Validation of the Simplified Chinese Version of FACT-Hep for Patients with Hepatocellular Carcinoma Based on Combinations of Classical Test Theory and Generalizability Theory

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Abstract

Background

Quality of life (QOL) is now concerned worldwide in cancer clinical fields and the specific instrument FACT-Hep (Functional Assessment of Cancer Therapy- Hepatobiliary questionnaire) is widely used in English-spoken countries. However, the specific instruments for hepatocellular carcinoma patients in China were seldom and no formal validation on the Simplified Chinese Version of the FACT-Hep was carried out. This study was aimed to validate the Chinese FACT-Hep based on Combinations of Classical Test Theory and Generalizability Theory.

Methods

The Chinese Version of FACT-Hep and the QLICP-LI were used to measure QOL three times before and after treatments from a sample of 114 in-patients of hepatocellular carcinoma. The scale were evaluated by indicators such as validity and reliability coefficients Cronbach $\alpha$, Pearson r, intra-class correlation (ICC), and standardized response mean. The Generalizability Theory (G theory) was also applied to addresses the dependability of measurements and estimation of multiple sources of variance.

Results

The Internal consistency Cronbach's $\alpha$ coefficients were greater than 0.70 for all domains, and test-retest reliability coefficients for all domains and the overall were greater than 0.80 (exception of emotional Well-being 0.74) with the range from 0.81 to 0.96. G-coefficients and $\Phi$-coefficients confirmed the reliability of the scale further with exact variance components. The domains of PWB, FWB and the overall scale had significant changes after treatments with SRM ranging from 0.40 to 0.69.

Conclusions

The Chinese version of FACT-Hep has good validity, reliability, and responsiveness, and can be used to measure QOL for patients with hepatocellular carcinoma in China.

Background

Hepatocellular carcinoma (HCC)/liver cancer is a severe disease with a marked heterogeneous geographical distribution in the world, with being the fifth most common of all malignancies and causes approximately one million deaths annually [1–4]. The highest incidence rates are in eastern and south-eastern Asia, western and central Africa [1]. It was estimated by International Agency for Research on Cancer (IARC) that there are 564,000 cases of liver cancer in the year 2000 in the world and 55% (306,000) are in China [5]. Besides, the survival rate remains poor over the past decades, with overall one
year survival being less than 20% [6–7]. Therefore, researchers and clinicians tend to pay more attention
to quality of life (QOL) of patients with HCC because of long course and difficulty in curing of the disease.
In the recent 20 years, the assessments of QOL have been applied as significant outcomes for patients
with HCC [2, 8–10]. And thus the several specific instruments have been developed such as the
Functional Assessment of Cancer Therapy (FACT) Hepatobiliary (FACT-Hep) questionnaire [11, 12], the
QLQ-HCC18 from European Organization for Research and Treatment of Cancer (EORTC) Quality of Life
Group [13, 14], the National Comprehensive Cancer Network Functional Assessment of Cancer Therapy
(NCCN-FACT) Hepatobiliary-Pancreatic Symptom Index (NFHSI)[15], the Nine-Item Chinese Patient
 Satisfaction Questionnaire (ChPSQ-9)[16], and the Quality of Life Instrument for Patients with Liver
Cancer QOL-LC[17, 18]. Of them, the FACT-Hep is a 45-item self-report instrument developed specifically to
measure QOL in patients with not only HCC but also pancreatic, biliary and metastatic liver cancer [11,
12].

There is very few QOL instruments developed and applied among Chinese general population, which is
the largest population in the world. In particular, the QOL instruments developed for liver cancer is scarce.
Therefore, the Simplified Chinese version of FACT-Hep (V4.0) for HCC was developed by the Center on
Outcomes, Research and Education (CORE). However, the formal validation of this scale was not carried
out when used in mainland China. Our study is aimed to evaluate the psychometric properties, especially
the validity, of FACT-Hep (V4.0) for HCC in mainland China. Due to the lack of a gold standard, we used
the QLICP-LI (Quality of Life Instruments for Cancer Patients-Liver cancer) developed by our research
group [19] in the present study in order to evaluate the criterion-related validity. The QLICPs (Quality of
Life Instruments for Cancer patients) is a Chinese QOL instruments system developed by module
approach with a general module (QLICP-GM) being used for all types of cancer, and different specific
modules for different cancers [20–24]. For example, the QLICP-CR is formed by combining the QLICP-GM
and the specific module of the colorectal cancer [21]. Similarly, the QLICP-BR, QLICP-HN, QLICP-LU are
formed by QLICP-GM and the specific modules of the breast cancer, head and neck cancer, and lung
cancer respectively [22–24].

