Brief Methodological Report

Cross-Cultural Adaptation and Psychometric Validation of the French Version of the FAMCARE-Patient (FFP-16) Questionnaire for Outpatients With Advanced-Stage Cancer

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Abstract

Context. Satisfaction is known to be correlated with the quality of care; it indicates the adequacy of the caregivers' responses in meeting the needs and expectations of patients. The FAMCARE-Patient questionnaire has been used to quantify satisfaction level in outpatients with advanced-stage cancers.

Objectives. To translate and cross-culturally adapt the FAMCARE-Patient questionnaire for French patients and to evaluate the psychometric properties of this version.

Methods. The original questionnaire was translated into French and adapted to French cultural context by an expert committee. The French FAMCARE-Patient Version 16 (FFP-16) was then pilot tested among 51 patients. Subsequently, psychometric properties were evaluated in a cross-sectional study by administrating the new tool to 176 adult outpatients with advanced-stage cancer who underwent oncological care at our university hospital.

Results. We performed a confirmatory factor analysis and assessed the reliability and validity of the questionnaire. The one-factor structure was confirmed, and it had an acceptable fit with a comparative fit index and root mean square error of approximation of 0.93 and 0.07, respectively. Internal reliability was high as shown by Cronbach's alpha ($\alpha = 0.95$). Reproducibility was very good (intraclass correlation coefficient 0.91). The FFP-16 score was independent of the Eastern Cooperative Oncology Group and the overall Edmonton Symptom Assessment Scale distress scores. It was significantly but weakly correlated with anxiety, well-being, and overall quality of life (Spearman's correlation coefficient = −0.18, −0.20, and 0.30, respectively; $P < 0.05$).

Conclusion. We found the FFP-16 questionnaire to be a reliable and valid instrument for the assessment of satisfaction in French outpatients with advanced-stage cancer. J Pain Symptom Manage 2020;■:■−■. © *2020 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words

Satisfaction, questionnaire, cancer, cross-cultural, validation, psychometric

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Accepted for publication: February 12, 2020.

0885-3924/$ - see front matter
https://doi.org/10.1016/j.jpainsymman.2020.02.007

Key Message

Assessment of satisfaction is necessary to evaluate the quality of care. The FAMCARE-Patient questionnaire has been used to quantify satisfaction level in outpatients with advanced-stage cancer. We translated and cross-culturally adapted this questionnaire for French patients. Psychometric properties are good and allow its use in clinical or research context in France.

Background

The quality of care indicates the adequacy of caregivers' responses in satisfying the needs and expectations of patients.[1] Using a sample of 2249 American patients, Jenkinson et al.[2] identified three areas of patient care that influence satisfaction: physical comfort and symptom management; emotional support and caregivers' availability, and respecting the patient's wishes and his/her place in decision making. In advanced stages of a serious illness, satisfaction level is known to be correlated to the quality of life[3] and quality of dying,[4] which includes accessibility, symptom management, emotional support, coordination and personalization of care, communication and education, and finally active participation in decision making.[5,6]

The FAMCARE-Patient scale or FAMCARE-P16 questionnaire[7,8] is the only satisfaction assessment tool specifically designed for outpatients with advanced-stage cancers. It is a self-administrated survey that was constructed on the basis of the 20-item FAMCARE measure for family satisfaction with care.[9] It is structurally composed of 16 items, cohered into a single patient satisfaction factor. Each item is evaluated using a five-point Likert scale (one to five; one [very dissatisfied]; five [very satisfied]), with a total score ranging from 16 to 80. Patients with an individual score of ≥64 are considered to be generally satisfied because this cutoff value is associated with a rating of four (satisfied) on all 16 items. This tool demonstrated high internal reliability, and patient satisfaction can be modified accordingly by a palliative care intervention.[10–12]

In French, there is currently no tool dedicated to the assessment of satisfaction in outpatients with advanced-stage cancers. This entails the use of nonvalidated and heterogeneous measurement tools in this population. The aim of our study was to cross-culturally adapt the FAMCARE-Patient questionnaire for the French population and to subsequently perform a psychometric validation of this French version.

