

The Functional Living Index – Cancer is a Reliable and Valid Instrument in Chinese Cancer Patients

Daniel Y.T. Fong¹, Alvina H.K. Lee², Stewart Y. Tung³, Janet Y.H. Wong¹, Y.M. Chan⁴, Cynthia R. Goh⁵, Y.B. Cheung^{6,7,8}

¹ School of Nursing, Li Ka Shing Faculty of Medicine, The University of Hong Kong, Pokfulam, Hong Kong, , 4/F, William MW Mong Block, Faculty of Medicine Building, 21 Sassoon Road, Hong Kong

² Community Outreach Service Team, North District Hospital, Hong Kong

³ Department of Clinical Oncology, Tuen Mun Hospital, Hong Kong

⁴ C&J's Medicare for Women Limited, Hong Kong

⁵ Department of Palliative Medicine, National Cancer Centre Singapore, 11 Hospital Drive, Singapore 169610

⁶ Department of Biostatistics, Singapore Clinical Research Institute, 31 Biopolis Way, Nanos #02-01, Singapore 138669

⁷ Center for Quantitative Medicine, Office of Clinical Sciences, Duke-NUS Graduate Medical School, 8 College Road, Singapore 6601 2682

⁸ Department of International Health, University of Tampere, ARVO Building FIN-33014 Tampere, Finland

Corresponding author:

Daniel Y.T. Fong

School of Nursing, Li Ka Shing Faculty of Medicine, The University of Hong Kong

Tel: +852 2819 2645

Fax: +852 2872 6079

Email: dytfong@hku.hk

Word count: 1492

Abstract

Purpose To evaluate the linguistic and psychometric properties of the Functional Living Index – Cancer (FLIC) in assessing the quality of life of Chinese cancer patients

Methods We followed the standard forward-backward procedure to translate the original English FLIC into Traditional Chinese. After cognitive debriefing, a Traditional Chinese FLIC was administered to 500 cancer patients in a major public hospital in Hong Kong. Of which, 200 were invited to complete the questionnaire in 2 weeks. Exploratory and confirmatory factor analyses were performed on two randomly split halves of the sample to identify a scale structure appropriate to Chinese.

Results We identified five scales of the Traditional Chinese FLIC which assess the physical, psychological, hardship, nausea and social aspects. These five scales and the overall scale demonstrated satisfactory fit in the independent half of the sample, and had the alpha coefficient ranged from 0.68 to 0.92. The intraclass correlation coefficient ranged from 0.67 to 0.88. In addition, all FLIC scales were negatively associated with the Eastern Cooperative Oncology Group performance status and also except the psychological scale had lower scores in patients who were treated by chemotherapy.

Conclusions The Traditional Chinese FLIC is an appropriate health indicator for Chinese cancer patients.

Keywords Cancer; Chinese; FLIC; psychometric; reliability; validity

Abbreviations

CFA	Confirmatory factor analysis
ECOG	Eastern Cooperative Oncology Group
EFA	Exploratory factor analysis
EORTC QLQ	European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire
FACT-G	Functional Assessment of Cancer Therapy-General
FLIC	Functional Living Index – Cancer
ICC	Intraclass correlation coefficient
RMSEA	Root mean square error of approximation
SD	Standard deviation
SRMR	Standardized root mean square residual

Introduction

Both survival and quality of life have been considered as important outcomes in cancer trials [1]. The 22-item Functional Living Index–Cancer (FLIC) is a cancer specific quality of life instrument [2] with emphasis on the extent cancer and its related treatments affected patients’ normal functions. It has good coverage of relevant aspects of quality of life [2,3], with good discriminative ability and high sensitivity [4-6]. Despite these, a properly tested Traditional Chinese FLIC had been unavailable. The Traditional Chinese has been a main written language in Guangzhou, Hong Kong, Macau and Taiwan, covering over 36 million people in 2012. Hence, the development of FLIC in Traditional Chinese is desirable. Moreover, the FLIC had varied scale structures reported [5,4,7,2,8] (Table 1), and their appropriateness had not been assessed.

Therefore, this study aimed to culturally adapt the FLIC in Traditional Chinese and assess the appropriateness of its scale structures identified in the literature.

