

Validation of Functional Assessment of Cancer Therapy with Nasopharyngeal Cancer Subscale (FACT-NP) for Quality of Life in Thai Patients

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Abstract:

Objective: To develop and validate the Thai version of the functional assessment of cancer therapy with nasopharyngeal cancer subscale (FACT-NP) with the abbreviated version of the World Health Organization Quality of Life-BREF instrument (WHOQOL-BREF).

Material and Methods: A cross-sectional study was performed in the Radiology Department between January 2014 and October 2016. Inclusion criteria: nasopharyngeal carcinoma patients aged greater than 18 years. Exclusion criteria: no comprehension of the Thai language, had other cancers (except for skin cancer and diagnosed with impaired cognition and/or overt psychosis), major depression or delirium. After signing the consent form, participants were interviewed and self-completed FACT-NP and WHOQOL-BREF. The structure of the FACT-NP was determined with exploratory factors analysis. The internal reliability of identified domains was evaluated using Cronbach's alpha. The correlation between domains of the modified FACT-NP and the domains of WHOQOL-BREF were examined with Spearman's correlation. Known-group validity was determined by comparing patients with different sociodemographic and clinical characteristics using the T-test, Ranksum test and analysis of variance. A p-value of less than 0.05 was considered significant.

Results: This study was terminated early due to a long accrual period. Of the 230 patients included in the study, only 220 completed both FACT-NP and WHOQOL-BREF. Exploratory factor analysis showed an accumulative variance

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of 0.56 with 4 factors. The internal reliability of modified FACT-NP was 0.92. There was moderate correlation between modified FACT-NP and WHOQOL-BREF. Both the modified FACT-NP and WHOQOL-BREF could identify differences between the groups.

Conclusion: The Thai modified FACT-NP was found to be both valid and reliable for measuring the quality of life in Thai nasopharyngeal cancer patients.

Keywords: FACT-NP, factor analysis, nasopharyngeal cancer, quality of life

Introduction

Nasopharyngeal cancer is a subset of head and neck cancers for which radiotherapy is a form of treatment that can cure the patient. This disease is rare in Western countries but more common in Southeast Asia. Incidence of nasopharyngeal cancer in Thailand is fifth in Asia.¹ Nowadays, combined radiotherapy and chemotherapy can improve progression-free survival and overall survival. It has become the standard treatment in patients with or without metastatic disease.²⁻⁴ The treatments depend on the stage of the disease. In the early stages nasopharyngeal carcinoma is treated with radical radiotherapy. In more advanced cases, combined radiotherapy and chemotherapy are prescribed. Generally, a total radiation dose of 70 gray in 35 fractions is prescribed. A total of 5 cycles of chemotherapy are given, according to the protocol of the institute. Cisplatin 100 milligram per square meter (mg/m^2) or carboplatin area under curve (AUC) 6 is given every 3 weeks for 3 cycles in the concurrent phase. After radiation is completed, an additional 2 cycles of cisplatin 75–80 mg/m^2 or carboplatin AUC5 on day 1 and 5-fluorouracil (5-FU) 1,000 mg/m^2 on days 1–4 every 4 weeks are administered. Doses of chemotherapy are adjusted based on patient hematological results and renal toxicity. Generally, radiotherapy causes patients to suffer from complications such as chronic dysphagia, xerostomia, and fibrosis of the neck. Additional chemotherapy is associated with higher levels of severe hearing loss.⁵

Quality of life (QOL) is a broad multidimensional concept that usually includes subjective evaluations of both the positive and negative aspects of life.⁶ Health-related quality of life (HRQOL) instruments have been developed to measure and classify generic HRQOL, disease-specific quality of life, and cancer-specific quality of life. Disease specific questionnaires may be more sensitive to detect differences when compared with generic quality of life questionnaires, which do not focus on the issues of particular concern to patients with a disease.⁷ Measuring quality of life in nasopharyngeal cancer: there are 2 common systems available, the functional assessment of cancer therapy with nasopharyngeal cancer subscale (FACT-NP) and the head and neck module (H&N35) from the European Organization for Research and Treatment of Cancer Quality of Life. Although H&N35 is widely used, this questionnaire was developed for all head and neck cancers.⁸ In contrast, FACT-NP was developed specifically for nasopharyngeal cancer. Thus, this questionnaire focuses on evaluating the suffering caused by treatment toxicities as a result of nasopharyngeal cancer treatment. This is the questionnaire we chose for the study.