**Methods**

**Instruments And Scorings**

Like the original one, the simplified Chinese version of FACT-Hep (V4.0) consists of two parts: the general
module on all cancers (FACT-G) and the additional concerns on HCC-specific module (HCS). The FACT-G
includes four domains, i.e. 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). It assesses symptoms and
other QOL concerns. The HCS is an 18-item, disease-specific hepatobiliary cancer subscale. It assesses
back and stomach pain, gastrointestinal symptoms, anorexia, weight loss and jaundice in patients with
hepatobiliary cancers.
Each item in FACT-Hep is rated in a five-point Likert-type scale (from 0–4 points) and gotten directly score of 0–4 for positively-stated items. The scores of negatively-stated items were reversed. We summed up the scores of items under specific domains to obtain the domain score, and then summed up the five domain scores to obtain the overall scale score [11, 12]. In this way, the higher score indicates better QOL.

The structure and scoring method of QLICP-LI(V2.0) is very similar to FACT-Hep [19], which consists of a general module (QLICP-GM) and a 12-items disease-specific domain (SLI1-SLI12). The QLICP-GM includes four domains with 32 items: physical 8 items (GPH1-GPH8), psychological 9 items (GPS1-GPS9), social 8 items (GSO1-GSO8), and common symptoms and side-effects of cancers 7 items (GSS1-GSS7). The domain score was obtained by summing up the score of each item in this domain, and the overall score was obtained by summing up the five domain scores. All domains/overall scores of the instrument were linearly converted to a 0-100 scale using the formula: $SS = (RS - Min) \times 100/R$, where SS, RS, Min and R represent the standardized score, raw score, minimum score, and range of scores, respectively. Similar to FACT-Hep, higher score indicates better QOL in QLICP-LI(V2.0).

**Data Collection**

This study recruited inpatients diagnosed with HCC at the Yunnan Tumor Hospital (the third affiliated hospital of Kunming Medical University). The study protocol and the informed consent form were approved by the IRB (institutional review board) of the investigators’ institutions and the hospital. The inclusion criterion is that the patients were capable to read and understand the questionnaires because the questions were about their self-perceived and subjective evaluation of QOL. The investigators explained the study and scales to the HCC inpatients at any stages and treatments. Finally, 114 HCC inpatients who met with the criteria gave their consent to participate in our study.

Participants completed the questionnaire when they were admitted to the hospital, and discharged after approximately 4 weeks of treatments to evaluate the responsiveness of questionnaire. Some patients with stable disease course were asked to complete the questionnaire again in one or two days after hospitalization to assess test-retest reliability of the simplified Chinese version of FACT-Hep.

**Data analysis**

The validity, reliability, and responsiveness of the simplified Chinese version of the FACT-Hep were evaluated.

The construct validity indicates the scale structures of FACT-Hep. In the present study, we evaluated item convergent and discriminant validity, which represented the construct validity, by using the multi-trait scaling analyses. [25] Pearson correlations was applied to exam the item-domain (subscale) correlations. The correlations were interpreted according to these two criteria: (1) convergent validity is supported when an item-domain correlation is 0.40 or greater; (2) discriminant validity is revealed when item-domain correlation is higher than that with other domains.
The criterion-related validity was evaluated by correlating corresponding domains of the two instruments FACT-Hep and QLICP-LI for lack of gold standard. Relatively high correlations among conceptually-related domains and relatively low correlation among conceptually-distinct domains would suggest high criterion-related validity. Also these correlation analyses with QLICP-LI can reveal convergent and discriminant validity to some extent.

The internal consistency of each domain was estimated by Cronbach's alpha coefficient. It was calculated based on data collected at the first measurement because of the relatively large sample size. If an alpha coefficient is greater than 0.7, it indicates an acceptable reliability[26]. The test-retest reliability is defined as the absolute for a single measure under two-way mixed model [27] between the first and second assessments, assessing by the Pearson's correlation and intra-class correlation (ICC).

