Original Article

Measurement Properties of the Chinese Language Version of the Functional Assessment of Cancer Therapy-General in a Singaporean Population

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Abstract

Introduction: Health-related quality of life is an important aspect of health outcome. The assessment of it must be done by validated instruments. There is no published data on the validity, reliability and sensitiveness to change of the official Chinese translation of the Functional Assessment of Cancer Therapy-General (version 4; FACT-G). Materials and Methods: A Chinese questionnaire package comprising the FACT-G and Functional Living Index-Cancer (FLIC, which was translated, modified and validated in Singapore) was filled in by 165 ethnic Chinese patients recruited from the National Cancer Centre, Singapore. Four weeks later, the patients were assessed again by a postal questionnaire survey. Results: The FACT-G and FLIC total scores were strongly correlated (r = 0.85). The Physical, Social/Family, Emotional and Functional Well-being scales of the FACT-G converged to and diverged from FLIC components as conceptually expected. The FACT-G and its 4 scales also demonstrated known-groups validity in differentiating patients with different performance status (each *P* <0.001). Their internal consistency ranged from 0.81 to 0.93 and test-retest reliability ranged from 0.74 to 0.85. The FACT-G and its Physical, Emotional and Functional Well-being scales showed trends of change in relation to change in performance status. The Social/Family Well-being scale was sensitive to decline but not improvement in performance status. Conclusions: The Chinese version of the FACT-G can be used to assess overall level and some specific aspects of health-related quality of life. However, researchers should be cautious in using this instrument to specifically investigate the social aspect of quality of life.

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Key words: Quality of life, Reliability, Sensitivity, Validity

Introduction

Health-related quality of life (HRQoL) is an increasingly important concern in the care of cancer patients. In the approval of oncology drugs, the United States (US) Food and Drug Administration (FDA) and European Agency for the Evaluation of Medicinal Products consider HRQoL an important end-point.[1] Most HRQoL instruments are developed in English, although about one-fifth of the world's population is ethnic Chinese.[2] Patients in many cancer centres in North America and Europe have a variety of ethnic and language backgrounds.[3] The Singapore 2000 census shows that 77% of the population were ethnic Chinese.[4] Among the ethnic Chinese, 32% used only Chinese language and 48% used both Chinese and English. Using Chinese as a primary language is especially common among those who were aged 55 or above,[5] who have a higher risk of developing cancer than their younger counterparts.

An FDA review of new cancer drug applications showed that HRQoL assessment in cancer trials often had unsatisfactory quality and re-emphasised that clinical trials should use validated HRQoL instruments.[6] There is an obvious need for translating English HRQoL instruments into Chinese and validating them. The Functional Assessment of Cancer Therapy is a widely used set of HRQoL questionnaires. Despite its popularity, the validity,

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reliability and sensitiveness to change of the Chinese version of the Functional Assessment of Cancer Therapy-General (Version 4; FACT-G) are unknown. The only published study on the validation of the Chinese translation of the FACT-G was conducted in Hong Kong,[7] using an unofficial translation of the FACT-G Version 3, which is not the same as the official translation produced by the FACT research team. For instance, the English term "energy" was translated as "*jingshen*" (written here in Chinese phonetic transcription) in the official version but "*jingli*" in the Hong Kong version. In the International Society for Quality of Life Research 2002 conference, a study of bone marrow transplant and head and neck cancer patients in Hong Kong presented differential item functioning analysis of the Physical and Functional Well-being scales of the official Chinese translation of the FACT-G Version 4 but did not provide other information.[8] Both Hong Kong studies used traditional Chinese characters, which are not used by the majority of Chinese people. In Singapore and China, the simplified characters are used.

The Chinese version of the Functional Living Index-Cancer (FLIC) was translated, adapted and validated in Singapore.[9,10] However, the FLIC has not been widely used internationally and therefore is not ideal for multicentre trials or international comparison. The European Organisation for Research and Treatment of Cancer Core Quality of Life Questionnaire also has a Chinese version available and has been used by various studies in Chinese societies. However, its score has a higher level of variability and therefore requires a larger sample size than FACT-G and FLIC for achieving the same research purpose.[11]

This is a secondary analysis of data from a previously reported study of cancer patients in Singapore. We aimed to examine the validity, reliability and other measurement properties of the official Chinese translation (simplified characters) of the FACT-G (Version 4). This will facilitate HRQoL assessment and future clinical trials of cancer patients in Singapore and other Chinese populations.

