Original Article

Internal Consistency of the Traditional Chinese Character Version of the Functional Assessment of Cancer Therapy - Head and Neck (FACT-H&N)

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Background: This study investigated the internal consistency of the Functional

Assessment of Cancer Therapy - Head and Neck (FACT-H&N) translated version in traditional Chinese characters (TChi). The FACT-H&N quality of life instrument is composed of the FACT-General (FACT-G) assessing four primary areas of well-being (physical, social/family, emotional, and functional).

tional) and 11 additional items specific to H&N cancer patients.

Methods: Two hundred and three patients with H&N cancer were recruited at a med-

ical center in northwestern Taiwan. All completed the TChi FACT-H&N along with demographic and clinical questionnaires written in traditional Chinese characters. Several psychometric properties of the TChi FACT-H&N

were examined, including Cronbach's alpha coefficients.

Results: Most of the 203 enrolled patients were men (78%). The median age was 52.5

years (range 23-81 years) and the median number of years of education was 9. All patients had a Karnofsky score of 70 or higher. The results showed that the TChi FACT-H&N scales demonstrated acceptable internal consistency. Translation of the physical and functional concepts was most straightforward. Translation of emotional items, however, posed some difficulties. The social/ family well-being subscale was problematic, as expected, based upon observations of cultural differences in social values and functioning. We also noted that concerns about hearing were different between patients with

nasopharyngeal carcinoma (NPC) and those with other H&N cancers.

Conclusion: The TChi FACT-H&N is reliable. Items related to problems with hearing

should be added to better evaluate the quality of life in patients with NPC.

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Key words: quality of life, head and neck cancer, traditional Chinese, nasopharyngeal carcinoma

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Head and neck (H&N) cancer, especially cancer of the oral cavity and nasopharyngeal cancer, has been one of the leading forms of cancer in Taiwan. Its incidence, especially of oral cavity cancer, has increased in recent years. Treatment of oral cavity cancer consists of destructive surgery and/or radiotherapy, while treatment of nasopharyngeal cancer uses high doses of radiation. This results in radiation-induced damage to normal tissue and may cause increased physical and function impairment, such as body image defects and problems with eating, speaking and hearing, with a resulting loss of quality of life (QOL).

The treatment of nasopharyngeal carcinoma (NPC) differs from other H&N cancers in many ways; radiotherapy is the major treatment modality for NPC while surgery is used for other H&N cancers in Taiwan. The damage to the body is quite different with these two treatment modalities. Treatment for advanced stage H&N cancer may combine radiotherapy with or without chemotherapy and surgical intervention. Since the changes in QOL after treatment may be different, especially for those receiving such radical treatment, we aimed to study whether and how the QOL of patients is different between patients with NPC and those with other H&N cancers after treatment.

As background, current definitions of QOL need to be taken into consideration. Saxena and Orley(2) presented the World Health Organization Quality of Life questionnaire's (WHOQOL) definition as follows: "individuals' perception of their position in life in the context of culture and value systems in which they live and in relation to their goals, expectations, standards and concerns. It is a broad -ranging concept affected in a complex way by the persons' physical health, psychological state, level of independence, social relationships and their relationship to salient features of their environment". Schipper et al.(3) considered QOL research to be "an attempt to quantify, in scientifically analyzable terms, the net consequences of a disease and its treatment on the patient's perception of his ability to live a useful and fulfilling life". This measure is necessarily subjective because it measures dimensions which are not physically observable, and the patient's view of the situation is of paramount importance.

Cella and colleagues agree that QOL is both subjective and multidimensional. They developed

the following working definition of QOL which laid the groundwork for measurement: "Quality of life refers to patients' appraisal of and satisfaction with their current level of functioning as compared to what they perceive to be possible or ideal". (4) This definition was later modified to incorporate the multidimensionality of QOL: "Health-related quality of life refers to the extent to which one's usual or expected physical, emotional, and social well-being are affected by a medical condition or treatment". (5) Thus, QOL measurement should include the patient's perspective and should encompass physical, mental, and social well-being.