Besides, we also applied Generalizability Theory (G theory) to investigate the score dependability of the FACT-Hep, which addresses the dependability of measurements and the simultaneous estimation of multiple sources of variance including interactions [28–30]. We employed a random effects design for both the G-study and D-study in measurement mode to estimate the variance components and dependability coefficients using a one-facet crossed design: persons (p) by items (i), represented as p x i, where the patients as the object of measurement and not a source of error and not considered a facet, but the items as one facet of measurement error. The variance components of generalizability coefficients (G-coefficients) and dependability indexes (Φ-coefficients) in each facet (items in this paper), as well as their interactions were calculated for the G-study. In the D-study, coefficients (G-coefficients and Φ-coefficients) were calculated from the object of measurement (p) and items (i), with G-coefficients being used to determine the ratio of universe-score variance to expected observed-score variance, while Φ-coefficients being calculated for absolute decisions. The different designs were created through changing measurement facet for items (p x i) for the D-study.

With regard to internal responsiveness, it was assessed by comparing the mean difference between the first and third assessments (pre-treatment and post-treatment) by paired t-tests. We calculated the standardized response mean (SRM) and effect size (ES) [31, 32]. SRM is the difference of the score between pre-treatment and post-treatment divided by its standard deviation and the ES is divided by the pre-treatment standard deviation.

Results

Socio-demographic And Clinical Characteristics Of Participants

The total sample included 114 inpatients with HCC. The mean age was 51 years (SD: 10; range: 31–73 years). About 80% of patients were male; the majority (96.5%) were married; 80% with Han ethnic background and more than 70% of patients had hepatitis history. The distributions of occupations were worker 14 cases (12.3%), farmer 41 (36.0%) and others 59 (51.7%). Regarding the educational level, 37
(32.5%) patients finished primary school, while 64 (56.1%) completed high school of professional secondary school, and 13 (11.4%) had a college degree. Regarding the treatments, 16 cases (14.0%) had surgery; 69 (60.5%) had minimally invasive treatments; and 29 (25.5%) had other treatments.

**Construct Validity**

Table 1 shows the correlation between items and domains of the FACT-Hep. All correlation coefficients $r$ were higher than 0.40 and most of them higher than 0.60 (exception of a few items of HCS such as Hep1, Hep2, Hep4 with HCS domain), which indicates strong correlations between items and their relevant domains and suggests a good item convergent validity. Additionally, there were weak correlations between items and non-relevant domains, which indicates a good discriminant validity. For example, the coefficients between domain of FWB and items within this domain (GF1-GF7) were higher than 0.70, higher than the correlation between the domain and any other items in other domains.
| Item | PWB  | SWB  | EWB  | FWB  | HCS  | Total |
|------|------|------|------|------|------|-------|
| GP1  | 0.66 | 0.08 | 0.34 | 0.53 | 0.48 | 0.57  |
| GP2  | 0.42 | 0.06 | 0.13 | 0.24 | 0.38 | 0.36  |
| GP3  | 0.72 | 0.15 | 0.22 | 0.39 | 0.36 | 0.49  |
| GP4  | 0.64 | 0.23 | 0.30 | 0.41 | 0.46 | 0.55  |
| GP5  | 0.62 | 0.00 | 0.16 | 0.35 | 0.36 | 0.42  |
| GP6  | 0.71 | 0.23 | 0.54 | 0.36 | 0.45 | 0.58  |
| GP7  | 0.69 | 0.19 | 0.31 | 0.43 | 0.38 | 0.53  |
| GS1  | 0.02 | 0.68 | 0.04 | 0.17 | 0.09 | 0.24  |
| GS2  | 0.05 | 0.71 | 0.01 | 0.15 | 0.05 | 0.23  |
| GS3  | 0.06 | 0.79 | 0.03 | 0.17 | 0.10 | 0.28  |
| GS4  | 0.24 | 0.72 | 0.43 | 0.50 | 0.35 | 0.56  |
| GS5  | 0.23 | 0.72 | 0.38 | 0.40 | 0.32 | 0.51  |
| GS6  | 0.24 | 0.67 | 0.15 | 0.34 | 0.30 | 0.45  |
| GS7  | 0.36 | 0.61 | 0.12 | 0.28 | 0.34 | 0.45  |
| GE1  | 0.29 | 0.19 | 0.67 | 0.40 | 0.42 | 0.50  |
| GE2  | 0.28 | 0.33 | 0.44 | 0.30 | 0.31 | 0.42  |
| GE3  | 0.40 | 0.07 | 0.42 | 0.31 | 0.27 | 0.37  |
| GE4  | 0.15 | 0.02 | 0.59 | 0.07 | 0.19 | 0.22  |
| GE5  | 0.18 | 0.10 | 0.62 | 0.17 | 0.18 | 0.23  |
| GE6  | 0.27 | 0.23 | 0.53 | 0.06 | 0.10 | 0.24  |
| GF1  | 0.56 | 0.28 | 0.25 | 0.80 | 0.49 | 0.66  |
| GF2  | 0.47 | 0.29 | 0.23 | 0.77 | 0.43 | 0.60  |
| GF3  | 0.40 | 0.27 | 0.19 | 0.79 | 0.43 | 0.59  |
| GF4  | 0.30 | 0.39 | 0.37 | 0.59 | 0.39 | 0.54  |
| GF5  | 0.44 | 0.23 | 0.35 | 0.70 | 0.57 | 0.65  |