To the best of our knowledge, no nasopharyngeal cancer specific questionnaire has been validated in the Thai language. This study aimed to develop and validate the Thai version of the FACT-NP for measuring quality of life, and compare it with the World Health Organization

Quality of Life-BREF (WHOQOL-BREF) in nasopharyngeal cancer patients.

Material and Methods

Ethical consideration

The study was approved by the Human Research and Ethics Committee of the Faculty of Medicine, Prince of Songkla University, REC: 56-006-07-1-3

Study design and setting

The cross-sectional study was performed in the largest radiation-oncology unit in southern Thailand, which serves approximately 2,500 new radiotherapy patients per year. The enrollment period was between January 2014 and October 2016.

Study samples

Nasopharyngeal carcinoma patients aged more than 18 years who visited the hospital for treatment or follow-up were included in the study. Those who did not understand the Thai language, had other cancers (except for skin cancer and diagnosed with impaired cognition and/or overt psychosis), major depression or delirium were excluded.

Instruments

FACT-NP is the functional assessment of cancer therapy general (FACT-G) with nasopharyngeal subscale. The researchers collaborated with the Functional Assessment of Chronic Illness Therapy Organization on the translation. The translation, back translation, and linguistic validation process were performed using the Functional Assessment of Chronic Illness Therapy translation project guidelines. The final version of the Thai FACT-NP was pilot tested with 10 treated nasopharyngeal carcinoma patients using an interview script. We did not find any misunderstandings in the translation.

FACT-NP comprises 43 items with a 5-point (0–4: not at all to very much) Likert scale and category to 5 domains: physical well-being (PWB), social/family well-being (SWB), emotional well-being (EWB), functional well-being (FWB) and nasopharyngeal cancer subscales (NPS). The ranges of the scores of these domains are 0–28, 0–28, 0–24, 0–28 and 0–64, respectively. The range of total score for FACT-NP is 0–172. Higher scores mean a higher QOL.

WHOQOL-BREF was validated in the Thai language with radiotherapy patients.^{9,10} The questionnaire comprises 26 items with a 5-point (1–5: not at all to very much) Likert scale and was categorized into 4 domains: physical health (PH), psychological well-being (PSW), social relationship (SR) and satisfaction with their environment (SE). The score of the subscale was calculated by summing the corresponding items in the subscale. The overall score ranged from 26–130. Higher scores mean a higher quality of life: categorized to bad (26–60), average (61–95) and good (96–130).

Independent variables were sociodemographic and clinical characteristics. Sociodemographic characteristics were age, religious, marital status, education level, and economic and working status. The clinical characteristics were clinical stage, Eastern Cooperative Oncology Group (ECOG) performance status, treatment and disease status, and history of percutaneous gastrostomy.

Data collection

All nasopharyngeal carcinoma patients who were eligible for the study were invited to participate. After signing the consent form, the research assistant interviewed them for sociodemographic data and reviewed their clinical characteristics. Next, patients answered the questionnaires by themselves. For the patients with reading difficulties, well-trained research assistants read aloud each item on the questionnaire and allowed the patients

to choose his/her answer by himself or herself. Total time spent on these procedures was around 30 minutes.