Materials and Methods

Design and Recruitment

From September 2003 to May 2004, patients were recruited from the National Cancer Centre Singapore. Patients were approached while they were in the waiting areas of the specialist outpatient clinics, ambulatory treatment unit and the therapeutic radiology department of the Centre. The inclusion criteria were broad: literate in Chinese or English and aged 18 years or older. Furthermore, all participants must give written informed consent. The patient group was heterogeneous and covered various types of cancers. This is suitable for the study of HRQoL instruments designed for application to all cancer patients. Participants who gave consent were required to self-administer the questionnaires. Upon request by the patients, interviews would be administered by one of the project research coordinators. The study used a complex design and the details had been reported previously.[11] The present secondary analysis only used data from ethnic Chinese patients who answered a Chinese questionnaire package that included the Chinese version of FACT-G (V4) and FLIC. The order of the 2 instruments in the package was randomised. Four weeks after the baseline interview, the same questionnaire was sent to each participant by post, together with a pre-paid return envelope. Up to 3 mailings were sent if the participant did not reply to the follow-up questionnaire. The study was approved by the Ethics Committee of the National Cancer Centre, Singapore.

Instruments

The FACT-G provides a total score and 4 domain scales, namely Physical (GP), Social/Family (GS), Emotional (GE) and Functional (GF) Well-being scales. The total score can range from 0 to 108. The maximum score for GP, GS and GF is 28 and that for the GE is 24. A larger score means better HRQoL. Factor analysis indicated that the FLIC's items can form Physical (Phy), Psychological (Psy), Symptoms (Sym), Family (Fam) and Social (Soc) scales.[10,12] The FLIC also gives a total score. The questionnaire package began with items on demographic and health particulars, such as Eastern Cooperative Oncology Group (ECOG) performance status[13] and whether the patients were on chemotherapy and/or radiotherapy.

Statistical Analysis

Missing values in the FACT-G and FLIC were imputed by the half-rule.[14] That is, the mean of the non-missing items in the same scale was used to replace the missing values if at least half of the items in the scale were answered. Convergent and divergent validity were assessed by correlation analysis between the FACT-G and FLIC and between their domain scales. It was hypothesised that GP would be most strongly correlated with Phy, GS with Fam and/or Soc, GE with Psy, and GF with Phy. Known-groups validity was assessed by a non-parametric test for trends developed by Cuzick,[15] which is an extension of the Wilcoxon rank-sum test, using ECOG performance status as a criterion. Cronbach's alpha was used to evaluate internal consistency. Sensitivity to change was assessed in relation to changes in ECOG performance status between baseline and follow-up. Test-retest reliability was assessed in a sub-sample of subjects who reported no change in performance status using the intraclass correlation coefficient (ICC) based on the ANOVA estimator.

Interviewer-administration of questionnaire is often unavoidable in practice and is allowed by the FACT-G.[16] In

supplementary analyses, we repeated the above analysis separately for the self- and interviewer-administration samples.

Table 1. Descriptive Summary of Patient Profile (n = 165)

Variable	Frequency (or mean)*	% (or SD)*
Age (y)	54	10
Female	97	58.8%
Education		
Primary	82	50.0%
Secondary school	60	36.6%
Post-secondary	22	13.4%
Marital status		
Married	135	81.8%
Single	19	11.5%
Divorce/Separated	6	3.6%
Widowed	5	3.0%
Tumour type		
Breast	52	31.5%
Colorectal	23	13.9%
Gynaecological	11	6.7%
Lung	15	9.1%
Nasopharyngeal cancer	29	17.6%
Head and Neck	11	6.7%
Others	24	14.6%
ECOG performance status		
0	55	33.3%
1	48	29.1%
2	43	26.1%
3	19	11.5%
On chemotherapy or RT	64	38.8%
Self-administered questionnaire	94	57.0%

* Mean and SD for age (in years); frequency and percentage for categorical variables.

Results

Patient Profile

A total of 180 ethnic Chinese patients answered the questionnaire package. Five requested to respond by proxies; 10 had missing values in the FACT-G or FLIC beyond imputation by the half-rule. These 15 patients were excluded from the analysis, leaving 165 participants.

Table 1 shows the descriptive characteristics of the patient sample. The mean age was 54 years and 41% of the patients were male. Half have only primary education level. The group was heterogeneous in terms of tumour types, ECOG performance status and treatment status. Fifty-seven per cent of the participants self-administered the questionnaires.