Methods

Cross-Cultural Adaptation Process

The FAMCARE-P16 questionnaire was translated into French following standard recommendations.[13] Forward-backward translations were performed by four people—two native English speakers and two native French speakers—fluent in French and English. The backward translation was compared with the original version by the author herself. The forward semantic translated version was adapted to French cultural context and lifestyle by an expert committee with oncology and palliative care physicians and nurses, psychologists, anthropologist, and linguistic researchers and methodologists as members. A prefinal version was pilot tested using cognitive debriefing interviews to evaluate the acceptability and comprehension of each item. Modifications were made according to patients' comments, and the final version of the French FAMCARE-Patient Version 16 (FFP-16) questionnaire was validated by the expert committee.

Psychometric Validation Process and Analyses

Design. This was a single-center, cross-sectional, and observational study specifically designed to validate the FFP-16 questionnaire. All procedures performed in the study were in accordance with the ethical standards of the institutional research committee (Committee for the Protection of Persons consenting to biomedical research, no. 2015-S15). This study was registered in the European trial register (EudraCT no. 2015-A01707-42).

Patients. Informed consent was obtained individually from all participants included in the study. The inclusion criteria were the same as those for the validation of the original English version: diagnosis of an advanced-stage cancer, that is metastatic gastrointestinal, genitourinary, breast, lung, or gynecological cancer (for lung cancer, Stages IIIA and B were included; patients with metastatic breast or prostate cancer who were refractory to hormonal therapy and those with locally advanced pancreatic cancer were included); older than 18 years; native French speakers; and ambulatory patients with an Eastern Cooperative Oncology Group (ECOG) performance status of 0–2. ECOG score is provided on a six-point scale (zero to five; zero [fully active]; five [dead]) that assesses the patient's ability for self-care and ambulation.

Patients were all recruited from the outpatient clinic or chemotherapy day hospital of the University Hospital of Tours (France).

Questionnaires and Data Collection. During the psychometric validation process, two other questionnaires were selected in addition to the FFP-16 questionnaire. Patients completed all questionnaires, that is, self-administrated FFP-16 questionnaire, the French versions of the Quality-of-Life in palliative cancer care (QLQ-C15-PAL) questionnaire from the European Organization for Research and Treatment of

Cancer (EORTC), and the Edmonton Symptom Assessment Scale (ESAS), in the hospital on Day 1.

EORTC-QLQ-C15-PAL is a 15-item quality-of-life questionnaire validated in advanced stages of cancer. Fourteen items, which are related to nine functional and symptom scales, were evaluated using a four-category Likert scale. The last item is a seven-point global quality-of-life scale with a score ranging from one (very poor) to seven (excellent).[14]

ESAS was designed to assess nine symptoms that commonly occur in patients with cancer. Severity of each symptom is rated from zero to 10 on a numerical scale.[15]

Questionnaires were collected by a protocol researcher. Some of the patients were asked to complete the FFP-16 questionnaire at home on Day 3 to provide data for the assessment of test-retest reliability. This interval was chosen to be long enough so that the patients forgot their previous answers and close enough so that their clinical condition has not changed. Completed questionnaires were mailed back to the coordinator of the participating center with a prestamped envelope.

Data on patients' clinical and demographic characteristics were also collected at inclusion.

Sample Size. A sample size of more than 100 patients is considered as a very good indicator of the quality of a patient-reported outcome measurement, according to the COnsensus-based Standards for the selection of health Measurement INstruments recommendations.[16] Our sample size determination was defined a priori with a subject to item ratio of 10 and was set to a minimum of 160 patients.