Statistical analyses

The sociodemographic and clinical data were determined with descriptive statistics. In the development process, exploratory factor analysis (EFA) was used to group the items in FACT-G. The number of factors was determined with a scree plot, with the eigenvalue closest to the unity. Acceptable loading for each variable was 0.32.¹¹ The oblimin was used in accordance with the previous study.¹² The group of domains from EFA was checked for internal reliability using Cronbach's alpha. An alpha value of at least 0.7 was considered acceptable for internal consistency. If the alpha values were at least 0.8 and 0.9, they were considered good and excellent for internal consistency, respectively. Spearman's correlation was calculated to determine the relationship between the domains of the modified FACT-NP and of WHOQOL-BREF for construct validity. The correlation coefficients ranged from -1 to +1 and were categorized into negligible correlation (0.00 to 0.30), low correlation (0.3 to 0.5), moderate correlation (0.5–0.7), high correlation (0.7–0.9), and very high correlation (0.9–1.0). Both scales were finally compared on their relationship with sociodemographic and clinical characteristics by t-test, Ranksum test and analysis of variance. A p-value of less than 0.05 was considered significant. Statistical analysis was conducted using the R program.

The sample size was calculated for testing the validity of the questionnaire by exploratory factor analysis. The adequate sample used was 1:5 item respondent ratio.¹¹ The total items of FACT-NP were 43. Hence, the estimated sample size was at least 215 cases. An additional 15.0% was added. Thus, a total of 245 participants were included in the study.

Results

Characteristics of the subjects

The study was terminated early due to a long accrual period. A total of 230 patients were recruited for the study. However, only 220 patients completed both FACT-NP and WHOQOL-BREF. These 220 participants were used in data analysis. The majority was Buddhist, married and male with an age of around 50 years; most had no economic problems. Of the subjects, 57.7% were educated at least at the secondary school level. Most of the diagnosed stage III and IV nasopharyngeal cancer patients were treated with chemo-radiation and had a history of prophylactic gastrostomy. Of them, 37.7% were in the active treatment phase and 55.5% had no evidence of cancer recurrence or metastasis. The details are shown in the Table 1.

Table 1 Socio-demographic and clinical characteristic of participants

Variables	Number (%) (n=220)
Age (mean and standard deviation)	50.6±12.2
Male	150 (68.2)
Religious	
Buddhism	190 (86.4)
Islamism	30 (13.6)
Status	
Single	26 (11.8)
Married or couple	183 (83.2)
Divorce	11 (5.0)
Education level	
Bachelor and above	59 (26.8)
Secondary school	68 (30.9)
Primary school	86 (39.1)
Unlettered	7 (3.2)
Working	127 (57.7)
Economic problem	45 (20.5)

Table 1 (continued)

Variables	Number (%) (n=220)
Stage	
I	9 (4.1)
II	20 (9.1)
III	86 (39.1)
IV	105 (47.7)
Eastern Cooperative Oncology Group performance status	
0-1	209 (95.0)
2-4	11 (5.0)
Active treatment	83 (37.7)
Disease status	
Loco-regional disease	70 (31.8)
No evidence of disease	122 (55.5)
Recurrence or metastases	28 (12.7)
Treatment	
Before treatment	66 (30.0)
Radiation	14 (6.4)
Chemo-radiation	138 (62.7)
Supportive treatment	2 (0.9)
Prophylactic gastrostomy	148 (67.3)

Exploratory factor analysis

The Kaiser-Meyer-Olkin of sampling adequacy was 0.87 and Bartlett's test of sphericity was significant with p -value<0.001, which shows these data were suited for factor analysis. Figure 1 revealed a relationship between eigenvalue and factor number. Then the number of factors in EFA was 4. The results of EFA are shown in Table 2. The factor loading in each domain from 1, 2, 3 and 4 was 0.17, 0.13, 0.13 and 0.13. The cumulative variance was 0.56. The new factors had the same names as the previous FACT-NP, which were social and family well-being, emotional well-being, physical well-being and functional well-being, respectively.

The Cronbach's alpha in each domain and the total items of FACT-NP ranged from 0.82–0.92. The details are shown in Table 3. The internal consistency of each domain was good or excellent.