PWB : Physical Well-being, SWB : Social / Family Well-being, EWB : Emotional Well-being, FWB : Functioning Well-being, HCS : Additional Concerns for HCC
| Item   | PWB | SWB | EWB | FWB | HCS | Total |
|--------|-----|-----|-----|-----|-----|-------|
| GF6    | 0.45| 0.35| 0.30| **0.79** | 0.53 | 0.67  |
| GF7    | 0.41| 0.20| 0.23| **0.70** | 0.40 | 0.54  |
| C1     | 0.27| 0.17| 0.26| 0.32 | 0.57 | 0.48  |
| C2     | 0.23| 0.17| 0.09| 0.25 | 0.42 | 0.36  |
| C3     | 0.24| 0.08| 0.30| 0.26 | 0.47 | 0.40  |
| C4     | 0.34| 0.13| 0.33| 0.40 | 0.64 | 0.55  |
| C5     | 0.22| 0.07| 0.15| 0.18 | 0.42 | 0.30  |
| C6     | 0.39| 0.17| 0.25| 0.47 | 0.66 | 0.58  |
| Hep1   | 0.24| 0.00| 0.17| 0.09 | 0.36 | 0.26  |
| CNS7   | 0.33| 0.15| 0.22| 0.27 | 0.39 | 0.39  |
| CX6    | 0.18| 0.20| 0.08| 0.27 | 0.39 | 0.34  |
| HI7    | 0.51| 0.38| 0.45| 0.62 | 0.58 | 0.69  |
| An7    | 0.53| 0.28| 0.25| 0.68 | 0.54 | 0.64  |
| Hep2   | 0.12| 0.10| 0.06| 0.08 | 0.28 | 0.21  |
| Hep3   | 0.31| 0.10| 0.17| 0.22 | 0.58 | 0.44  |
| Hep4   | 0.06| 0.01| 0.04| 0.00 | 0.21 | 0.10  |
| Hep5   | 0.40| 0.17| 0.21| 0.36 | 0.63 | 0.54  |
| Hep6   | 0.36| 0.08| 0.19| 0.16 | 0.48 | 0.38  |
| HN2    | 0.32| 0.24| 0.21| 0.33 | 0.58 | 0.51  |
| Hep8   | 0.36| 0.15| 0.25| 0.31 | 0.48 | 0.45  |

PWB : Physical Well-being, SWB : Social / Family Well-being, EWB : Emotional Well-being, FWB : Functioning Well-being, HCS : Additional Concerns for HCC