Analyses. Analyses were conducted using Stata 15.1 (StataCorp LLC, College station, TX). Missing data were handled by Personal Mean Score imputation.[17] Validity of the questionnaire was appreciated using several indices.[18]

- Content validity was determined on the basis of qualitative evaluation, which involves the judgment of coherence between the original and translated items and their relevance, by experts.
- Face validity was defined on the basis of interviews with the patients included in the cross-cultural adaptation process and by a quantitative analysis of the validation sample (rate of missing data and time to complete the questionnaire).
- Structural validity was evaluated by a confirmatory factor analysis (CFA) of patients' responses during the validation process, to confirm the one-factor structure of the original English tool. A good fit is indicated by a comparative fit index (CFI) of >0.95 and a root mean square error of approximation (RMSEA) of <0.05. An acceptable fit is indicated by a CFI of 0.90−0.95 and an RMSEA of 0.05−0.08.[19] A factor loading of >0.5 was expected for each item.
- Reliability of the FFP-16 score was computed using the Cronbach's alpha coefficient ($\alpha > 0.7$ was expected).[18]
- Coherence of the FFP-16 responses was evaluated using the Mokken's model (a correct fit is indicated by Loevinger's coefficient of scalability (H) >0.3, a good fit by H >0.5).[20]
- Reproducibility of the FFP-16 score was computed using intraclass correlation coefficient (>0.6 was expected).[21]
- Criterion validity was determined by analyzing nontrivial Spearman's correlation of the FFP-16 score with scores obtained from the EORTC-QLQ-C15-PAL and ESAS questionnaires.[18] Our a priori hypothesis was an independence between the concept of satisfaction, performance status, symptoms, and quality of life.

Results

Cross-Cultural Adaptation and Face Validity

According to the original author of the FAMCARE-Patient questionnaire, there is no difference in meaning between the original version and the backward translated version. Content validity of the French version was assessed by the expert committee, and some items were reformulated to facilitate adaptation to French language and cultural context (Appendix). A pilot version was tested by conducting interviews with 29 eligible patients. Most of the items were found to be clear and easy to understand; however, changes in format were needed with regard to three items (questions about prognosis and family) to limit misunderstanding and missing data. These successive modifications were tested with 12, then 10 additional patients, that is, 51 patients in the cross-cultural adaptation process (Fig. 1).

With regard to acceptability, the translated questionnaire was considered to be good or very good by all patients. The completion mean time was 5.1 minutes (SD 1.4).

Psychometric Validation Process

Patients. One hundred seventy-six adults participated in the validation study. Their sociodemographic and clinical characteristics are presented in Table 1. The overall educational level was low. Time since diagnosis was less than two years in 95 patients (54%). Most patients received chemotherapy or hormonotherapy

a

*Legend: **1** (very dissatisfied), **2** (dissatisfied), **3** (undecided), **4** (satisfied), **5** (very satisfied)*

How satisfied are you with:

1. Doctor's attention to your description of symptoms
2. the accuracy with which doctors assess your symptoms
3. Information given about how to manage pain
4. Information given about side effects
5. Speed with which symptoms are treated
6. Information given about your tests
7. The way tests and treatments are performed
8. The way tests and treatments are followed up by the doctor
9. How you are informed about your illness' progress
10. Answers from health professionals
11. Referrals to specialists, if necessary
12. The availability of doctors to answer your questions
13. The availability of nurses to answer your questions
14. Coordination of care

About your close surroundings:

Who are your loved ones: family, friends, other ?

How satisfied are you with:

15. The availability of doctors to your loved ones

Whould you involve them in the medical decisions that concern you: yes/no

How satisfied are you with:

16. The way doctors respect this choice

b

*Echelle : **1** (très insatisfait), **2** (insatisfait), **3** (mitigé), **4** (satisfait), **5** (très satisfait)*

Quelle est votre satisfaction sur:

1. L'attention portée par les médecins à votre description des symptômes
2. La precision avec laquelle les médecins évaluent vos symptômes
3. Les informations données sur la gestion de la douleur
4. Les informations données sur les effets secondaires
5. La rapidité avec laquelle les symptômes sont traités
6. Les informations données sur vos examens
7. La manière dont les examens et traitements se déroulent
8. La manière dont les examens et traitements sont suivis par le médecin
9. La manière dont on vous informe de l'évolution de votre maladie
10. Les réponses des professionnels de santé
11. La possibilité de faire appel à des spécialistes si necessaire
12. La disponibilité des médecins pour répondre à vos questions
13. La disponibilité des infirmier(e)s pour répondre à vos questions
14. La coordination des soins

