Validating the Saligan Fatigue Inventory (SalFI)

Kristin Dickinson[1], Tara Albrecht[2], Christina Wilson[2], Sumiyya Raheem[1], Xuemin Zhang[1], Leorey N. Saligan [1]

Affiliations:

1. National Institute of Nursing Research, National Institutes of Health, Bethesda, Maryland, USA
2. School of Nursing and Massey Cancer Center, Virginia Commonwealth University, Richmond, Virginia, USA

Corresponding Author:

Leorey N. Saligan, PhD, RN, CRNP, FAAN
National Institute of Nursing Research, National Institutes of Health
9000 Rockville Pike, Building 3, Room 5E, Bethesda, MD 20892
Email: saliganl@mail.nih.gov

Abstract

Background: Cancer-related fatigue (CRF) is a very distressing symptom reported by oncology patients. Currently, CRF is measured by self-report instruments. Although clinician-administered questionnaires are more sensitive than self-report scales, there is no available clinician-administered instrument that is validated to measure CRF.

Purpose: This nurse-led, prospective, repeated measures study investigated the reliability and validity of a 7-item Saligan Fatigue Inventory (SalFI), a recently developed, clinician-administered tool to measure CRF.

Methods: Significant correlations between SalFI and other reliable and valid CRF measures (Functional Assessment of Cancer Therapy–Fatigue [FACT-F], revised Piper Fatigue Scale [rPFS]) were explored using Spearman correlation tests. A global correlation matrix to compare correlations among study time points was developed using the Benjamin-Hockberg method. Study subjects were followed at baseline (T1, before primary cancer treatment), one month (T2) and 3 months (T3) after cancer treatment initiation from two study centers. The study was approved by the Institutional Review Boards of both recruitment centers.

Results: A total of 60 subjects were enrolled in the study. The SalFI was highly correlated with both FACT-F (rho=0.69, $p<.001$) and rPFS (rho=0.63, $p<.001$) at T1. It continued to be significantly correlated with both measures at T2 and T3 with rho=0.65-0.74 at $p<.001$. Cronbach's alpha for SalFI was 0.77, suggesting good internal consistency reliability. Exploratory factor analyses revealed that the SalFI measures physical and cognitive/affective domains of fatigue separately.

Conclusion: The SalFI is a reliable and valid clinician-administered measure of CRF. Validation studies in other cancer populations, other clinical populations, and in other languages are warranted.

Current, successful treatments available for cancer patients have increased disease-free survival rates and life expectancy, but they also have led to increase treatment-related side effects including fatigue. Cancer-related fatigue (CRF) is reported as one of the most prevalent symptoms and is experienced by 50-90% of cancer patients (Campos et al., 2011). Currently, only self-report instruments are available to assess CRF. The sensitivity of self-report instruments is often questioned (Nallet et al., 2013; Zimmerman et al., 2011). Clinician-administered instruments have many benefits for research and the clinical setting, including being more sensitive than self-report scales (Goldberg et al., 2012). However, there is no validated clinician-administered instrument to measure CRF.

A single-item, clinician-administered fatigue questionnaire obtained from the Clinical Global Impression (CGI) scale was recently used to assess fatigue in psychiatric patients diagnosed with Major Depressive Disorder, Bipolar disorder, or schizophrenia (Targum, Hassman, Pinho, & Fava, 2012). This scale showed temporal stability and convergent validity, when compared with the Massachusetts General Hospital Cognitive and Physical Functioning Scale (Targum et al., 2012). One concern raised for the CGI fatigue scale was on its validity because of the lack of studies comparing it with more established self-report fatigue scales (Ferrentinos, Kontaxakis, Havaki-Kontaxaki, Dikeos, & Papadimitriou, 2010). Another concern was the uncertainty that a single-item questionnaire could fully capture the physical, cognitive, and emotional domains of fatigue (Targum et al., 2012). Hence, there is a need to develop a tool that can fully assess the concept of fatigue and also be administered by clinicians in practice.

The Saligan Fatigue Inventory (SalFI) was developed to address this need. The magnitude of the association between fatigue and depression among cancer patients was shown to be large (Jacobsen et al., 2003). It is inferred that it is challenging to distinguish one from the other (Brown & Kroenke, 2009). The current psychometric properties of SalFI make it uniquely useful for conducting research and in determining outcomes for clinical interventions because it can efficiently evaluate fatigue separately, but also within the context of the established relationship between depression and fatigue. This nurse-led study explored the reliability and validity of the SalFI as a measure of CRF when compared with reliable and valid CRF measures, such as the Functional Assessment Cancer Therapy – Fatigue (FACT-F) and the revised Piper Fatigue Scale (rPFS).