Translation of QOL questionnaires has been an important methodological step in conducting crosscultural research. Instruments such as the Functional Assessment of Chronic Illness Therapy (FACIT),(6) the European Organization for Research and Treatment of Cancer Core Quality of Life Questionnaire (EORTC QLQ C-30),⁽⁷⁾ the Functional Living Index - Cancer (FLIC),(8) and the Medical Outcomes Study Short-Form 36-Item Health Survey (SF-36)⁽⁹⁾ have undergone translation from the source questionnaire in English to a number of other languages. These translation efforts have focused on major Western European languages in particular, and have expanded to include most European languages as well as some Asian languages such as Chinese and Japanese.

Issues to consider in Chinese translation

Chinese is the largest population group in the world. It is estimated that around one- fifth to onefourth of people worldwide speak Mandarin Chinese. People migration has resulted in significant Chinese communities in almost every country in the world. Chinese-speaking peoples constitute some of the largest minority groups in North America and in many European and Asian- Pacific countries. Many migrants retain the written and spoken Chinese language, and for older migrants Chinese, it may be the only language they know. An important research topic is the development of a test for similarities and differences in cultural groups, both within the same country and across geographic boundaries. Furthermore, some cancers, such as NPC, are highly prevalent in Chinese people. It is important to understand these differences and the specific needs for research on the QOL of Chinese patients with different primary sites of cancer. In recent decades, economic conditions have improved rapidly in Southeast Asia, and patients may no longer be satisfied with only medical treatment but also desire good QOL after medical treatment. It is, therefore, important to have well translated versions of QOL instruments in Chinese that reflect the expectations and needs of Chinese people.

FACT translation methodology

Functional Assessment of Cancer Therapy -General (FACT-G) is a self-report questionnaire with a Likert-type response set, ranging from "not at all" to "very much", (10) and it is the core questionnaire of the FACT Measurement System Version 4.(10) The 27item FACT-G measures four QOL domains (subscales) on which patients are queried, Physical Well-Being (PWB; 7 items), Social/Family Well-Being (SFWB; 7 items), Emotional Well-Being (EWB; 6 items), and Functional Well-Being (FWB; 7 items). In addition, the FACT Measurement System includes disease-specific and condition-specific questionnaires. In this study, we focused on H&N cancer with a special interest in NPC patients, and thus chose to use the FACT-H&N with its 11 additional H&N cancer-specific questions.

The FACT translation project was initiated due to widespread interest in using the FACT Measurement System in international studies. Bonomi et al. (6) presented results of initial translation and pre-testing of several FACT scales from English into Dutch, French, German, Italian, Norwegian, and Swedish. This article also presents the methodology developed by the FACT group to carry out multilingual development of the measurement system.

The detailed steps of the FACT Translation Methodology include the following: (1) two forward translations from English into the target language, performed by two independent native language-speaking translators; (2) a reconciliation of the two forward translations by a third native language-speaking translator, resulting in a reconciled version; (3) a back-translation of the reconciled version into English by a native English speaker fluent in the target language who has not seen the source English version. Comparisons are done by the translation team at the Center on Outcomes, Research and Education (CORE) of Evanston Northwestern Healthcare by comparing the back-translation with

the source English to identify problems in the translation. Three reviewers then select the most appropriate translation for each item or provide alternative translations to resolve discrepancies detected in the back-translation. These recommendations are discussed by the coordinating team until at least two of the three reviewers agree on the translation of an item. Finally, the target language version is pre-tested with patients in the native language-speaking country.

This method has shown promise as an example of the creation of adequate cross-cultural QOL measures. One limitation, however, is that in the study presented by Bonomi et al., (6) all languages were Western European languages, which share language structures similar to English. The cultures of the target language countries were also similar to that in the United States. Further research has been deemed necessary to ascertain whether appropriate cross-cultural instruments can be developed for Chinese cultures using the same methodology.

Therefore, it is important to carry out a translation into Chinese using this translation method and then evaluate its performance in a Chinese-speaking population in Taiwan. In addition, because H&N cancers, including NPC, are one of the ten leading cancers in Taiwan and the incidence has increased in recent years, it is important to investigate the difference in QOL between different cultures and specific cancer sites such as H&N.

METHODS

Participants

Convenience sampling of patients with H&N cancer was conducted at Chang Gung Memorial Hospital (CGMH), Lin-Kuo Medical Center.

