Brief Methodological Report

Clinimetric Properties of the Brief Fatigue Inventory Applied to Oncological Patients Hospitalized for Chemotherapy

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Abstract

Background. The clinimetric properties of the Brief Fatigue Inventory (BFI) were not previously assessed in oncological patients hospitalized for chemotherapy.

Objective. To assess the reliability and validity of the construct, ceiling and floor effects, and responsiveness of the BFI administered to oncological patients hospitalized for chemotherapy.

Methods. This test-retest study included 100 oncological patients hospitalized for chemotherapy. The clinimetric properties tested were as follows: internal consistency (Cronbach's alpha), reliability (intraclass correlation coefficient [$ICC_{2,1}$] and 95% CI), agreement (standard error of measurement and minimum difference changed [MDC90%]), validity of the construct (Pearson's correlation [r] with the Piper Fatigue Scale), responsiveness (effect size [ES] and correlation), and ceiling and floor effects (minimum and maximum score frequencies). The BFI was applied on the first day of chemotherapy and 48 hours and 15 days after the start of chemotherapy.

Results. The BFI presented adequate values of internal consistency (α Cronbach = 0.94), substantial reliability [$ICC_{2,1}$ (95% CI) = 0.87 (0.81 to 0.91)] and very good agreement (standard error of measurement = 1% and MDC90% = −0.37). The BFI had a positive and strong correlation with the Piper Fatigue Scale ($r = 0.84$; $P < 0.001$). Internal responsiveness was considered moderate (ES = 0.5), and external responsiveness was absent. A floor effect was present (35%).

Conclusion. BFI applied to oncological patients hospitalized for chemotherapy replicates its original version with adequate reliability, validity, and internal responsiveness. However, in this population, the BFI showed a floor effect. J Pain Symptom Manage 2019;57:297−303. © *2018 American Academy of Hospice and Palliative Medicine. Published by Elsevier Inc. All rights reserved.*

Key Words
Fatigue, inpatients, cancer, chemotherapy, hospitalization, clinimetry

Introduction

Fatigue is a symptom present in 90% of oncological patients.[1] Cancer-related fatigue is associated with the disease and treatment and is defined as a "condition characterized by suffering and decreased functional capacity due to energy reduction."[2,3] Fatigue causes a disproportional subjective sensation of physical, emotional, and cognitive fatigue or exhaustion in relation to the activity performed.[4] To measure fatigue, some questionnaires were developed.[5] The Brief Fatigue Inventory (BFI) is a one-dimensional questionnaire based on the Brief Pain Inventory that assesses the severity and impact of oncologic pain.[6] The BFI was developed and translated into more than 30 languages by MD Anderson Cancer Center[7] and has

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unique characteristics: it is short, it requires no more than 5 minutes for the patient to complete, and it is easily adaptable to other languages because it has items that show the interference of fatigue specifically in the activities of daily living.[6] These features may make BFI useful for administration during hospitalization for the prescription of comfort measures for oncological patients in an acute situation such as chemotherapy.

Even with no mention of the transcultural translation and adaptation process to BFI used by MD Anderson Cancer Center,[7] the internal consistency and validity of the construct were measured in Chinese,[8] Philippine,[9] German,[10] Greek,[1] Indonesian,[11] Italian, Dutch, Japanese,[12] Korean,[13] Russian,[14] and English versions.[6] There are no other clinimetric properties tested in other populations what is important because every questionnaire must make sense, be intelligible to the patient, and be accurate at measuring what is proposed.[15] Therefore, the aim of this study was to test the reliability, validity, responsiveness, ceiling, and floor effects of BFI applied to oncological patients hospitalized for chemotherapy.

Methods

Participants

Adult patients diagnosed with cancer for at least six months and hospitalized consecutively for chemotherapy treatment between September 2016 and November 2017 at AC Camargo Cancer Center—Antônio Prudente Foundation. The exclusion criteria were surgery less than 30 days previously, clinical decompensation such as high fever or intense vomiting, the need for transfer to an intensive care unit, or hemodynamic instability between BFI test and retest.