Parallel analysis scree plots

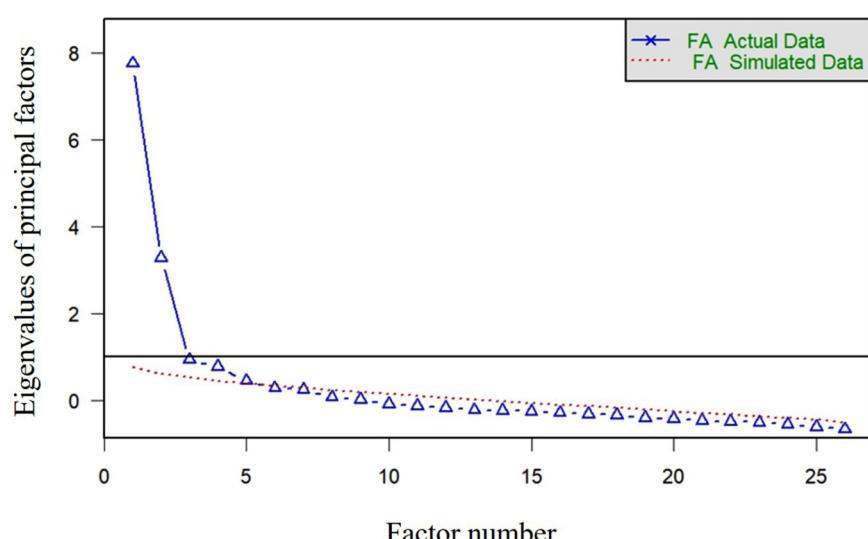
**Figure 1** Relationship between number of factor and eigenvalue

Table 2 The exploratory factor analysis of the modified functional assessment of cancer therapy general in relation to factor structure and loadings

Factor structure originally	Component in this analysis					
	1	2	3	4	h2	u2
GP1 I have a lack of energy		0.70		0.60	0.40	1.1
GP2 I have nausea		0.40		0.25	0.75	1.6
GP4 I have pain		0.62		0.45	0.55	1.1
GP6 I feel ill		0.77		0.67	0.33	1.1
GP7 I am forced to spend time in bed		0.73		0.57	0.43	1.1
GS1 I feel close to my friends	0.57			0.45	0.55	1.5
GS2 I get emotional support from my family	0.78			0.69	0.31	1.1
GS3 I get support from my friends	0.61			0.45	0.55	1.2
GS4 My family has accepted my illness	0.82			0.72	0.28	1
GS5 I am satisfied with family communication about my illness	0.91			0.80	0.20	1
GS6 I feel close to my partner (or the person who is my main support)	0.77			0.60	0.40	1
GS7 I am satisfied with my sex life	0.55			0.45	0.55	1.3
GE1 I feel sad		0.56		0.52	0.48	1.6
GE2 I am satisfied with how I am coping with my illness			0.33	0.38	0.62	2.4
GE3 I am losing hope in the fight against my illness		0.65		0.56	0.44	1.1
GE4 I feel nervous		0.85		0.75	0.25	1
GE5 I worry about dying		0.84		0.70	0.30	1.1
GE6 I worry that my condition will get worse		0.49		0.39	0.61	1.5
GF2 My work (include work at home) is fulfilling	-0.44		0.45	0.47	0.53	2.2
GF3 I am able to enjoy life			0.85	0.72	0.28	1
GF4 I have accepted my illness			0.74	0.67	0.33	1.2
GF5 I am sleeping well			0.44	0.41	0.59	1.8
GF6 I am enjoying the things I usually do for fun			0.66	0.61	0.39	1.1
GF7 I am content with the quality of my life right now			0.54	0.54	0.46	1.4
Cumulative variance 0.56	0.17	0.13	0.13	0.13		