Methods

Linguistic validation

Two professional translators independently translated the English FLIC into Traditional Chinese. A consensus meeting comprising the two translators and two authors [DF, AL] was then convened to obtain a consensus Chinese version. Its back-translated version, by a third professional translator, was compared with the original English version by [DF, AL] and a clinical oncologist [YC]. The revised Chinese version was then tested in five Chinese adult cancer patients after seeking their written consent. The patients were debriefed for the clarity and relevance by

responding on a 5-point Likert scale. Ethics approval of the study was sought from recognized local ethics committees.

Psychometric evaluation

Subjects

500 cancer patients visiting an outpatient oncology department in Hong Kong who were 18 years or older and literate in Traditional Chinese were recruited with informed consent. The sample size was based on the use of exploratory/confirmatory factor analyses on two randomly split halves of the sample, by the usual rule of 10 subjects per item for a factor analysis. Ethics approval of the study was also sought from ethics committees.

Measurements and Procedures

All consented patients self-completed the Traditional Chinese FLIC. We also obtained their demographics, medical history and the Eastern Cooperative Oncology Group (ECOG) performance status [9]. 200 patients were randomly selected, and asked to complete the Traditional Chinese FLIC again as well as also five global rating scales on whether they had significant change in physical health, emotional health, social life, family hardship and nausea since last clinical visit in 7-14 days after their first completion.

Statistical Analysis

We randomly split the sample into two halves with 248 in a training set and 252 in a validation set [10]. The training set was used to perform an exploratory factor analysis (EFA) with the number of factors determined by scree plot and factor loadings

estimated by maximum likelihood after a promax rotation [11]. The identified factor structure was then assessed in the validation set by confirmatory factory analysis (CFA). Goodness-of-fit was assessed by the root mean square error of approximation (RMSEA), standardized root mean square residual (SRMR), and the Bollen Δ_2 [12]. A CFA model was considered acceptable when RMSEA is close to 0.06 or below, SRMR is close to 0.08 or below, and Bollen Δ_2 is close to 0.95 or greater [13]. A second order scale structure incorporating the overall factor was also fitted to assess the adequacy of having the overall scale. The same CFA analysis was used to assess the fit of scale structures reported in the literature [2,4,7,5,8]. Our identified scale structure was further assessed for its internal consistency by calculating the Cronbach's alpha, and its clinical validity by examining the hypothesized negative association with the ECOG performance status and the experience of chemotherapy using regression analysis.

Test-retest reliability was assessed by the intraclass correlation coefficient (ICC) based on patients who reported no significant change in all the global rating scales in the retest.

The Statistical Analysis System (SAS) was used for the analysis (SAS Institute, Cary, NC, US).

Results

Cognitive Debriefing

The five (three females) patients had age ranged between 44 to 60 years, and either breast, renal, sigmoid colon, lung or nasopharyngeal cancer. The median completion time of the Traditional Chinese FLIC was 3 minutes (range = 2 to 9 minutes). All

patients considered the length of instrument acceptable. The median relevance rating was moderate and that for clarity was high.

Psychometric Validation

The training and validation sets had no significant differences (Table 2). Using the training set, EFA identified five factors, namely physical, psychological, hardship, nausea and social (Table 1). Their between-scale correlation ranged from 0.29 to 0.47. Using the validation set, the EFA derived 5-factor structure and those previously identified factor structures had satisfactory fit although the EFA derived model slightly fitted better than the others (Table 1). The second order models did not substantially deteriorate the fit indices.

All scales had small floor and ceiling effects, with only the nausea and social scales exhibited high ceiling effects (Table 3). A significant negative association was identified in all scales, except for the insignificant association between the psychological scale and experience of chemotherapy.

155 (78%) patients completed the re-test and returned the questionnaires by post. Of which, 49 patients reported no significant change in all the global rating scales since the last visit; based on which, the ICCs were satisfactory (Table 3).

Discussions

The reasons of differential factor structures reported in the literature may be three-folded. First, several factor structures were identified from an EFA after a varimax rotation [4,7,2], which constraints the factors to be uncorrelated; but then there appeared moderate correlation among the five factors identified in our EFA and also in Ruckdeschel & Piantadosi [8]. Second, EFA was conducted on samples of size

ranged from 84 to 438 but a small sample size may yield an unstable factor structure. Third, there could be cultural difference in conceptualization of quality of life; even the English version when administered in Singapore showed a factor structure different from those reported in Australia and North America.