Patients who agreed to participate signed an informed consent to enroll into the study. A total of 203 patients completed the survey. Most patients were men (158 patients, 78%). The median number of years of education was 9 years, ranging from 0 to 20 years. The median age was 52.5 years (range 23-81 years). All patients had good performance status (Karnofsky score: 70). The leading cancer in this study population was NPC followed by buccal-gum and oral tongue cancer. All patents had completed radical treatment for at least one year without evidence of disease recurrence. Detailed patient and

clinical information can be found in Table 1.

Surgical patients with oral cavity cancer usually had a radical operation to remove the gross tumor area with at least 1 cm margins. This was usually combined with elective neck dissection in clinically negative neck disease and modified neck dissection in clinically positive neck disease. Radical radiotherapy with or without chemotherapy was the major treatment modality for NPC and pharyngeal wall cancer. Surgery was reserved for salvage. Radiotherapy was given for two categories of disease. A dose of 70-72 Gy was delivered to the gross tumor area with margins and a dose of 60 or 66 Gy was delivered to the post-operative tumor bed, depending on the risk factors in the pathology findings. A radiation dose of 46-60 Gy was given for first echelon subclinical disease and 45-46 Gy for subclinical disease above the clavicle area. The radiotherapy schedule was 1.8-2 Gy a day and 5 fractions per week. Chemotherapy was delivered with Cisplatin based agents for those patients with advanced- stage disease.

Measures

Translation Process for the Traditional Chinese Character FACT-H&N. The development of the FACT-H&N in Chinese paralleled that of the English questionnaire. Instead of being translated all at one time, different portions of the questionnaire were translated at different times, under different circumstances, and by different translators. The first scale from the FACT Measurement System translated into Chinese was the FACT-G (Version 3). With subsequent development of Version 4 in 1997, similar changes were made to the Traditional Chinese version in the context of a study on bone marrow transplantation in Hong Kong.(11) The version done by Lau et al. provided an updated FACT-G which was then incorporated into the FACT-H&N in traditional Chinese characters used in this study. Therefore, this particular project involved the translation of only the 11 additional items specific to H&N cancer. This translation was initiated by Maria Law in Hong Kong, who provided the two forward translations and the reconciled version. CORE's consultants performed the back-translation and one review was done by a native of Taiwan with the other reviews being done by native speakers from Hong Kong. Because the majority of the H&N subscale translators were

Table 1. Patient Characteristics (N = 203)

Characteristic	N	%
Age		
Median (SD)	52.5 (12.4)	
Education (total number of years)	32.3 (12.1)	
Median (range)	9 (0-20)	
Mean (SD)	10.3 (3.6)	
Gender	10.5 (5.0)	
Female	45	22.2%
Male	158	77.8%
Occupational status	150	77.070
Employed full time	128	63.1%
Employed part time	25	12.3%
Homemaker	15	7.4%
Unemployed	12	5.9%
Retired	20	9.9%
Disabled	3	1.5%
Marital status	3	1.5 %
Married	172	84.7%
Single	2	1.0%
Separated	6	3.0%
Divorced	4	2.0%
Widowed	19	9.4%
Living arrangements	1)	2.470
Alone	12	5.9%
With other adults (no children)	108	53.2%
With other adults and children	79	38.9%
With children only	4	2.0%
Type of cancer	•	2.0%
Nasopharynx	114	56.2%
Tonsil	7	3.4%
Hypopharynx	5	2.5%
Oral tongue	22	10.8%
Buccal-gum	27	13.3%
Parotid	11	5.4%
Larynx	9	4.4%
Nasal cavity	5	2.5%
Others	3	1.5%
Type of treatment	3	1.5 %
Radiotherapy alone	89	43.8%
Surgery alone	38	18.7%
Radiotherapy and surgery	21	10.3%
Radiotherapy and chemotherapy	41	20.2%
Surgery, radiotherapy and chemotherapy		7.0%

from Hong Kong, it was especially important to linguistically validate the translation with a Taiwanese population to ensure that the wording was understandable and acceptable, and that the translation had acceptable internal consistency and showed face validity.