This study was approved by the Research Ethics Committee of Universidade Cidade de São Paulo and followed all ethical recommendations. All patients were informed about all study procedures and signed the informed consent form.

Instruments

The BFI is a scale with 11 points (0 to 10), including a dichotomous question about whether the patient felt tired or fatigued in the last 7 days.[6] For each question, zero is considered "no fatigue" and 10 is "worst fatigue possible," except for the dichotomous question that is not scored. Among the other questions, 3 measures the severity of fatigue in the current, daily situations, and in the last 24 hours. Six questions measure the influence of fatigue in general activities, mood, walk, work, relationship with other people, and recreation. The total score is the average of all questions. According to the total score, fatigue is classified as mild (1 to 3 points), moderate (4 to 6 points), and severe (7 to 10 points).[6]

The Piper Fatigue Scale (PIPER) was used to test the validity of the BFI because it presents adequate clinimetric properties in Brazilian-Portuguese version.[16] The PIPER has 22 questions. Five of these questions are open-ended. The score ranges from 0 to 10 points for each item. The PIPER assesses three dimensions: behavioral, affective, and psychological. The total score is the average score for each question. Higher scores mean more severe fatigue.[16]

The Global Effect Perception Scale (GEP) is used to test the responsiveness of the BFI. The GEP aims to check the overall patient impression of recovery by comparing his condition on the onset and currently. The GEP is a numerical scale of 11 points (−5 to +5), with −5 being "extremely worse," 0 being "unmodified," and +5 being "fully recovered." Higher scores mean greater recovery.[15]

Procedure

The patients were selected and included in the study on the first day of hospitalization. At the baseline, the GEP, PIPER, and BFI (test) were applied to patients. Forty-eight hours after the chemotherapy started, the BFI was applied again (retest). The interval between BFI test and retest was established to ensure patient clinical stability and to avoid memorization bias.

Fifteen days after the start of chemotherapy, GEP and BFI were again applied via call phone or face-to-face interview, if the patient remained hospitalized. The 15-day interval was determined to be considered the peak time of fatigue because chemotherapy causes blood myelosuppression.

Analysis of Clinimetric Properties

Reliability shows how much the information from the instrument is free of measurement errors between the test and retest.[17–20] It encompasses the following properties:

- **Internal consistency** checks that the survey questions are related to each other, measuring the same construct.[15] It is assessed by the total Cronbach's alpha and with each question deleted. Very low values indicate poor consistency. Values of $0.70 \leq \text{alpha} < 0.95$ are considered adequate. Values > 0.95 indicate redundancy of the questions.[17,21]
- **Measurement error** checks for random and systematic errors in the score of an instrument not attributed to true clinical changes of the patient.[21,22] The measurement error encompasses the standard error of measure (SEM) and minimal

detectable change (MDC).[22–25] The SEM was calculated as the standard deviation of the mean of the differences between the test and retest divided by the square root of 2 (SD of the differences/$\sqrt{2}$).[22] The SEM percentage of a questionnaire scores is the agreement indicator. The agreement is very good if SEM $\leq$ 5%, good if 5% $<$ SEM $\leq$ 10%, and negative if 10% $<$ SEM $\leq$ 20%.[22,24] The MDC was calculated as 1.645 $\times$ $\sqrt{2}$ $\times$ SEM,[22] and we considered a 90% confidence interval (CI), reflecting the smallest detectable change for the patient. Changes in questionnaire scores greater than the MDC characterize a change above the measurement error and reflect a clinical change rather than a questionnaire error.[22]

- **Reliability** checks the relative measurement error. It assesses how patients can be distinguished from each other, despite the measurement error of the questionnaire. Reliability was calculated by the intraclass correlation coefficient (ICC) of type 2.1 and their respective 95% CI with the total score obtained from the test and retest. Reliability is poor if ICC $<$ 0.40, moderate if 0.40 $\geq$ ICC $<$ 0.75, substantial if 0.75 $\geq$ ICC $<$ 0.90, and excellent if ICC $\geq$ 0.90.[21–26]