Distribution of FACT-G Scores

Table 2 summarises the distribution of the FACT-G scales. The mean FACT-G total scores was 84.0. There was no major floor effect in this sample. No patient reached the lowest possible total score. No patient reached the floor of GP, GE and GF, but 1.2% had the lowest possible GS score. The scales showed more ceiling effects in this sample, with 1.8%, 19.4%, 9.7%, 0.0% and 20.0% reaching the ceiling of the total, GP, GS, GE and GF scales.

Validity

Table 2 also presents the Pearson's correlation coefficient (r) between FACT-G and FLIC scales. The FACT-G and FLIC total scores were strongly correlated (r = 0.85; 95% CI, 0.80 to 0.89). The correlation pattern between FACT-G and FLIC scales was as expected from instruments with convergent and divergent validity. For example, GP was more strongly correlated to FLIC-Physical (r = 0.76) than to other FLIC scales and GE was more strongly correlated to FLIC-Psychological (r = 0.72) than to other FLIC scales.

Table 3 shows findings on known-groups validity. Apart from GE, all the FACT-G total and domain scores clearly showed the expected decremental relationship (each P <0.001 in non-parametric test for trends). For GE, those

Table 2. Descriptive Summary of FACT-G Scales and Correlation With FLIC Scales

	No. of items	Mean	SD	First quartile	Median	Third quartile	% at floor	% at ceiling	Correlation with FLIC scales					
									FLIC	Psy	Phy	Sym	Fam	Soc
FACT-G	28	84.0	16.6	73.3	85.9	98.7	0.0%	1.8%	0.85	0.80	0.78	0.58	0.70	0.66
GP	7	23.0	5.0	20.0	24.0	27.0	0.0%	19.4%	0.75	0.62	0.76	0.70	0.61	0.37
GS	7	21.5	5.4	19.0	22.2	25.0	1.2%	9.7%	0.47	0.48	0.37	0.23	0.41	0.49
GE	6	19.3	4.6	17.0	21.0	23.0	0.0%	0.0%	0.68	0.72	0.58	0.49	0.51	0.50
GF	7	20.1	6.6	16.0	21.0	26.0	0.0%	20.0%	0.73	0.66	0.69	0.41	0.63	0.63

* GP, GS, GE and GF denote, respectively, Physical, Social/Family, Emotion and Functional Well-being scales of the FACT-G; Psy, Phy, Sym, Fam and Soc denote, respectively, Psychological, Physical, Symptoms, Family and Social scales of FLIC.

Table 3. Mean HRQoL Scores by Level of ECOG Performance Status

ECOG	FACT-G	GP	GS	GE	GF
0	95.6	26.6	23.3	21.4	24.3
1	85.1	23.4	21.4	19.9	20.5
2	74.7	20.6	20.1	17.0	17.1
3	68.4	17.0	19.9	17.2	14.3
Effect size*	-0.58	-0.62	-0.24	-0.37	-0.52
P value†	<0.001	<0.001	<0.001	<0.001	<0.001

* Difference in HRQoL scores in SD per grade worse in ECOG performance status, estimated assuming a linear trend.

† Cuzick's non-parametric test for trend.

who had ECOG 2 and 3 appeared to have similar scores. Nevertheless, the number of patients with ECOG 3 was small (n = 19) and a non-parametric test for trend showed a significant trend. Assuming a linear trend, the effect size per grade worse in ECOG performance score was -0.58 SD for FACT-G and was between -0.24 SD to -0.62 SD for the 4 domain scores.

Internal Consistency

The internal consistency (Cronbach's alpha) of the FACT-G total score, GP, GS, GE and GF were 0.93, 0.87, 0.87, 0.81 and 0.90, respectively.

Sensitiveness to Change

One hundred and four patients returned the follow-up questionnaires. Ten of them were excluded from analysis due to missing values. Table 4 presents the changes in FACT-G scores (post-test scores minus pre-test scores) by changes in ECOG status. Apart from GS, all the FACT-G scores showed significant trends in relation to changes in ECOG. The GS score showed significant decline (-3.7; 95% CI, -6.2 to -1.2) among patients who had worse performance status than before, but no increase among patients who reported better performance status (-1.4; 95% CI, -3.2 to 0.3). For comparison purpose, we note that change in FLIC-Family score showed a significant trend in relation to changes in ECOG (P <0.001) but the FLIC-Social score did not (P = 0.082) (details not shown).

Test-retest Reliability

The 47 patients who had the same performance status in the baseline and follow-up assessments were included in the test-retest reliability analysis. The ICC's of the FACT-G total score, GP, GS, GE and GF were, respectively, 0.81 (95% CI, 0.72 to 0.92), 0.72 (0.58 to 0.86), 0.72 (0.58 to 0.86), 0.70 (0.56 to 0.85) and 0.74 (0.61 to 0.87).