Concernant votre entourage:

Quelles sont les personnes les plus proches de vous: famille, amis, autres

Quelle est votre satisfaction sur:

15. La disponibilité des médecins pour vos proches

Souhaitez-vous les associer aux décisions médicales qui vous concernent: oui, non

Quelle est votre satisfaction sur:

16. La manière dont les médecins respectent ce choix

Fig. 1. French version of the FAMCARE-Patient (FFP-16) questionnaire in English (a) and in French (b).

(97%) and were recruited from the chemotherapy day hospital (91%).

Acceptability and Item-Descriptive Statistics. Item acceptability was considered to be good, except for three items with >10% missing data. Table 2 presents standardized factor loading for each item, all of which are >0.6—better than the expected value. There were no floor or ceiling effects for all the items.

Table 1
Characteristics of the Participants Involved in the Validation Process ($N = 176$)

Characteristic	N (%) or Mean (SD)	Minimum–Maximum	α
Sex			
Female	96 (55%)		
Male	81 (45%)		
Age (yrs)	64 (11)	23–89	
Married/common-law	117 (70%)		
Bachelor's degree or higher	55 (31%)		
Disease site			
Gastrointestinal organs	52 (30%)		
Breast	40 (23%)		
Lung	42 (24%)		
Female reproductive organs	14 (8%)		
Genitourinary organs	27 (15%)		
Other	1 (1%)		
Performance status (ECOG)	0.86 (0.60)	0–2	
EDS	19 (14)	0–73	
FFP-16 score	68 (23)	28–74	0.95

ECOG = Eastern Cooperative Oncology Group; EDS = Edmonton Symptom Assessment Scale Distress Score; FFP-16 = French FAMCARE-Patient Version 16.
α = Cronbach's alpha; maximum possible score for EDS = 90; maximum possible score for FFP-16 = 80.

Statistical Analyses. CFA indicated that a one-factor structure had an acceptable fit to the FFP-16 questionnaire, with CFI = 0.93 and RMSEA = 0.07. Internal reliability was high as shown by Cronbach's alpha ($\alpha = 0.95$), and coherence of the responses to the questionnaire was strong as shown by H values (significantly positive and >0.5) (Table 2). Furthermore, reproducibility of the FFP-16 score in 43 patients was very good (intraclass correlation coefficient 0.91).

We correlated the summed score of the FFP-16 questionnaire with that of the ECOG, ESAS Distress Score, individual ESAS items, and individual QLQ-C15-PAL subscales. The FFP-16 score did not significantly correlate with the scores of these scales, with the exception of the anxiety-related and well-being-related scores of ESAS (Spearman's correlation coefficient = −0.18 and −0.20, respectively; $P < 0.05$) and the overall quality-of-life score of QLQ-C15-PAL (Spearman's correlation coefficient = 0.30; $P < 0.05$).

Discussion

The cross-cultural adaptation of the FAMCARE-Patient questionnaire for the French population was achieved with satisfaction, and this version showed satisfactory psychometric properties in terms of structure, reliability, coherence, and reproducibility. CFA confirmed the validity of original one-factor model of the FFP-16 questionnaire. Regarding the reliability of the FFP-16 questionnaire, statistical analysis demonstrated an adequate internal consistency. This questionnaire was confirmed to be