**Criteria-related Validity**

Table 2 presents the Pearson correlation coefficients between domains of FACT-Hep and QLICP-LI. The correlation coefficients of relevant domains in these two instruments were higher than those of non-relevant domains. For example, the correlation between EWB of FACT-Hep and PSD of QLICP-LI was 0.53, higher than other any correlations in this row. The correlations of HCS in FACT-Hep with SSD and SPD in QLICP-LI were 0.74 and 0.75 respectively. The correlation between total scores of FACT-Hep and QLICP-LI was 0.86.
Table 2
Correlation coefficients among domains of FACT-Hep and QLICP-LI (n = 114)

| FACT-Hep                                | QLICP-LI | PHD | PSD | SOD | SSD | SPD | TOT |
|-----------------------------------------|----------|-----|-----|-----|-----|-----|-----|
| Physical Well-being (PWB)               |          | 0.62| 0.41| 0.44| 0.64| 0.42| 0.70|
| Social / Family Well-being (SWB)        |          | 0.30| 0.21| 0.12| 0.26| 0.26| 0.33|
| Emotional Well-being (EWB)              |          | 0.28| 0.53| 0.18| 0.30| 0.38| 0.48|
| Functioning Well-being (FWB)            |          | 0.70| 0.44| 0.27| 0.61| 0.51| 0.73|
| Additional Concerns (HCS)               |          | 0.71| 0.39| 0.25| 0.74| 0.75| 0.82|
| Overall Scales (Total)                  |          | 0.76| 0.50| 0.33| 0.74| 0.68| 0.86|

Reliability From Classical Test Theory

Table 3 shows the Cronbach’s α and test-retest reliability coefficients (correlation coefficients r and ICC) of all domains. 63 inpatients completed the questionnaires that were used for test-retest reliability analysis. The paired t-tests indicated that there was no statistically significant change in domain scores between the first and the second assessments (p > 0.05), indicating equal traits and suitable conditions for test-retest reliability. Cronbach's α coefficients of all domains were greater than 0.70. Both correlation coefficients r and ICC for all domains were larger than 0.80 exception of EWB (0.74).
Table 3
Reliability of the Chinese version of FACT-Hep ($n = 114$ for $\alpha$, $n = 63$ for $r$ and ICC)

| Domains(subscales/items) | Internal consistency (Cronbach's $\alpha$) | Test-retest reliability * (Correlation coefficients $r$) | Test-retest reliability (ICC and 95% CI) |
|--------------------------|--------------------------------------------|--------------------------------------------------------|----------------------------------------|
| Physical Well-being(PWB) | 0.76                                       | 0.89                                                   | 0.89 (0.82–0.93)                       |
| Social / Family Well-being(SWB) | 0.81                          | 0.81                                                   | 0.81 (0.70–0.88)                       |
| Emotional Well-being(EWB) | 0.72                                       | 0.74                                                   | 0.73 (0.59–0.83)                       |
| Functioning Well-being(FWB) | 0.85                                      | 0.92                                                   | 0.92 (0.86–0.95)                       |
| General module (FACT-G) | 0.89                                       | 0.93                                                   | 0.93 (0.88–0.96)                       |
| Additional Concerns(HCS) | 0.81                                       | 0.96                                                   | 0.96 (0.93–0.98)                       |
| Overall Scale (Total)    | 0.92                                       | 0.95                                                   | 0.95 (0.92–0.97)                       |
| Trial Outcome Index (TOI) | 0.90                                       | 0.96                                                   | 0.96 (0.94–0.98)                       |

* All correlation coefficients are statistically significant ($p < 0.05$). ICC: intra-class correlation, CI: confidence interval

Reliability From Generalizability Theory

Table 4 showed the estimated $G$ study results based on the $p \times i$ design, in which 114 patients filled out the 45 items of FACT-Hep. For most domains, the largest source of variance was due to item, such as 90.25% in PWB, 91.11% in SWB, 97.66% in EWB, 85.78% in HEPCS. $D$ studies were performed to estimate the $G$-coefficients and $\Phi$-coefficients for the $p \times i$ design, as well as the alternative design with different numbers of items in the five domains (see Table 5 in detail), with PWB ranging from 6 to 13, SWB and FWB from 6 to 10, EWB from 6 to 18, and HCS from 13 to 28. Generally, the $G$ coefficients and $\Phi$ coefficients increased as the number of items in each domain increased. Under the current designs, the $G$ and $\Phi$ coefficients were higher or close to 0.70 in four out of five domains, except for EWB. In addition, Table 5 showed the effects of the various levels of items (from 6 to 22) on reliability with $G$ ranging from 0.517 to 0.888, and $\Phi$ ranging from 0.335 to 0.883.
Table 4
The estimated variance components and percentage of variance accounted for by effects (percent) for p × i design in G-study for four domains of quality of life instrument FACT-Hep()