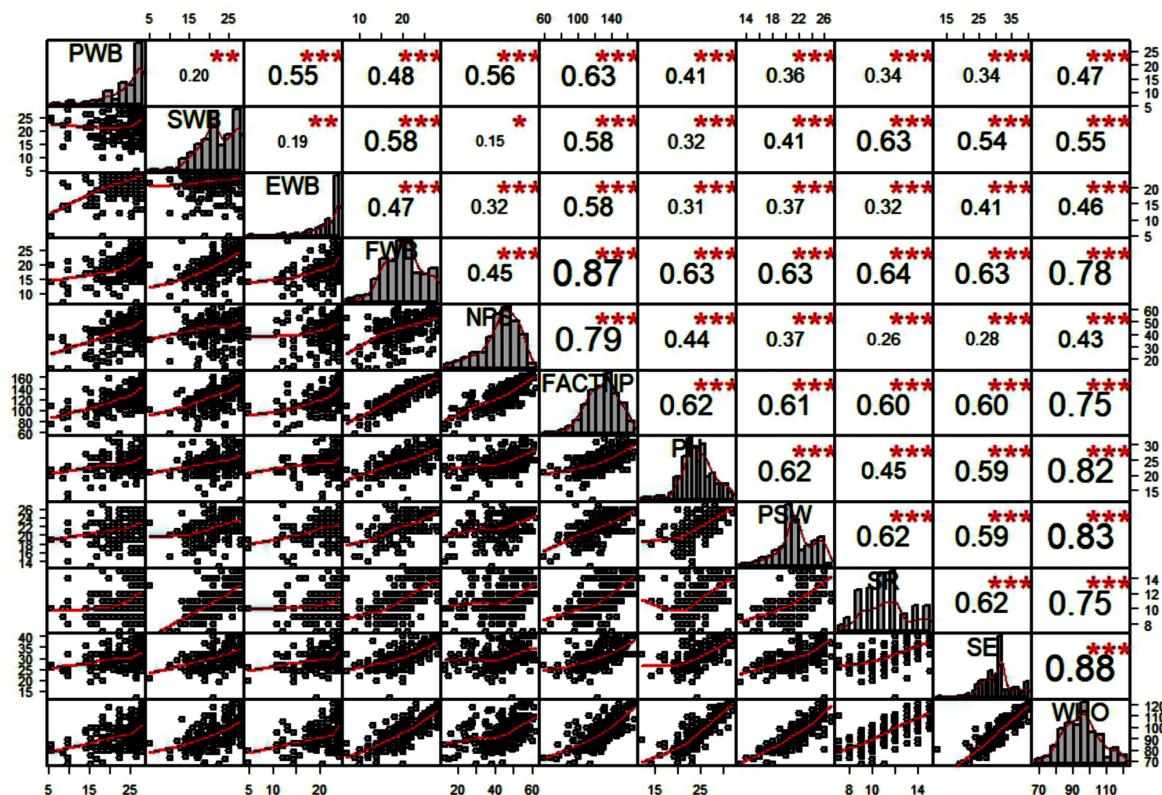
GP=general physical, GS=general social, GE=general emotional, GF=general functional, h2= communality, u2=uniqueness, com=Hoffmann's item complexity

Table 3 Scoring method and Cronbach's alpha coefficients of modified functional assessment of cancer therapy with nasopharyngeal subscale

Subscales	Items	Score range	Cronbach's alpha
Physical well-being	5	0-28	0.82
Social and family well-being	7	0-28	0.88
Emotional well-being	5	0-24	0.85
Functional well-being	7	0-28	0.87
Nasopharyngeal cancer subscales	16	0-64	0.86
Total score	40	0-172	0.92

Validity

Convergent validity: the details of correlation between the domains in the modified FACT-NP and the WHOQOL-BREF are shown in Figure 2. The PWB and EWB had a low positive correlation with each domain in WHOQOL-BREF, but a 0.41 in the PH domain. The SWB had a moderate correlation with the SR and SE domains. The FWB had a moderate positive correlation with each domain of WHOQOL-BREF. The NPS had a low positive correlation with PH and PSW.



The statistic calculated by Spearman's correlation.

*p-value ≤ 0.05, **p-value ≤ 0.01, ***p-value ≤ 0.001, PWB=physical well-being, SWB=social and family well-being, EWB=emotional well-being, FWB=functional well-being, NPS=nasopharyngeal cancer subscales, FACT-NP=functional assessment of cancer therapy with nasopharyngeal cancer subscale, PH=physical health, PSW=psychological well-being, SR=social relationship, SE=satisfaction with the environment and WHO=overall score of abbreviated version of World Health Organization Quality of Life

Figure 2 Correlation matrix between domain in modified functional assessment of cancer therapy with nasopharyngeal cancer subscale and abbreviated version of World Health Organization Quality of Life.