Methods

This was a prospective, repeated measures study to validate a newly developed, clinician-administered questionnaire. The study enrolled adult oncology patients scheduled to receive primary or adjunctive cancer therapy from two study sites. Institutional Review Board approval from both institutions were obtained prior to study implementation. Power analysis was conducted to determine the sample size needed to determine significant correlations ($r \geq 0.7$) between the SalFI with FACT-F and rPFSA at an alpha = 0.05. Assuming that the data are normally distributed, the study needed to enroll at least 13 participants to have a power of 0.8.

Study participants were followed at baseline (T1, before primary cancer treatment) and at one month (T2) and 3 months (T3) after cancer treatment initiation. CRF is reported to increase during treatment (Cheville, 2009). At each study visit, two self-report fatigue questionnaires, known to be valid and reliable measures of CRF (Yellen et al., 1997; Piper et al., 1998) were co-administered with SalFI: the 13-item FACT-F and the 31-item rPFS. These questionnaires are further described below.

The SalFI originated from the National Institutes of Health – Brief Fatigue Inventory (NIH-BFI) (Saligan et al., 2915), which was created from existing items of valid, clinician-administered depression scales (e.g., Hamilton Depression Rating Scale [HDRS], Montgomery-Asberg Depression Rating Scale [MADRS], Young Mania Rating Scale [YMRS]), and Structured Interview Guide for the Hamilton Depression Rating Scale with Atypical Depression (SIGH-SAD). Initial investigation of the reliability and validity of the SalFI was conducted in 88 patients enrolled in the National Institute of Mental Health clinical trials at the NIH. For content validity, four NIH fatigue researchers rated items (0-4 rating, 4=closest semblance) from the HDRS, MADRS, YMRS and SIGH-SAD scales based on their perceived semblance to the concept of fatigue. A total of 10 items, with >3 rating were initially selected. A Cronbach's alpha was calculated to determine whether these items fit into a coherent construct. Alphas were examined with individual items deleted to determine whether specific items decreased the coherence of the underlying construct. In addition, Pearson correlations among individual items were examined to determine whether individual items were not strongly related to other symptoms. If an item was not strongly related to other items and it reduced the alpha substantially, then it was removed from the total fatigue item list before the process was re-done. The process was continued until no substantial reduction in alpha occurred. The final NIH-BFI

model consisted of seven items with a Cronbach's alpha of 0.87, suggesting a coherent construct among the items and the inter-item correlations ranged between 0.23 and 0.88. Further, intra-class correlation (ICC) from the model was 0.49. The Cronbach's alpha and ICC illustrate that the NIH-BFI can provide a more reliable measure of the construct than using single items, separately. Support for the validity of the total NIH-BFI score were the moderate to strong correlations with self-reported fatigue items of both clinician-administered (MADRS, HDRS) and self-report depression (Beck Depression Index) scales, which indicated that NIH-BFI converged with other subjective fatigue items when measured over time within the context of depression.

The NIH-BFI showed good psychometric properties and included items addressing cognitive, emotional, and physical entities of fatigue (Saligan et al., 2015). The NIH-BFI has also shown utility in longitudinally measuring fatigue in clinical trials (Saligan et al., 2016). One major limitation of the NIH-BFI is its inability to separate scores from patient-reported items and observer-reported items. Therefore, the SalFI was developed to separate the patient-reported items from the observer-reported items for optimal scoring (see Appendix 1). The SalFI consists of 8-items.

The FACT-F subscale has shown good test-retest reliability (r = 0.90) and internal consistency (alphas = 0.93 and 0.95) on initial and test-retest administration, suggesting that it can be administered as an independent, unidimensional measure of CRF (Yellen, Cella, Webster, Blendowski, & Kaplan, 1997). The rPFS measures 4 fatigue dimensions: behavioral/severity (6 items), sensory (5 items), cognitive/mood (6 items), and affective meaning (5 items) using a 0 to 10 intensity rating scale (0 = none; 10 = worst intensity). Significant fatigue is defined as a score of $\geq$6. Psychometric characteristics for the rPFS showed excellent reliability and validity estimates (internal consistency = 0.69-0.95) when used in cancer patients (Piper et al., 1998).

Using the previous classic guidance to calculate appropriate sample size (Walter et al., 1998), we calculated the sample size for this study based on two methods: (1) considering that the rho0 (interclass correlation coefficient, ICC) = 0.7 as the lower internal consistency reliability acceptable, and rho1 = 0.85 as expected estimate, n=7 for the seven subcategories of the SalFI at an alpha = 0.05 with a power = 0.8, the required sample size (k) was 21. This sample size (k) was negatively correlated with (rho1-rho0), alpha, power and n. (2) With the expected Pearson correlation coefficient r (assuming the data is normally distributed) between SalFI and

one of the SalFI to be at least 0.7 with an alpha = 0.05 and a power = 0.8, the calculated sample size was n = 13. This sample size was also negatively correlated with r, alpha and power. Considering that we have enrolled N = 60 for this study, we have more than enough power to find significant results.

