answering the questions (four patients, two for each group). Both interviewers were fluent in both Mandarin and Taiwanese. Answers were checked immediately by the interviewers if the patients completed the questionnaires by themselves. For patients in the follow-up group, the retests were conducted by self-administration, telephone interview (13 patients), or mailed questionnaire (1 patient) 2 weeks after the first contact. The time interval was based on the recommendation of Streiner and Norman [20].

Data analysis

Answers to the three questionnaires were scored according to the instructions and computer programs provided [21]. Intraclass correlation coeffi-

cient and κ coefficient were used to examine the test–retest reliability of scales and single items with four or two choices, respectively. Pearson's correlation coefficient was used to examine the correlation between similar dimensions of the different questionnaires. Cronbach's α coefficient was used to evaluate the internal consistency of each dimension. Wilcoxon's rank sum test, Cochran Mantel–Haenszel test, and χ^2 test were used to examine the difference between the two groups of patients on each dimension.

Results

Most patients were male, aged 40–49 years, had an education of or above senior high school, and spoke Mandarin or Taiwanese (Table 1). Patients of two major sub-groups other than Mandarin could read and understand the questions well. Each patient required about 30 min to complete all three questionnaires, regardless of mode of administration. Half of the time was spent on the QLQ-C30 and QLQ-H&N35. Patients for whom the retest was conducted by phone reported more serious problems of teeth and opening mouth than those who was interviewed or completed the questionnaire by mail.

Only the test–retest reliability of the follow-up group was examined. The intraclass correlations of the multi-item scales varied from 0.33 (social functioning) to 0.82 (global health status/quality of life) for the QLQ-C30 and from 0.71 (senses) to 0.80 (speech) for the QLQ-H&N35. The κ coefficients of single items varied from 0.37 (appetite loss) to 0.66 (constipation and diarrhea) for the QLQ-C30 and from 0.38 (open mouth) to 1 (weight gain) for the QLQ-H&N35. All of the

Table 1. Basic characteristics of patients

Characteristics	Active treatment N (%)	Follow-up N (%)
Gender		
Male	39 (78.0%)	37 (74.0%)
Female	11 (22.0%)	13 (26.0%)
Age (years)		
<40	13 (26.0%)	14 (28.0%)
40–49	25 (50.0%)	21 (42.0%)
⩾50	12 (24.0%)	15 (30.0%)
Education		
Primary	10 (20.0%)	10 (20.0%)
Junior high school	9 (18.0%)	5 (1.0%)
Senior high school	11 (22.0%)	17 (34.0%)
College or above	16 (32.0%)	16 (32.0%)
Major language		
Mandarin	35 (70.0%)	38 (76.0%)
Taiwanese	33 (66.0%)	32 (64.0%)
Hakka	4 (8.0%)	3 (6.0%)

Table 2. Test–retest reliability and internal consistency of the EORTC QLQ-C30 and the EORTC QLQ-H&N35

	Test–retest reliability Follow-up group	Internal consistency All patients
QLQ-C30	Intraclass correlation	Cronbach's
Scales	coefficients	α
Physical functioning	0.75	0.75
Role functioning	0.56	0.85
Emotional functioning	0.54	0.90
Cognitive functioning	0.77	0.51
Social functioning	0.33	0.86
Quality of life	0.82	0.82
Pain	0.67	0.76
Nausea and vomiting	0.53	0.86
Fatigue	0.56	0.77
Single items	κ	
Dyspnea	0.63	–
Sleep disturbance	0.58	–
Appetite	0.37	–
Constipation	0.66	–
Diarrhea	0.66	–
Financial difficulty	0.51	–
QLQ-H&N35		
Scales		
Pain	0.83	0.83
Swallowing	0.76	0.78
Senses	0.71	0.78
Speech	0.80	0.75
Social eating	0.73	0.89
Social contact	0.77	0.84
Sexuality	0.58	0.92
Single items	κ	
Teeth	0.47	–
Opening mouth	0.38	–
Dry mouth	0.56	–
Sticky saliva	0.41	–
Coughing	0.59	–
Feeling ill	0.40	–
Analgesics	0.70	–
Nutritional supplement	0.62	–
Feeding tube	–	–
Weight loss	0.68	–
Weight gain	1.00	–

Cronbach's α coefficients for scales of the QLQ-C30 and the QLQ-H&N35 were $\geqslant 0.70$ except for cognitive functioning (0.51) (Table 2).

Most scales of the QLQ-C30 were highly or moderately correlated with the scales measuring similar dimensions in the SF-36 ($|r| = 0.47$–0.74). Scales of the QLQ-H&N35 were only moderately correlated with similar scales of the QLQ-C30 and the SF-36 ($|r| = 0.40$–0.49).

Patients in the follow-up group had better scores than those in the active treatment group for role functioning, global status/quality of life, nausea and vomiting, appetite loss, and constipation (Table 3). More patients in the active treatment group used analgesics and had weight loss, while patients in the follow-up group had more serious problems in swallowing, speech, of teeth problem, opening mouth, dry mouth, and sticky saliva (Table 4).