The scale structure of the Traditional Chinese FLIC closely resembles to those reported by the original developer and Ruckdeschel & Piantadosi [2,8]. Indeed, our CFA shows all three factor structures had satisfactory model fit. They may all be validly used in Chinese.

Both the nausea and social scales had high ceiling effects, with around 50% of patients had no nausea or social concern. Nausea and reduced willingness to social in cancer patients would be mainly induced by chemotherapy. In our validation sample, 138 (55%) either had not had chemotherapy or had completed chemotherapy for at least six months; which may have contributed to the high ceiling effects.

The internal consistency of the Traditional Chinese FLIC with Cronbach's alpha ranged between 0.68 and 0.92 is satisfactory according to the criteria of 0.7 suggested by Nunnally [14]. They are comparable to those reported in the original English (range: 0.64 to 0.87), and the Simplified Chinese (range: 0.57 to 0.92) versions [15-17]. In addition, to our knowledge, only the Simplified Chinese FLIC had its test-retest reliability assessed with the reliability coefficient for its overall scale as 0.78 [6]. The 2-week test-retest reliability of the Traditional Chinese FLIC is satisfactory.

Our study is however limited to patients with good performance status. Patients with poorer health status may tend to not participate. Exclusion of them would attenuate the association between the FLIC scales and the ECOG performance

status. However, the clear supporting evidence of their associations indicating a good clinical validity of the FLIC.

Conclusion

The overall and five scales of the Traditional Chinese FLIC are reliable and valid for assessing the quality of life of cancer patients.

Acknowledgements

This work was supported by the Small Project Funding of The University of Hong Kong. YBC was supported by the Singapore Ministry of Health's National Medical Research Council under its Clinician Scientist Award.

References

1. Johnson, J. R., & Temple, R. (1985). Food and Drug Administration requirements for approval of new anticancer drugs. *Cancer Treatment Reports*, 69(10), 1155-1159.
2. Schipper, H., Clinch, J., McMurray, A., & Levitt, M. (1984). Measuring the quality of life of cancer patients: the Functional Living Index-Cancer: development and validation. *Journal of Clinical Oncology*, 2(5), 472-483.
3. Laenen, A., & Alonso, A. (2010). The Functional Living Index-Cancer: estimating its reliability based on clinical trial data. *Quality of Life Research*, 19(1), 103-109, doi:10.1007/s11136-009-9568-x.
4. King, M. T., Dobson, A. J., & Harnett, P. R. (1996). A comparison of two quality-of-life questionnaires for cancer clinical trials: the functional living index--cancer (FLIC) and the quality of life questionnaire core module (QLQ-C30). *Journal of Clinical Epidemiology*, 49(1), 21-29.
5. Goh, C. R., Lee, K. S., Tan, T. C., Wang, T. L., Tan, C. H., Wong, J., et al. (1996). Measuring quality of life in different cultures: translation of the Functional Living Index for Cancer (FLIC) into Chinese and Malay in Singapore. *Annals Academy of Medicine Singapore*, 25(3), 323-334.
6. Cheung, Y. B., Goh, C., Thumboo, J., Khoo, K. S., & Wee, J. (2005). Variability and sample size requirements of quality-of-life measures: a randomized study of three major questionnaires. *Journal of Clinical Oncology*, 23(22), 4936-4944.
7. Morrow, G. R., Lindke, J., & Black, P. (1992). Measurement of quality of life in patients: psychometric analyses of the Functional Living Index-Cancer (FLIC). *Quality of Life Research*, 1(5), 287-296.