| Domain | $p$(person) Variance component | Percent (%) | $i$(item) Variance component | Percent (%) | $p\times i$ Variance component | Percent (%) |
|--------|--------------------------------|-------------|------------------------------|-------------|--------------------------------|-------------|
| PWB()  | 2.011                          | 7.83        | 23.168                       | 90.25       | 0.493                          | 1.92        |
| SWB()  | 2.047                          | 7.49        | 24.887                       | 91.11       | 0.382                          | 1.40        |
| EWB()  | 0.997                          | 1.58        | 61.626                       | 97.66       | 0.482                          | 0.76        |
| FWB    | 3.508                          | 47.40       | 3.357                        | 45.36       | 0.536                          | 7.24        |
| HCS()  | 3.536                          | 11.93       | 25.418                       | 85.78       | 0.677                          | 2.28        |

$p$: person effect, $i$: item effect, $p\times i$: person-by-item interaction effect

Due to technical limitations, Table 5 is provided in the Supplementary Files section.

**Responsiveness**

68 patients completed the questionnaires with regard to evaluation of responsiveness at the third assessment. As shown in Table 6, the scores of SRM regarding PWB and FWB were 0.69 and 0.40 ($p < 0.05$) indicate the statistically significant changes after treatments. In addition, the score changes in the general module, the overall scale and Trial Outcome Index were statistically significant with SRM being 0.56, 0.46 and 0.40, and ES being 0.50, 0.47 and 0.30 respectively.
Table 6
Responsiveness of FACT-Hep for patients with cancer (n = 68)

| Domains (subscales) | Pre-treatment Mean SD | Post-treatment Mean SD | Differences Mean SD | t   | p    | SRM | ES  |
|---------------------|-----------------------|------------------------|---------------------|-----|------|-----|-----|
| Physical Well-being | 22.49 3.88            | 19.34 4.22             | 3.15 4.54           | 5.72| 0.000| 0.69| 0.81|
| Social/Family Well-being | 20.90 3.77            | 20.63 3.56             | 0.27 2.75           | 0.81| 0.419| 0.10| 0.07|
| Emotional Well-being | 18.68 2.68            | 18.25 2.67             | 0.43 2.77           | 1.27| 0.209| 0.15| 0.16|
| Functional Well-being | 17.35 5.12            | 15.56 4.13             | 1.79 4.44           | 3.33| 0.001| 0.40| 0.35|
| General module      | 79.42 11.19           | 73.78 11.04            | 5.64 10.11          | 4.60| 0.000| 0.56| 0.50|
| Additional Concerns | 58.43 7.57            | 57.78 7.09             | 0.65 5.54           | 0.96| 0.339| 0.12| 0.09|
| Overall Scale       | 137.84 17.20          | 131.56 16.47           | 6.29 13.71          | 3.78| 0.000| 0.46| 0.37|
| Trial Outcome Index | 98.26 14.14           | 92.68 13.05            | 5.59 11.28          | 4.09| 0.000| 0.50| 0.40|

SD: standard deviation, SRM: standardized response mean, ES: effect size

Discussions
The present study shows that the Simplified Chinese Version of FACT-Hep has relatively good psychometric properties, that is, validity, reliability and responsiveness among Chinese patients with hepatocellular carcinoma. Compared with the original version of FACT-Hep, our study shows that the Chinese version had comparably good validity, and reliability [11]. The Cronbach’s α coefficient of the Chinese version of the FACT-Hep ranged from 0.72 to 0.90, which is similar to the range of the result of original scale (i.e. 0.72 to 0.94). The test-retest reliability indicators of the Chinese version of the FACT-Hep (i.e. correlation range: 0.74 to 0.96; intra-class correlation coefficient range: 0.73 to 0.96) are also similar to those of the original one (i.e. correlation range: 0.84 to 0.91; intra-class correlation coefficient range: 0.82 to 0.90). However, our findings showed that test-retest reliability for the EWB was lower than that of the original one both in Pearson r (0.74) and ICC (0.73). It is needed further study to find the reasons. One possible reason is they validated original scale in only 51 patients and thus the results on test-retest reliability may not be reliable.