Validity of the construct shows how much the instrument measures the concept to which it is proposed. It was measured by Pearson's correlation between the BFI and PIPER. The correlation is weak if $r < 0.30$, moderate if $0.30 \leq r > 0.60$, and strong if $r \geq 0.60$.[25,26] Our hypothesis is that the correlation between those questionnaires is positive and moderate because BFI is one dimensional and the PIPER is a multidimensional questionnaire. The PIPER was chosen because it is the most popular instrument to assess cancer-related fatigue in clinical practice.[5,16]

Ceiling and floor effects show whether the instrument can discriminate patients with different levels of impairment. The effects are considered as present when more than 15% of patients present a minimum or maximum score in the questionnaire test.[21–26]

Responsiveness

- **Internal responsiveness** is a longitudinal measure and checks whether the instrument can detect changes over a preestablished period of time.[15] Internal responsiveness is measured by the effect size (difference between the initial and final measurements divided by the standard deviation of the initial measurement). Responsiveness is small if the effect size is <0.2, moderate if between 0.3 and 0.7, and large if >0.8.[27]
- **External responsiveness** checks whether the instrument can detect the magnitude of changes over time related to the other reference measure by the ROC curve.[15,28]

Statistical Analysis

A sample of 100 patients is required to test properly reliability, validity, ceiling and floor effects, and responsiveness according to COSMIN.[21] All analyses were performed using IBM software SPSS 17.0.

Results

Initially, 118 patients were included in the study. Four of them were excluded because of clinical complications between test and retest and two patients refused to continue in the study. Six patients were discharged between the test and retest. In the follow-up period, one patient died and four were lost to follow-up. Therefore, 100 patients completed the study. Fifty-three were men, and 55 had comorbidities. Hematologic cancers such as lymphomas, leukemia, and multiple myeloma were the most frequent in our population, followed by pelvic cancers. Metastasis was observed in almost half of the patients. Most of the patients previously underwent some type of treatment such as chemotherapy (Table 1).

The mean hospitalization time was 5.9 $\pm$ 6.19 days. The BFI score was 2.92 $\pm$ 2.50 in the test and 3.58 $\pm$ 2.66 points in the retest. After 15 days, the BFI score was 3.35 $\pm$ 2.66 ($P > 0.05$). After 15 days, 26% of the patients reported worsening of fatigue compared with the initial assessment, according to the GEP (Table 2).

The analysis of properties showed adequate levels of reliability and agreement and internal consistency. The measurement error was considered very good with SEM $<$ 5% of the total score. The floor effect was observed in this population. There was a strong and positive correlation between the BFI and PIPER. Responsiveness was considered moderate (Table 3). Table 4 shows the clinimetric properties of other versions of the BFI when administered in other populations.

Discussion

Our results showed that the clinimetric properties of BFI are adequate when applied to hospitalized oncological patients, preserving the properties of the original version.[6] In addition, properties such as the reliability, validity of construct, ceiling and floor effects, and responsiveness were tested with methodological rigor[17] and novelty in relation to all other versions previously tested. Adequate values of internal consistency were found when the BFI was applied to acute patients. Reliability between the test

Table 1
Characteristics of Patients ($n = 100$)

Characteristics	Values
Age (years), mean (SD)	50.32 (14.38)
Male, n	53
BMI (kg/m^2), mean (SD)	25.67 (4.94)
Physically active, n	22[a]
Comorbidities	
Systemic hypertension, n	30
Diabetes mellitus, n	16
Depression/anxiety, n	3
Smokers, n	34
Time since diagnosis of cancer (months), mean (SD)	14.02 (20.36)
Metastasis, n	46
Oncological groups	
Hematological, n	35
Pelvic, n	33
Abdominal, n	22
Head and neck, n	4
Gynecological, n	3
Mastology, n	2
Thorax, n	1
Previous treatment	
Chemotherapy, n	82
Radiotherapy, n	12
Surgery, n	39

n = number of patients; BMI = body mass index; SD = standard deviation.
[a]Classification according to Baecke questionnaire.

and retest was classified as substantial, and the measurement error considered very good. The BFI was also considered valid in the assessment of fatigue, using the PIPER as the reference. Internal responsiveness was considered moderate. However, there were the presence of a floor effect and the absence of external responsiveness.