8. Ruckdeschel, J. C., & Piantadosi, S. (1994). Quality of life in lung cancer surgical adjuvant trials. *Chest*, *106*(6 Suppl), 324S-328S.
9. Oken, M. M., Creech, R. H., Tormey, D. C., Horton, J., Davis, T. E., McFadden, E. T., et al. (1982). Toxicity and response criteria of the Eastern Cooperative Oncology Group. *American Journal of Clinical Oncology*, *5*(6), 649-655.
10. Fong, D. Y., Lam, C. L., Mak, K. K., Lo, W. S., Lai, Y. K., Ho, S. Y., et al. (2010). The Short Form-12 Health Survey was a valid instrument in Chinese adolescents. *Journal of Clinical Epidemiology*, *63*(9), 1020-1029, doi:10.1016/j.jclinepi.2009.11.011.
11. Costello, A. B., & Osborne, J. W. (2005). Best Practices in Exploratory Factor Analysis: Four Recommendations for Getting the Most From Your Analysis. *Practical Assessment, Research & Evaluation*, *10*(7), 1-9.
12. Hu, L. T., & Bentler, P. M. (1998). Fit indices in covariance structure modeling: Sensitivity to underparameterized model misspecification. *Psychological Methods*, *3*(4), 424-453.
13. Hu, L. T., & Bentler, P. M. (1999). Cutoff Criteria for Fit Indexes in Covariance Structure Analysis: Conventional Criteria Versus New Alternatives. *Structural Equation Modeling*, *6*(1), 1-55.
14. Nunnally, J. C. (1978). *Psychometric theory* (2d ed., McGraw-Hill series in psychology). New York: McGraw-Hill.
15. Schipper, H., & Levitt, M. (1985). Measuring quality of life: risks and benefits. *Cancer Treatment Reports*, *69*(10), 1115-1125.
16. Bektas, H. A., & Akdemir, N. (2008). Reliability and validity of the Functional Living Index-Cancer in Turkish cancer patients. *Cancer Nursing*, *31*(1), E1-7, doi:10.1097/01.NCC.0000305684.51884.1f.

17. Cheung, Y. B., Ng, G. Y., Wong, L. C., Koo, W. H., Tan, E. H., Tay, M. H., et al. (2003). Measuring quality of life in Chinese cancer patients: A new version of the Functional Living Index for Cancer (Chinese). *Annals Academy of Medicine Singapore*, 32(3), 376-380.

Table 1 Factor structures of the Functional Living Index-Cancer (FLIC)

Item No.	Items in FLIC	Goh et al. (1996) [Singaporean – Chinese] (n=84)					Goh et al. (1996) [Singaporean – English] (n=124)					King et al. (1996) [Australian] (n=98)					Morrow et al. (1992) [American] (n=244)					Ruckdeschel & Piantados (1991) [American] (n=438)					Schipper et al. (1984) [Canadian] (n=175)					Factor loadings from exploratory factor analysis [Traditional Chinese]									
		1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5	1	2	3	4	5					
15.	Able to complete housework?	●					●					●					●					●					●					●					0.52				
4.	Maintain leisure activities?	●					●					●					●					●					●					●					0.36				
7.	Well enough for meals or repairs?	●					●					●					●					●					●					●					0.75				
10.	Satisfied with work?		●						●					●					●					●					●					●			0.49				
13.	Pain/discomfort interfering activities?	●					●					●					●					●					●					●							0.62		
20.	Pain/discomfort related to cancer?	●					●					●					●					●					●					●							0.54		
11.	Feel uncomfortable?	●					●					●					●					●					●					●					0.56				
22.	Appear well?			●			●					●					●					●					●					●					0.71				
6.	Feel well?			●			●					●					●					●					●					●					0.62				
18.	Frightened of future?		●					●					●					●					●					●					●					0.50			
9.	Discouraged about life?		●					●					●					●					●					●					●					0.73			
3.	Think about illness?		●					●					●					●					●					●					●					0.27			
2.	Cope well with stress?			●				●					●					●					●					●					●					0.42			
1.	Feel depressed?			●				●					●					●					●					●					●					0.56			
21.	Confident of treatment?					●		●					●			●		●			●		●			●		●			●		●			●		0.29			
12.	Disruptive to the closest?	●							●			●					●					●					●					●							0.49		
8.	Hardship on the closest?	●							●			●					●					●					●					●							0.51		
14.	Hardship on yourself?	●						●				●					●					●					●					●							0.71		
5.	Nausea affecting daily functioning?				●					●					●					●					●					●					●					0.39	
17.	How much nausea?			●						●					●					●					●					●					●					0.98	
16.	Willing to spend time with family?					●					●					●					●					●					●					●				0.62	
19.	Willing to spend time with friends?					●					●					●					●					●					●					●				0.77	
Fit indices in confirmatory factor analysis (First order model/Second order model)																																									
χ^2 (degrees of freedom)		394.6 (192) / 424.2 (192)					368.4 (190) / 390.6 (190)					364.1 (192) / 378.5 (192)					384.8 (193) / 389.0 (193)					361.8 (194) / 392.3 (194)					347.0 (191) / 372.9 (191)					340.2 (192) / 366.3 (192)									
RMSEA		0.067 / 0.071					0.063 / 0.067					0.062 / 0.064					0.065 / 0.066					0.061 / 0.066					0.059 / 0.064					0.057 / 0.062									
SRMR		0.063 / 0.067					0.065 / 0.063					0.059 / 0.061					0.061 / 0.061					0.054 / 0.059					0.055 / 0.058					0.057 / 0.60									
Bollen $\Delta 2$		0.91 / 0.90					0.92 / 0.91					0.92 / 0.92					0.92 / 0.91					0.93 / 0.91					0.93 / 0.92					0.94 / 0.92									