In the known group validity, the discrimination pattern between WHOQOL-BREF and modified FACT-NP in patient characteristics was similar. The details are shown in Table 4.

Table 4 The quality of life score of abbreviated version of World Health Organization Quality of Life and modified functional assessment of cancer therapy with nasopharyngeal cancer subscale classified by patient characteristics (n=220)

Patient characteristics (%)	Quality of life score			
	WHOQOL-BREF		Modified FACT-NP	
	Mean (S.D.)	p-value	Mean (S.D.)	p-value
Age (years)				
≥60 (20.0)	94.2 (13.7)	0.421	125.9 (20.1)	0.559
<60 (80.0)	95.9 (11.4)		128 (21.3)	
Working				
Yes (57.7)	98.5 (11.7)	<0.001	134.1 (19.2)	<0.001
No (42.3)	91.5 (10.9)		118.6 (20.1)	
Economic problem				
Yes (20.5)	92.2 (11.6)	0.031	119 (23.3)	0.002
No (79.5)	96.4 (11.8)		129.7 (19.9)	
Stage				
I (4.1)	98.2 (14.4)	0.011	132 (16.1)	0.002
II (9.1)	98.2 (10.1)		136.2 (19.3)	
III (39.1)	98 (12.1)		131.9 (21.9)	
IV (47.7)	92.8 (11.3)		122 (19.7)	
ECOG performance status				
0–1 (95.0)	96.1 (11.8)	0.003	129.2 (20.1)	<0.001
2–4 (5.0)	85.4 (8.1)		97 (14.6)	
Active treatment				
Yes (37.7)	92.1 (10.5)	<0.001	121 (108.9, 134.1)*	<0.001
No (62.3)	97.6 (12.2)		134 (118.8, 148)*	
Disease status				
Loco-regional disease (31.8)	91.8 (10.5)	<0.001	122.4 (18.5))	<0.001
No evidence of disease (55.5)	98.8 (11.7)		134.2 (19.1)	
Recurrence or metastases (12.7)	90.8 (11.8)		111.4 (23.1)	
Prophylactic percutaneous gastrostomy				
Yes (67.1)	96.3 (11.8)	0.172	129.3 (20.9)	0.069
No (32.9)	94.0 (11.9)		123.9 (20.8)	
Quality of life				
Good (51.4)	102 (98, 110)*	<0.001	141 (132, 152)*	<0.001
Average (48.6)	86 (82, 91)*		(104.2, 125.3)*	

*Median (interquartile range), S.D.=standard deviation, WHOQOL-BREF=abbreviated version of World Health Organization Quality of Life, FACT-NP=functional assessment of cancer therapy with nasopharyngeal cancer subscale, ECOG=Eastern Cooperative Oncology Group, The statistic calculated by Ranksum test, t-test and ANOVA F-test

Discussion

The Thai version of FACT-NP is a nasopharyngeal cancer quality of life questionnaire. It has 39 items and includes 5 domains: PWB, SWB, EWB, FWB and NPS. The questionnaire has excellent internal consistency. Although the construct validity and convergent validity were shown to have a low to moderate correlation with the domain in WHOQOL-BREF, the pattern of differentiation by socioeconomic and clinical characteristic between modified FACT-NP and WHOQOL-BREF is similar.

There had been no developed and validated study of FACT-NP in other languages before. Pattern of factor analysis in this study followed Ding et al.'s study¹³, which performed factor analysis only in the FACT-G part and added the cervical cancer subscale to functional assessment of cancer therapy with cervical cancer subscale (FACT-CX). The cumulative variances were 0.5. In the validation of Thai FACT-G, which was mainly performed in breast cancer patients, it had cumulative variances of 0.56. The factor loading pattern was not the same as the original version of FACT-G. The items GS1: "I feel close to my friends" and GS3: "I get support from my friends" were loaded in FWB instead of SWB. The item GE2: "I am satisfied with how I am coping with my illness" was loaded in FWB instead of EWB.¹² Compared to our study, the cumulative variance is not different. The factor loading in our study had the same pattern as in the Thai version of FACT-G. However, the items were reduced to 24. The GF1: "I am able to work (includes work at home)" had singularity with GF2: "My work (includes work at home) is fulfilling". The other items were dropped during factor analysis. For the total score of FACT-NP, although some items were dropped, our study calculated the total score with reference to the original version. The score in each domain in the modified version will be changed to the original version scale by proportion. Then the total score can be compared to the original FACT-NP in the future.