Data collection

Eligible patients were approached by one of two trained research assistants. Standard recruiting procedures were followed and executed. After agreeing to participate, patients were given the Traditional Chinese Character FACT-H&N questionnaire and was encouraged to complete it by themselves. A research assistant was available on-site to help those who had difficulty reading complete the questionnaire. After completing the FACT-H&N questionnaire, a debriefing interview was conducted by a research assistant to examine whether the patient had any difficulty understanding the questions, was upset by any questions, had additional items to suggest, or had comments on the questionnaire overall. The whole process took about 15-20 minutes.

Analysis

Several psychometric properties of the traditional Chinese character version of the FACT-H&N were examined. Means, standard deviations and Cronbach's alpha coefficients were calculated for each subscale of the FACT-H&N using the SPSS statistical analysis package. (12) Results from the original English FACT-H&N validation study (13) were included for comparison.

RESULTS

The patients invited to participate in this study were treated by the Taipei Chang Gung Head and Neck Oncology Group. Overall, 235 patients were invited and 203 entered the study and were included in the analysis. All 203 patients were able to complete the translated questionnaire with or without assistance. Among them, 143 patients (70.4%) completed the questionnaire by themselves and 60 patients required assistance from a research assistant because of difficulty reading the questionnaire. Most patients had no difficulty in understanding the traditional Chinese character FACT-H&N items, but a relatively small number of patients mentioned problems

with some items in the PWB and SFWB scales. On the PWB, 4 had difficulty with GP3, 2 with GP6, and 2 with GP7. On the SFWB, 1 had difficulty with GS4, 1 with GS5, and 1 with GE2. Item GS7 received the most negative comments as 11 patients (5.4%; 7 men and 4 women) found this item offensive. These patients stated that sexual issues were private and not definitely related to their QOL situation and/or disease. This is similar to the study of Bonomi et al., in which seven patients in Western Europe tended to dislike being asked about their sex lives.

Table 2 shows that Cronbach's alpha coefficients of the FACT-H&N subscales in the Chinese translated version were acceptable, ranging from 0.72 to 0.89.

The Cronbach's alpha coefficients for the Chinese and original English language versions of the FACT-H&N are reported in Table 2. No significant difference was found between the two versions. There were 144 (75%) NPC patients who complained of hearing problems related to loss of QOL in the FACT-H&N questionnaire, however other H&N cancer patients did not report this problem. When a known-groups comparison between the NPC and non-NPC patients was conducted, a statistically significant difference between the NPC and non-

Table 2. Reliability (Cronbach's Alpha) of the Traditional Chinese Character Version of the Functional Assessment of Cancer Therapy-Head & Neck (FACT-H&N)

Scale	Traditional Chinese	
Physical Well-Being (7 items)	0.79	0.79
Social/Family Well-Being (7 items)	0.81	0.59
Emotional Well-Being (6 items)	0.72	0.59
Functional Well-Being (7 items)	0.88	0.75
FACT-G total (27 items)	0.89	0.89
Head and Neck subscale	0.75	0.70
FACT-H&N total	0.91	

NPC patients on the functional well- being subscale was found. However, no difference in the FACT-H&N total score, measuring overall QOL, was found. The result was listed in Table 3.

DISCUSSION

The results revealed that the Chinese translated subscales of the FACT-H&N have acceptable internal consistency, justifying its further improvement and implementation in clinical research with Chinese-speaking patients. Most of the translated subscales appeared to measure the same constructs, as evidenced by their high internal consistency coefficient, and they seemed to perform better than their original English language versions⁽¹⁰⁾ (Table 2).

List et al.⁽¹³⁾ showed that the FACT-H&N is reliable and valid when applied to H&N cancer patients in the United States. After the FACT H&N was translated into the traditional Chinese character ver-

Table 3. Scores for the Traditional Chinese Character Version of the Functional Assessment of Cancer Therapy - Head and Neck (FACT-H&N) by Subsite of Cancer