Discussion

Lower test–retest correlations for scores in some scales/single items of the QLQ-C30 (most were below 0.70) was found in this study than in the study of Hjermstad et al. [5]. Four days [5] might be too short for patients to wash out memories in the first interview. It is also possible that some of the patients' conditions changed in 2 weeks although we had assumed that their conditions should be stable across time.

The internal consistency coefficients of most scales of the QLQ-C30 were satisfactory except that of cognitive functioning, consistent with the findings of previous studies [4, 7, 8, 11, 13]. The internal consistency coefficients of all scales in the QLQ-H&N35 were also satisfactory, consistent with previous studies [9–11].

The Taiwan Standard version 1.0 of SF-36 has been proven to have good reliability and validity [16–19]. Therefore, the moderate to high correlation between scales measuring similar scales of the QLQ-C30 and the SF-36 implied that the validity of the QLQ-C30 is also satisfactory. The moderate correlation between scales of the QLQ-H&N35 with similar dimensions with the QLQ-C30 was consistent with previous studies, and implied that these scales measure different problems [9–11].

The scores of most scales of the QLQ-C30 of the follow-up group were similar to the reference values of all head and neck cancers, stage III/IV, and pharynx cancer [22], the disease-free patients in the 12-country study [9] but better than the scores of the American study [11]. However, the social functioning scale scores of the QLQ-C30 and most

Table 3. Comparison of quality of life scores in the EORTC QLQ-C30 among two groups of patients

	Active treatment Mean ± SD	Follow-up Mean ± SD	*p*-Value
Scales			Wilcoxon's rank sum test
Physical functioning	82.6 ± 14.3	88.5 ± 10.3	0.0658
Role functioning	71.7 ± 25.0	88.0 ± 14.7	0.0003*
Emotional functioning	76.0 ± 20.7	78.0 ± 19.3	0.7650
Cognitive functioning	81.3 ± 18.0	81.3 ± 17.4	0.9138
Social functioning	66.3 ± 23.2	69.7 ± 21.7	0.7082
Quality of life	60.0 ± 18.7	71.5 ± 18.6	0.0022*
Fatigue[a]	37.3 ± 19.1	28.0 ± 14.2	0.0030*
Nausea/vomiting[a]	43.3 ± 25.0	6.0 ± 11.5	0.0001*
Pain[a]	23.3 ± 22.1	18.7 ± 17.7	0.3371
Single items			Cochran Mantel–Haenszel test
Dyspnea[a]	11.3 ± 17.3	7.3 ± 13.9	0.205
Sleep disturbance[a]	24.7 ± 26.8	22.7 ± 20.7	0.675
Appetite loss[a]	42.7 ± 27.8	14.7 ± 25.3	0.001*
Constipation[a]	22.0 ± 22.9	12.0 ± 19.9	0.023*
Diarrhea[a]	14.7 ± 16.7	8.7 ± 16.2	0.072
Financial difficulty[a]	22.7 ± 28.1	27.3 ± 32.8	0.444

* $p < 0.05$.

[a] High scores reflect worse quality of life.

Table 4. Comparison of quality of life scores in the EORTC QLQ-H&N35 among two groups of patients

	Active treatment Mean ± SD	Follow-up Mean ± SD	*p*-Value
Scales[a]			Wilcoxon's rank sum test
Pain	13.5 ± 16.2	17.3 ± 17.7	0.1487
Swallowing	9.3 ± 12.2	25.0 ± 18.3	0.0001*
Senses	20.3 ± 18.5	24.0 ± 25.7	0.7481
Speech	10.4 ± 11.8	18.7 ± 21.9	0.0368*
Social eating	25.5 ± 20.6	22.8 ± 22.8	0.1936
Social contact	17.5 ± 17.1	13.9 ± 16.8	0.1974
Sexuality	31.3 ± 26.9	25.0 ± 30.4	0.0968
Single items[a]			Cochran Mantel–Haenszel test
Teeth	24.0 ± 25.2	38.0 ± 26.1	0.008*
Opening mouth	12.0 ± 22.1	31.3 ± 27.3	0.001*
Dry mouth	27.3 ± 18.7	63.3 ± 28.8	0.001*
Sticky saliva	22.7 ± 18.4	59.3 ± 28.8	0.001*
Coughing	23.3 ± 19.3	24.7 ± 22.1	0.747
Feeling ill	32.0 ± 22.3	26.0 ± 23.6	0.193
Binary items	Present (%)	Present (%)	χ^2 test
Analgesics	17 (34.0%)	8 (16.0%)	0.038*
Nutritional supp.	24 (48.0%)	16 (32.0%)	0.102
Feeding tube	0 (0.0%)	2 (4.0%)	–
Weight loss	28 (56.0%)	18 (36.0%)	0.045*
Weight gain	17 (34.0%)	26 (52.0%)	0.069

[a] High scores reflect worse quality of life.

scales of the QLQ-H&N35 of the follow-up group of this study indicated more serious problems compared with previous studies [9–11]. It is possible that NPC patients have more chronic or late complications of radiation. Like known group comparison in other studies [8–11], we observed significant differences between the two groups for most scales/single items of the two questionnaires. In the active treatment group, the major problems were symptoms of disease and acute toxic effects of chemotherapy, while in the follow-up group, the late effect of radiation appeared gradually. These findings are consistent with our hypothesis for known group selection.

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