RMSEA = root mean square error of approximation

SRMR = standardized root mean square residual

Table 2 Sample characteristics

Characteristics	Training set (n = 248)		Validation set (n = 252)		p-value
	n	%	n	%	
Age (years)					0.140
mean±SD	49.0±10.2		50.2±9.8		
Gender					0.653
Female	153	61.7	161	63.9	
Male	95	38.3	91	36.1	
Marital status (missing: n = 4)					0.346
Single	34	13.8	37	14.8	
Married or cohabitated	180	73.2	185	74.0	
Widowed or separated	32	13.0	28	11.2	
Education (missing: n = 1)					0.751
Primary or below	74	30.0	74	29.4	
Secondary	148	59.9	145	57.5	
College	11	4.5	13	5.2	
Tertiary or above	14	5.7	20	7.9	
Recurrence (missing: n = 10)					0.648
No	218	90.1	227	91.5	
Yes	24	9.9	21	8.5	
Diagnosis					0.516
Breast	64	25.8	71	28.2	
Digestive	51	20.6	43	17.1	
Gynecological	27	10.9	32	12.7	
Lung	26	10.5	19	7.5	
Nasopharyngeal	31	12.5	40	15.9	
Thyroid	27	10.9	20	7.9	
Others	22	8.9	27	10.7	
ECOG performance status					0.773
0	90	36.3	87	34.5	
1	143	57.7	149	59.1	
2	11	4.4	10	4.0	
3	3	1.2	6	2.4	
4	1	0.4	0	0	
On or completed chemotherapy					0.776
No	84	33.9	82	32.5	
Yes	164	66.1	170	67.5	
Duration of diagnosis (years)					0.900
mean±SD	2.9±5.9		2.6±3.8		

ECOG Eastern Cooperative Oncology Group

SD Standard deviation

Table 3 Scale summary and clinical validity of the FLIC in the validation set

FLIC scales (No. of items)	n	Mean±SD	Range	% Floor	% Ceiling	Cronbach's alpha	ECOG		Experience of chemotherapy		
							Regression coefficient (95% CI)	p-value	Regression coefficient (95% CI)	p-value	ICC
Overall (22)	251	71.5±18.3	9.1-100	0	2.8	0.92	-11.9 (-15.1, -8.7)	<0.001	-7.8 (-12.5, -3.0)	0.002	0.83
Physical (7)	251	73.9±20.2	14.3-100	0	10.0	0.84	-13.2 (-16.7, -9.7)	<0.001	-7.4 (-12.6, -2.1)	0.006	0.70
Psychological (6)	251	68.5±20.7	0-100	0.4	8.4	0.80	-5.8 (-9.7, -1.83)	0.004	-1.1 (-6.6, 4.3)	0.682	0.67
Hardship (5)	251	64.1±25.9	0-100	1.6	10.4	0.82	-16.1 (-18.6, -9.7)	<0.001	-14.0 (-20.6, -7.3)	<0.001	0.86
Nausea (2)	250	82.0±25.0	0-100	0.8	51.2	0.68	-14.1 (-18.6, -9.7)	<0.001	-13.3 (-19.7, -6.9)	<0.001	0.88
Social (2)	251	80.7±26.2	0-100	2.0	49.4	0.73	-12.5 (-17.3, -7.7)	<0.001	-8.3 (-15.1, -1.4)	0.019	0.74

CI Confidence interval

ECOG Eastern Cooperative Oncology Group

ICC Intraclass correlation coefficient

SD Standard deviation

Fig. 1 Standardized estimates of a second order factor model in the validation set