The validity is the most important psychometric property because it can capture what it intends to measure. Our findings confirmed the construct validity and criterion-related validity of the FACT-Hep. Almost all item-domain correlation coefficients met the standards of item convergent validity and discriminant validity. Overall the correlations between relevant domains of FACT-Hep and QLICP-LI were higher than those between non-relevant domains. These correlations supported the criterion-related validity and also demonstrated the domains’ convergent validity and divergent validity.

In addition, we have applied the traditional classical test theory analysis as well as the Generalizability Theory to the present study. Both G-coefficients and Φ-coefficients were presented. G- and Φ-coefficients changes as the items are assumed to change. It can be seen from Table 5 that G-coefficients and index of dependability were all greater than or close to 0.70 for the current design, and changed a little as items changes for four out of five domains (exception of EWB). Therefore, current items are considered to be reasonable and acceptable for these domains. Regarding the EWB domain, we estimated a G-coefficient of 0.517 and an index of dependability of 0.335 for the current design, which was below the acceptable level of 0.70. Hence, the domain’s items need to be improved. Regarding an alternative design with 13 items, the G-coefficient estimated to be 0.699. Therefore, it will be better to increase the numbers of items of EWB in order to achieve an acceptable dependability. To sum up, the analysis from Generalizability Theory confirmed the reliability of the scale further. However, the numbers of items for EWB domain should be increased in order to obtain better reliability if possible.

In terms of responsiveness, we assessed the score changes between the pre-treatment and post-treatment assessments by the classical paired t-test as well important indicators, SRM and ES. Our study shows moderate and large responsiveness regarding PWB, FWB, the general module and overall scale, which supports for the good responsiveness of Chinese version of FACT-Hep. Additionally, we found some domains not statistically significant in our study, which may be explained by these two reasons: (1) the observation period (about four weeks) might be too short to observe significant changes; (2) the score in these domains are of no change in nature. Regarding HCC domain, another possible reason is that
some patients would become better after treatments and some patients become worse, and thus no change can be found when we pooled all patients scores together.

Though our study showed the Chinese version of FACT-Hep is a reliable and valid instrument, some limitations should be mentioned. First, nearly half of the participants did not complete the third assessment because they were not in the wards when the investigators attempted to interview with them at the appointed times, because of a variety of reasons (e.g., going to other departments for treatments, being discharged early for financial reasons). This may have some influence on the responsiveness evaluation. If these events happened randomly, it might be slight. Second, the participants were selected only from inpatients admitted to hospital. We recommended testing the psychometric properties of the instrument in other populations, such as outpatients at clinic visits.

Conclusions

Our study shows that the Chinese version of FACT-Hep has good validity, reliability, and responsiveness. It can be used to measure QOL for patients with hepatocellular carcinoma in Mainland China. However, the responsiveness needs to be tested in other settings such as outpatients at clinics, and in larger sample.

Abbreviations

ChPSQ-9: the Nine-Item Chinese Patient Satisfaction Questionnaire; EORTC: European Organization for Research and Treatment of Cancer; FACT-Hep: Functional Assessment of Cancer Therapy- Hepatobiliary; HCC: Hepatocellular carcinoma; ICC: intra-class correlation; NFHSI: the National Comprehensive Cancer Network Functional Assessment of Cancer Therapy Hepatobiliary-Pancreatic Symptom Index; QOL: Quality of life; QLICP-LI: Quality of Life Instruments for Cancer Patients-Liver cancer; SRM: Standardized response mean.

Declarations

Ethics approval and consent to participate

The study protocol was approved by the Institutional Review Board (IRB) of the investigators’ institutions and the hospitals (IRB of the first Affiliated Hospital of Guangdong Medical University, PJ2012052). The respondents were voluntary and provided consent for participation.

Consent to publish

The authors understand and agree to publish.

Availability of data and materials

The data can be available by request.
Competing interests
The authors declare that they have no competing interests.

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Authors' contributions
CW PGL and ZY designed the study. QM, WL, YLC, GL performed the data collection and JQO,ZY and CW performed data analyses. CW and ZY wrote the first draft, which was critically revised by all others. All authors have read and approved the final manuscript.

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