	Nasopharynx cancer (n = 114)	Other cancers (n = 89)	<i>p</i> -value
	Mean (SD)	Mean (SD)	
Physical Well-Being (7 items)	21.84 (5.17)	21.59 (5.84)	0.712
Social/Family Well-Being (7 items)	21.15 (5.44)	20.17 (6.47)	0.291
Emotional Well-Being (6 items)	19.28 (4.27)	19.34 (4.12)	0.915
Functional Well-Being (7 items)	19.40 (7.06)	16.57 (7.72)	0.006*
FACT-G total (27 items)	81.66 (16.74)	77.67 (17.89)	0.103
Head and Neck subscale (9 items)	20.34 (6.43)	19.38 (8.58)	0.440
Trial outcome index (23 items)	61.49 (15.74)	57.54 (18.96)	0.111

^{*:} t-test p < .01.

sion using the standard FACT translation methodology, we found similar internal consistency. The overall QOL of our patients was relatively higher because the data were collected from an outpatient setting where most patients had a better performance status rating.

However, QOL after cancer treatment may differ in important ways in patients with cancers in different areas of the body, as they may have different issues and concerns. Even within similar locations. such as H&N cancer, the treatment complications are quite different between patients with NPC and those without. For instance, the usual NPC treatment complications may consist of nerve tissue damage, and ear, salivary function and neck symptoms. (14,15) Another contributing factor to the nature and extent of disability is the type of treatment. Surgery, radiotherapy and combined chemoradiotherapy for advanced disease all carry unique acute as well as chronic toxicities. For example, while surgery for larynx cancer may result in significant communication impairment, radiotherapy or concomitant chemoradiotherapy may result in dry mouth, stiffening or constriction of local tissues, and subsequent problems with chewing and swallowing solid foods. (16-18) Even with radiotherapy alone, different techniques result in varying incidences and severity of treatment complications and quality of life. (19,20) Hearing impairment is a common complication in NPC treatment but not usually in other H&N cancer therapy, because the radiation is delivered to the auditory apparatus. (21,22) In this study, about threefourths of NPC patients complained about hearing impairment but did not show a reduction in QOL on the FACT-H&N questionnaire; however, other H&N cancer patients did not have this problem. It seems that hearing problems should be included in QOL assessment of NPC patients.

Huguenin et al. (23) had noted that NPC patients reported the highest morbidity on the H&N module (dry mouth, sticky saliva, trismus, problems with teeth, trouble eating). However, these symptoms did not have a high impact on global QOL or function scores. They found that non-NPC patients had lower scores in functional well -being than NPC patients but no difference in total QOL scores.

Overall, our results are encouraging. Although the FACT-G was initially developed in the United States with a Western medical context in mind, its QOL dimensions and constructs within those dimensions appear to adequately address QOL issues of head and neck patients in Taiwan. While there were some discrepancies, they helped to shed light on some of the cultural differences that do exist, especially with relation to the role of the family and the patient's social environment. Further studies should be done to compare different disease subsites in head and neck cancer, different treatment methods and different complications that may related to different health-related quality of life.

Permission to use the FACT-H&N and its traditional Chinese character translation must be obtained from CORE. (www.facit.org)

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FACT-H&N (第四版)

以下是那些跟您有同樣疾病的人所認爲重要的一些陳述,請在每一行陳述之後圈選出一個數字,以表達您認爲在過去七天來各項陳述的真實程度。

	生理健康狀況	一點 也不	有一點	有此	相	非常
	工工程度原形化	也小	油	些	當	币
GP1	我精神不好	0	1	2	3	4
GP2	我有反胃噁心的情形	0	1	2	3	4
GP3	因爲我的身體狀況,我有困難達到家人的需求	0	1	2	3	4
GP4	我有疼痛	0	1	2	3	4
GP5	我對治療的副作用感到困擾	0	1	2	3	4
GP6	我覺得身體不適	0	1	2	3	4
GP7	我因病被迫要臥床休	0	1	2	3	4
		一點	有一	有	相	非
	社會/家庭健全狀況	也不	點	些	當	常
GS1	我覺得與我的朋友親近	0	1	2	3	4
GS2	我從我家人獲得情緒上的支持	0	1	2	3	4
GS3	我從我朋友獲得支持	0	1	2	3	4
GS4	我家人已接受我的疾病	0	1	2	3	4
GS5	我滿意家人之間對我疾病的溝通方式	0	1	2	3	4
GS6	我覺得與我的伴侶 (或我主要支持者) 親近	0	1	2	3	4
Q1	不管你近期的性生活的程度,請回答下面的問題					
	如果你不願回答,請在這裡註明 □					
GS7	我對我的性生活感到滿意	0	1	2	3	4
		一點	有一	有	相	非
	情緒穩定狀況	也不	點	些	當	常
GE1	我感到悲傷	0	1	2	3	4
GE2	我滿意自己處理疾病的方式	0	1	2	3	4
GE3	我逐漸失去對抗我的疾病的希望	0	1	2	3	4
GE4	我覺得緊張	0	1	2	3	4
GE5	我擔心死亡	0	1	2	3	4
GE6	我擔心我的狀況會惡化	0	1	2	3	4