The reliability of modified FACT-NP is, at least, good. In the original version of FACT-NP, Cronbach's alpha in each domain ranged from 0.84–0.90 and 0.95 for total items. In the FWB domain, the original version had excellent internal consistency, but was only good in the modified version.¹⁴ When compared to the validated Thai FACT-G study, Cronbach's alpha in each domain ranged from 0.75–0.87. The internal consistency was acceptable in SWB and good in the others.¹² Our internal consistency result was good, although there were fewer items.

In the structural evaluation by convergent validity: The modified Thai FACT-NP had a high positive correlation with WHOQOL-BREF. But in the domains it had a low to moderate correlation to WHOQOL-BREF. This result was explained by Yu et al.¹⁵ who performed the validation study of FACT-G in Hong Kong. The results also showed a low correlation between WHOQOL-BREF and FACT-G study. The original version of FACT-NP evaluated convergent validity by using the correlation between FACT-NP and the Quality of Life–Radiation Therapy Instrument–Head and Neck companion module (QOL-RT-H&N which was a cancer specific questionnaire). The original FACT-NP had a high positive correlation with total QOL-RT-H&N score. However, in general, QOL and socio-economic domains had a high positive correlation and moderate correlation with the FWB domain, respectively. The functional and head-and-neck domains had a high positive correlation with the NPS domain. The emotional domain also had a moderate positive correlation with NPS domain.¹⁴ These results explain that the quality of life questionnaire did not measure the same aspects of general health as the cancer specific questionnaire. Thus, carefully consideration is necessary when choosing the questionnaire.

Although the discriminative pattern between modified FACT-NP and WHOQOL-BREF were the same, the difference of QOL scores in financial burden, treatment

status and disease stage results in our study were also similar to the original Thai FACT-G.¹² Two previous prospective randomized studies showed that prophylaxis percutaneous gastrostomy in head and neck cancer improved 6-month QOL after treatment. From 173 cases, there were only 2 cases of nasopharyngeal carcinoma patients in the reactive gastrostomy arm.^{16,17} The benefit of prophylactic percutaneous gastrostomy in nasopharyngeal carcinoma is unknown. The modified FACT-NP showed that patients who have undergone prophylactic percutaneous gastrostomy tend to have better QOL. These results indicate that general health related quality of life, disease specific quality of life, and cancer specific quality of life had a common ability to differentiate patients with financial burdens, treatment status, and disease stage. The specific issues which influence QOL in nasopharyngeal cancer, such as dry mouth, hearing loss and dysphagia, were not included in this study. The benefits of the cancer specific quality of life questionnaire could not be seen in the study. Modified FACT-NP is an option in quality of life measurement in nasopharyngeal cancer. The FACT-NP is available on <https://www.facit.org>.

There are some limitations: First, this study was a cross-sectional study. The other properties of the cancer specific questionnaire, such as responsiveness were not determined. Second, type of radiation therapy technique was not considered in the study. Radiation technique influences nasopharyngeal cancer patient QOL, although many studies have shown that intensity modulated radiotherapy technique (IMRT) can reduce radiation toxicities with better QOL outcomes than the conventional or three-dimension radiotherapy technique.¹⁸⁻²⁰ At the time of this study, IMRT was not routinely performed in nasopharyngeal cancer patients in our institution.

Conclusion

The Thai modified FACT-NP was found to be both valid and reliable for measuring quality of life in nasopharyngeal carcinoma patients.

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Conflict of interest

The authors declare that there is no conflict of interest regarding the publication of this article.

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