Supplementary analysis repeating the above assessments separately for patients who self-administered the questionnaire and those who were interviewed at baseline gave mostly similar findings (details not shown). For example, pooling all patients the effect size of ECOG score on FACT-G total score was -0.58 SD (Table 3), whereas the figures in the self- and interviewer-administration groups were -0.57 SD and -0.59 SD, respectively. However, the test-retest reliability of the scales was stronger in respondents who self-administered the questionnaire at baseline (n = 33). Among these patients, the ICC's of the FACT-G total score, GP, GS, GE and GF were, respectively, 0.85 (95% CI, 0.76 to 0.94), 0.76 (0.62 to 0.90), 0.74 (0.59 to 0.89), 0.76 (0.61 to 0.90) and 0.80 (0.68 to 0.92). Among the patients who were interviewed at baseline, the ICC's for the 5 scores were, respectively 0.61 (95% CI, 0.25 to 0.97), 0.52 (0.09 to 0.94), 0.62 (0.26 to 0.97), 0.52 (0.10 to 0.94) and 0.47 (0.02 to 0.92).

Table 4. Mean Changes In HRQoL Scores by Change in ECOG Performance Status

ECOG	FACT-G	GP	GS	GE	GF
Better (n = 20)	0.2	1.2	-1.4	0.2	0.2
Same (n = 47)	-2.8	-1.5	0.3	-0.6	-0.9
Worse (n = 27)	-12.3	-2.3	-3.7	-2.3	-4.0
P value*	<0.001	0.002	0.154	0.038	0.009

* Cuzick's non-parametric test for trend.

Conclusions

HRQoL is an important patient outcome in oncology. As many Singaporeans and many of the world's population primarily use the Chinese language, evidence of appropriate measurement properties of the Chinese versions of HRQoL instruments is useful not only for Singapore but also for other countries. Despite the popularity of the English and Chinese versions of the FACT-G, there has been no published data on the validity, reliability and other measurement properties of the official Chinese translation of the FACT-G.

In this study of Chinese cancer patients in Singapore, correlation analyses demonstrated the convergent and divergent validity of the FACT-G and its 4 domain scales. Assessment of HRQoL scores in relation to ECOG performance status evidenced their known-groups validity. All of them have high levels of internal consistency in terms of Cronbach's alpha.[17] The FACT-G total score had strong test-retest reliability while those of the 4 scales were at an acceptable level.[18] Most HRQoL instruments are designed for self-administration but allow interviewer-administration. In this study, the mode of administration had little impact on the results concerning association. However, test-retest reliability was stronger among participants who self-administered the questionnaires. The follow-up survey by

post had to be self-administered. Previous studies suggested that the mode of administration can make a difference in the recorded level of HRQoL.[19] The poorer agreement between pre- and post-test scores among those who were interviewed at baseline may be due to the effect of different modes of administration in the 2 assessments.

The FACT-G, GP, GE and GF showed expected trends of changes in HRQoL scores in relation to change in ECOG status over time but GS did not. The GS scale was sensitive to decline but not improvement in health status. Cross-sectionally, the effect size per grade worse in ECOG performance status was also smaller on GS (-0.24 SD) than the other scales. Previously we noted that the operationalisation of "social" or "family" domains of HRQoL can be highly variable.[11] The FACT-G questionnaire combines social and family and sex life into a single GS scale and mainly asks how patients feel about their interaction with others. In contrast, the FLIC had 2 separate factors on social/family aspects[10,12] and they asked about the impact of the patients' disease on others. Perhaps these social and family elements may respond to an improvement of health status in different ways. Researchers who specifically want to study these elements of HRQoL need to carefully consider what exactly is to be measured and which instrument's contents are most appropriate for the specific purpose. The FACT-G total score, GP, GE and GF only showed small increase in HRQoL scores among patients whose performance status improved. This may reflect the ceiling effect seen in Table 2 and the relatively healthy status of the patients of this study (e.g. no patients with ECOG grade 4). Further studies of the FACT-G's sensitiveness to change in groups of patients who were more sick would be useful.

In conclusion, we have found that the simplified Chinese character version of FACT-G (V4) had suitable measurement properties in this study of cancer patients in Singapore, with the caveat that its Social/Family Well-being scale is limited in sensitiveness to the improvement in performance status. If the social elements of quality of life are important concerns in a study, one should consider using other instruments to supplement the FACT-G.

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