The assessment of the internal consistency of the Brazilian Portuguese version of the BFI applied to oncological patients hospitalized for chemotherapy showed that the values were similar to the original English version.[6] Cronbach's alpha was 0.96 and ranged for each deleted item from 0.95 for items related to general activities to 0.96 for the remaining items in the original version.[6] In our study, the BFI also presented similar internal consistency to other versions. The Japanese,[12] Korean,[13] Philippine,[9] Greek,[1] German,[10] and Taiwan[11] versions presented Cronbach's alpha between 0.92 and 0.97. The Chinese[8]

Table 2
Distribution of Fatigue Classification According to the BFI ($n = 100$)

Classification (%)	Baseline	After 15 days
Absent fatigue	35	26
Mild fatigue	27	33
Moderate fatigue	30	30
Severe fatigue	8	11

BFI = Brief Fatigue Inventory; n = number of patients.
Mild = 1 to 3 points; Moderate = 4 to 6 points; Severe = 7 to 10 points.

Table 3
Classification of BFI Clinimetric Properties in Hospitalized Cancer Patients ($n = 100$)

Proprieties	Values	Classification
Internal consistency		
Cronbach's alpha *(variation with* exclusion item to item)	0.95 (0.94-0.95)	Adequate
Reliability		
$ICC_{2,1}$ (95% CI)	0.87 (0.81-0.91)	Substantial
Measurement error		
Standard error measurement	1%	Very good
Minimal Detectable Change	−0.37	
Validity of the construct		
Correlation with PIPER (r)	0.84[a]	Good
Responsiveness		
Internal	0.50	Moderate
Ceiling and floor effects	Floor 35%	Inadequate

BFI = Brief Fatigue Inventory; n = number of patients; ICC = intraclass correlation coefficient; r = Pearson's correlation.
Classification according to COSMIN.[26]
ICC = 0.87; 95% CI = 0.81−0.91.
[a]$P < 0.05$.

version assessed the internal consistency for two blocks: the three first questions that evaluate fatigue severity (Cronbach's alpha = 0.92) and the last six questions that evaluate fatigue intensity (Cronbach's alpha = 0.90).

The reliability of BFI was only previously tested in the study in Taiwan[11]; however, it was assessed via Pearson's correlation (r). The authors correlated the total BFI score between the test and retest[11] with a three-day interval of administration in 12 outpatients from oncology centers. The reliability was $r = 0.89$. Reliability is an important clinimetric property because it shows the ability of an instrument to obtain similar responses as long as patients are in a stable condition.[19] In our study, reliability was assessed using the $ICC_{2,1}$ and respective 95% CI, and a sample of 100 patients, as suggested by COSMIN.[26]

The agreement between the test and retest of the BFI was assessed for the first time in our study. Even so, our results showed 1% of error of measurement in an instrument with a maximum score of 10 points, indicating very good and high concordance.[23,26] In this way, we can understand that the BFI is sufficiently sustainable to be applied to hospitalized population.

In the assessment of the validity of the construct, a strong and positive correlation between the BFI and PIPER was observed. Our results are similar to those reported for the original version of the BFI.[6] Mendoza et al.[6] showed the validity of the BFI, with strong correlation with the FACT instrument-F. The correlation ranged from 0.81 for fatigue severity to 0.92 for fatigue interference in general activities. Not all studies compared the BFI to other instruments with an identical construct, so moderate values in these