FACT-H&N (第四版)

以下是那些跟您有同樣疾病的人所認爲重要的一些陳述,請在每一行陳述之後圈選出一個數字,以表達您認爲在過去七天來各項陳述的真實程度。

	功能健全狀況	一點 也不	有一點	有些	相當	非常
GF1	我能夠工作 (包括在家的工作) ····································	0	1	2	3	4
GF2	我的工作(包括在家的工作)令人滿意	0	1	2	3	4
GF3	我能夠享受生活	0	1	2	3	4
GF4	我已接受我的疾病	0	1	2	3	4
GF5	我睡得好	0	1	2	3	4
GF6	我依然享受我以前常做的有趣的事	0	1	2	3	4
GF7	我滿足我現在的生活品質	0	1	2	3	4
		一點	有一	有	相	非
	附加關注事項	也不	點	些	當	常
H&N1	我能夠吃我愛吃的食物	0	1	2	3	4
H&N2	我覺得口乾舌燥	0	1	2	3	4
H&N3	我呼吸有困難	0	1	2	3	4
H&N4	我聲音的音質和音量跟平常一樣	0	1	2	3	4
H&N5	我能想吃多少就吃多少	0	1	2	3	4
H&N6	我對自己臉部及頸部的樣子感到不快	0	1	2	3	4
H&N7	我能吞嚥自如	0	1	2	3	4
H&N8	我抽香煙或其它煙草產品	0	1	2	3	4
H&N9	我喝酒 (例如:啤酒、葡萄酒等等)	0	1	2	3	4
H&N10	我能夠與其他人溝通	0	1	2	3	4
H&N11	我能吃固態的食物	0	1	2	3	4

繁體中文版頭頸部癌症功能評估生活品質 問卷之內部一致性評估

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目的: 本研究是在探討頭頸部癌症功能評估生活品質問卷 (Functional Assessment of Cancer Therapy - Head and Neck, FACIT-H&N) 繁體中文翻譯版本之內部一致性。

方法: FACT-H&N 這份生活品質問卷包含四項一般性評估項目 (身體、社會/家庭、情緒及功能)和11 題針對頭頸癌病患所附加之關注事項。在台灣北部某醫學中心共收集了203 位頭頸癌病患,所有的病患都完成人口統計學、臨床資料收集及繁體中文版的FACT-H&N 生活品質問卷。多數病患是男性 (78%),平均年齡是 52.5 歲 (範圍為23~81 歲),接受教育時間之中位數為 9 年。所有病人之行為能力分數 (Karnofsky Performance Scale)為 70 分或更高。我們同時檢定數個有關 FACT-H&N 繁體中文翻譯版本心理測量的指標,其中包括 Cronbach's alpha 之係數。

結果: 研究結果顯示 FACT-H&N 繁體中文翻譯版本有很好的內部一致性,身體和功能概念的翻譯簡單明確,而評估情緒題目的翻譯有些困難。另外,就像我們預期的一樣,以不同的文化社會價值為基礎,來測量社會/家庭這個項目會產生些許問題。我們同時注意到特別在聽力部分,鼻咽癌病患與其他頭頸癌病患之間有不同的狀況。

結論:使用 FACT-H&N 繁體中文翻譯版本是可用來評估頭頸癌病患其功能與生活品質情況的,但是我們應該考慮增加有關聽力評估的題目,以提高針對鼻咽癌病患生活品質的評估。

(長庚醫誌 2008;31:384-94)

閣鍵詞:生活品質,頭頸部癌症,繁體中文,鼻咽癌

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