Table 2
Characteristics of FFP-16 Items

Item	Mean (SD)	Missing date rate (%)	Floor and Ceiling Effects (%)	Factor Loading	Loevinger's Coefficient (H)
1	4.4 (0.6)	1	1–49	0.76	0.64
2	4.3 (0.7)	1	1–42	0.79	0.63
3	4.2 (0.7)	4	1–36	0.70	0.55
4	4.1 (0.8)	1	1–31	0.72	0.59
5	4.3 (0.8)	1	1–41	0.77	0.61
6	4.1 (0.8)	1	2–34	0.70	0.58
7	4.4 (0.7)	1	1–52	0.65	0.54
8	4.4 (0.7)	2	1–53	0.72	0.60
9	4.2 (0.7)	2	2–37	0.73	0.58
10	4.2 (0.6)	4	1–33	0.81	0.66
11	4.2 (0.7)	12	2–37	0.74	0.58
12	4.3 (0.7)	1	2–42	0.76	0.60
13	4.5 (0.7)	2	1–54	0.67	0.56
14	4.3 (0.7)	1	1–46	0.69	0.55
15	4.2 (0.7)	15	1–31	0.64	0.52
16	4.3 (0.6)	19	2–40	0.71	0.55

FFP-16 = French FAMCARE-Patient Version 16.

acceptable to patients. However, there was a significant quantity of missing data with regard to two items about loved ones (Items 15 and 16). Most of the patients who did not answer these items did not identify relatives (family or friends) for the dedicated previous question. They may not have been concerned, but they had no possibility of a not applicable response.

Compared with the original English version, the FFP-16 questionnaire showed an acceptable fit of a single-factor structure, with higher Cronbach's alpha (0.95 vs. 0.94), higher CFI (0.93 vs. 0.88), and lower RMSEA (0.07 vs. 0.11).[8] Factor loadings of the French version were approximately same as those of the original version.[7,8] An English shorter 13-item version (FAMCARE-P13) showed an acceptable fit compared with the poor one of the original 16-item version but with a lower internal reliability.[8] The FAMCARE-P13 was also translated from English to Greek.[22] In this study, the CFA showed a very poor CFI with a one-factor structure (0.59). It could be explained by translation errors or by Greek cultural specificities. Moreover, the Greek study used the FAMCARE-P13 in patients hospitalized in palliative care units, contrary to the original tool in ambulatory patients. In this work, the secondary exploratory factor analyses identified a two-factor structure with an acceptable fit. In our study, CFA confirmed a one-factor model with an acceptable fit, and we found a good reliability of the 16-item version, better than the 13-item version (Cronbach's alpha 0.95 vs. 0.94).

In our work, the satisfaction score was not correlated with the patient's overall condition. Indeed, the ECOG score assesses the patient's ability to take care of himself and to move around. In advanced stages of cancer, this autonomy is often limited and decreased by fatigue. The absence of correlation between the FFP-16 score and ECOG status demonstrates that satisfaction is a distinct concept, independent of the patient's physical performance. We also found that satisfaction was not correlated with the overall ESAS distress score as well as individual ESAS physical symptom score. These results further show that the concept of satisfaction is independent of the patient's general and physical condition. FFP-16 score was significantly correlated with the well-being and anxiety scores of ESAS as well as the overall QLQ-C15-PAL quality-of-life score. This could be explained by the subjective dimension of the concept of satisfaction, which can be influenced by uneasiness, anxiety, or a feeling of poor quality of life. It was similar for the original English FAMCARE-Patient questionnaire validation.[8] However, these correlations are weak and close to independence. Moreover, we did not find correlation between FFP-16 score and the emotional functioning dimension scale of QLQ-C15-PAL questionnaire, which does not allow us to conclude that there is a clear correlation between these concepts. A French questionnaire assessing outpatient satisfaction with care in ambulatory chemotherapy or radiotherapy treatment was adapted from the In-Patsat32 questionnaire from the EORTC.[23] It was not dedicated to patients with advanced-stage cancer but exclusively to patients undergoing cancer treatment. CFA revealed good convergent validity and excellent internal consistency. Items and subscales of this questionnaire were not significantly correlated to the quality of life, emphasizing that satisfaction and quality of life are distinct concepts.