Table 4
Clinimetric Properties of Other Versions of BFI in Previous Studies

Characteristics and Properties	Mystakidou[1]	Mendoza[6]	Wang[8]	Mendoza[9]	Radbruch[10]	Lin[11]	Okuyama[12]	Yun[13]	This Study
Language	Greek	English	Chinese	Philippine	German	Taiwanese	Japanese	Korean	Portuguese
Population (n)	Outpatient (102)	Outpatient + inpatient (305)	Outpatient + inpatient (249)	Outpatient + inpatient (206)	Outpatient (117)	Outpatient (439)	Outpatient (252)	Outpatient + inpatient (178)	Inpatient (100)
Reliability									
Internal consistency (*Cronbach's alpha*)	0.95	0.96	0.92	0.95	0.93	0.97	0.96	0.95	0.93
Reliability, $ICC_{2,1}$ (95% CI)	NP	NP	NP	NP	NP	NP	NP	NP	0.87 (0.81-0.91)
Measurement error, points (%)	NP	NP	NP	NP	NP	NP	NP	NP	1%
Validity of the Construct *r*	0.90	0.81	−0.92	0.70	0.78	0.94	0.78	0.90	0.84
Ceiling and floor effects	NP	NP	NP	NP	NP	NP	NP	NP	35% (floor)
Responsiveness	NP	NP	NP	NP	NP	NP	NP	NP	TE = 0.5

n = sample size; NP = not presented; ICC = intraclass correlation coefficient; r = Pearson's correlation.
ICC = 0.87; 95% CI = 0.81-0.91.

cases can be considered adequate. Mystakidou et al.[1] compared the BFI to the hemoglobin level and fatigue tests,[29] and they found a weak and negative correlation ($r = -0.21$; $P = 0.004$). Our initial hypothesis was to find a moderate correlation because we compared a one-dimensional instrument to a multidimensional one, but we found a strong correlation. Our hypothesis for this finding is that the impact of fatigue on dimensions measured by the PIPER is similar that in performing general activities by oncological patients.

Responsiveness was small in our study. The reduced number of patients who reported worsening of fatigue after 15 days of treatment was unexpected and may have interfered with our results and decreased BFI responsiveness. Our results are similar to those reported by Lin et al.[11] The authors assessed BFI responsiveness in 20 patients with breast cancer undergoing chemotherapy at the day hospital. They assessed fatigue via the BFI before, during, and at the end of the treatment. The authors used ANOVA for repeated measures and found that fatigue was linearly decreasing during treatment, as well as in our population.[11] We believe that other studies should assess internal and external responsiveness in oncological patients to confirm our finds.

Ceiling and floor effects were not assessed in studies testing other versions of BFI. In our study, BFI demonstrated a floor effect. No ceiling effect was observed. Instruments that have a high percentage of ceiling or floor effects may not capture or measure the construct to which it is proposed, that is, to differentiate who does or does not have the health condition goal.[20] One hypothesis for our finding was the selection of patients at the beginning of treatment because severe fatigue may not occur. As this was the first study to measure this property, we can not state whether the same floor effect could be detected if the BFI were applied to patients at the end of many cycles of chemotherapy, or if in this population a ceiling effect would be found because, possibly, many patients would present worse clinical condition, including severe fatigue.

The results of this study indicate that BFI administered to oncological patients hospitalized for chemotherapy has acceptable levels of reliability, validity of the construct and internal responsiveness. In this way, we emphasize the importance of measuring cancer-related fatigue with accurate and simple instruments such as the BFI.

The limitations of this study were the administration of the BFI via call phone in the third interview. This may have made it difficult for the patient to understand, but it was the only way to make the study viable. In addition, we obtained the floor effect in our sample probably due to the short diagnosis time of the disease

and small number of chemotherapeutic cycles performed until the moment of the study. A sample with more severe patients might be more appropriate to assess responsiveness.

Conclusion

The BFI has adequate reliability, validity, and internal responsiveness when used to assess cancer-related fatigue in patients hospitalized for chemotherapy. The BFI presents the floor effect and lack of external responsiveness and should be tested in other populations to confirm these findings.

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This article is original, and no part of it has been published before or is being considered for publication in another journal. In addition, there are no conflicts of interest to disclose.

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