Our study could be criticized for choosing a questionnaire that is based on the data initially collected

from American or Canadian patients. Indeed, it has not been demonstrated that French patients with advanced stages of cancer do have the same areas of satisfaction with care as North American patients. However, during the individual interviews for the cross-cultural adaptation process, most patients felt that the tool was suitable for assessing their satisfaction—with no missing areas identified. Furthermore, using the same questionnaire that is validated in several languages, improves the possibility of promoting international research. Secondarily, our work could also be criticized for changing the form of the questionnaire, particularly with regard to family related items. This was necessary to limit missing data for these items. During the individual interviews, questions about family and its place in medical decisions were misinterpreted because patients were committed to medical confidentiality and self-decision. This could be explained by a French cultural specificity. That is why this change in form can be justified by a rigorous transcultural adaptation according to the French cultural context. Finally, we regret the absence of items related to the emotional, social, and spiritual dimensions, especially in a questionnaire dedicated to patients with advanced stages of cancer. However, we have chosen to focus on the existing questionnaire without creating a new one. Despite these potential shortcomings, we obtained a version of the FAMCARE-Patient questionnaire adapted to the French cultural context, with good psychometric properties and according to a rigorous methodology.

Conclusion

The present study will allow the use of a validated French scale to evaluate the satisfaction of outpatients with advanced stages of cancer. This will facilitate the improvement of the quality of patient care by caregivers and physicians. This will also allow the use of a validated tool in clinical research for international multicenter studies. This study will be continued with the development of a new clinical tool to assess patients' issues and supportive care needs to improve their satisfaction of care.

Disclosures and Acknowledgments

The authors thank R. Aubry and D. Leboul for their help in designing the study and A. Caille, B. Discepoli, F. Etourneau, and D. Mallet for their expert advice. They are grateful to all the patients who participated in this study and to the clinical and research staff of the Chemotherapy Day Hospitals of Oncology, Pneumology, and Gastroenterology Department of the University Hospital of Tours.

This study was supported by grants from Fondation de France, Fonds pour les Soins Palliatifs, Ligue contre le Cancer, and Société Française d'Accompagnement et de Soins Palliatifs. They had no involvement in the study design, collection, analysis, and interpretation of data, writing the report, or decision to submit the article for publication.

The authors declare no conflicts of interest.

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Appendix

Initial translated version (left side) and French-cultural-context-adapted version before pilot testing (right side)

Quelle est votre satisfaction sur :		Quelle est votre satisfaction sur :
1. L'attention portée par le médecin à votre présentation des symptômes		1. L'attention portée par le médecin à votre description des symptômes
2. L'attention portée par le médecin à évaluer vos symptômes		2. La précision avec laquelle le médecin évalue vos symptômes
3. Les informations fournies sur la manière de traiter la douleur		3. Les informations données sur la gestion de la douleur
4. Les informations fournies sur les effets secondaires		4. Les informations données sur les effets secondaires
5. La rapidité de traitement des symptômes		5. La rapidité avec laquelle les symptômes sont traités
6. Les informations communiquées sur vos analyses		6. Les informations données sur vos examens
7. La manière dont les examens et traitements sont effectués		7. La manière dont les examens et traitements sont réalisés
8. La manière dont les examens et traitements sont suivis par le médecin	→	8. La manière dont le médecin suit les examens et traitements
9. Les informations communiquées sur votre pronostic		9. Les informations délivrées concernant votre pronostic
10. Les réponses des professionnels de santé		10. Les réponses des professionnels de santé
11. Les renvois à des spécialistes		11. Les recours à des spécialistes
12. La disponibilité des médecins pour répondre à vos questions		12. La disponibilité des médecins pour répondre à vos questions
13. La disponibilité des infirmières pour répondre à vos questions		13. La disponibilité des infirmier(e)s pour répondre à vos questions
14. La manière dont l'entourage familial est pris en compte dans les décisions de traitement et de soins		14. La manière dont l'entourage familial est intégré dans les décisions de traitement et de soins
15. La coordination des soins		15. La coordination des soins
16. La disponibilité des médecins auprès de votre entourage familial		16. La disponibilité des médecins pour votre entourage familial