Significant correlations between SalFI and other reliable and valid CRF measures (Functional Assessment of Cancer Therapy–Fatigue [FACT-F], and revised Piper Fatigue Scale [rPFS]) were explored using Spearman correlation tests. A global correlation matrix to compare correlations between study time points was developed using the Benjamin-Hockberg method. Cronbach's alpha reliability analyses were conducted to determine internal consistency of the SalFI. Exploratory factor analyses (EFA) explored the fatigue domains that can be discriminated using the SalFI.

Results

A total of 60 participants were enrolled in this study. The age ranged from 28 to 84 (mean=65.4$\pm$10.1). About 78% (n=47/60) of the participants were men, and 82% (n=49/60) were White Americans. About 63% (n=38/60) of participants were scheduled scheduled to receive external beam radiation therapy (EBRT) for non-metastatic prostate cancer. Table 1 describes the clinical and demographic characteristics of the sample.

For the entire cohort, although not statistically significant, fatigue scores worsened overtime, especially from time point 1 (Table 2). FACT-F has a reported threshold score to compare fatigue symptoms with the general population (Cella et al., 2002). Based on that threshold score, even at baseline, our sample had worst fatigue symptoms compared to the US general population (FACT-F mean = 43.6$\pm$9.4). However, the mean fatigue score of our sample is consistent with the reported mean fatigue score of non-anemic cancer patients (FACT-F mean = 40.00$\pm$9.8).

As expected, since some participants received more aggressive chemotherapy for their metastatic disease (n = 15), their fatigue scores were mostly significantly higher than subjects with localized disease, especially using SalFI and FACT-F. The differences in fatigue scores between participants with metastatic disease and those with localized disease are described in table 3.

Internal Consistency. Cronbach's alpha among the SalFI items was 0.77 at all three study time points, suggesting strong internal consistency reliability. These scores were well above the correlation size of .70, which is a frequently cited minimum recommendation for Cronbach's alpha (Bland, 1997).

Assessing Fatigue Domains. EFA yielded three factors, which suggests that specific SalFI items can identify CRF domains. SalFI items 2 ("Do you have difficulty feeling motivated to start activities?"), 4 ("Do you feel fatigued this past week?"), and 5 (Do you have difficulty performing activities this past week?) are strongly correlated with factor 1 (factor loadings 0.66, 0.87, 0.82, respectively. Items 1 ("Do you have difficulty concentrating?") and 3A (Have you been feeling especially tense or irritable?) were strongly correlated with factor 2 (both with factor loadings of 0.76), and item 7 (Observation: slowness of thought and speech) alone was strongly correlated with factor 3 (factor loading = 0.99). These findings suggest that physical/motivation-type of CRF can be measured using items 2, 4, and 5; while, items 1 and 3A can measure cognitive/affective domains of CRF.

Convergent Validity. The SalFI was highly correlated with both FACT-F (rho=0.69, $p<.001$) and rPFS (rho=0.63, $p<.001$) at T1. It continued to be significantly correlated with both measures at T2 and T3 with rho=0.65-0.74 at $p<.001$, which suggest good convergent validity.

Discussion

This study is the first to investigate the psychometric development of the SalFI as a clinician-administered measure designed to objectively measure CRF and its dimensions. The study findings indicated that the SalFI is a valid and reliable instrument to assess CRF. Furthermore, the study findings confirm that SalFI is a multidimensional instrument that can measure the different domains of CRF. It is reported that data obtained from clinician-administered assessments can measure severity of symptoms more accurately than self-report (Rush et al., 1987; Berrios & Hen, 1993).

Fatigue is a multidimensional construct (Cheville, 2009). The study findings revealed that the SalFI measured different domains of CRF, providing empirical support for its multidimensionality. Specific items of the SalFI can independently measure physical /

motivational domain from the cognitive / affective domain of CRF. This is a strength of the SalFI, considering that there are no available clinician-administered questionnaires that assess the multidimensional nature of CRF.

A limitation of the study is its clinical population. Most of the participants were men with non-metastatic prostate cancer, but there is also a huge percentage of study participants with more advanced disease and were receiving more aggressive cancer therapy, causing big disparities in fatigue scores between those two cohorts (Table 3). Fatigue scores of participants with metastatic disease were significantly worst that those with more localized disease. However, this is only observed when using SalFI and FACT-F. Perhaps this discrepancy may be related to the number of items for each of these questionnaires. SalFI and FACT-F are relatively short forms (7-item, and 13-item, respectively), but rPFS has 27 items. Further validation of the SalFI in other clinical populations and languages is warranted to support its generalizability. However, the heterogeneous study sample provides evidence that the SalFI can be useful in assessing CRF from a specialized, tertiary hospital and from community cancer centers.

The SalFI showed that it is sensitive to detect statistically-significant changes in fatigue symptoms overtime, as it was administered before and following cancer therapy. However, the clinical relevance of these observed significant statistical changes is necessary to explore. The approach to determine minimally important difference (MID) for all patient-reported outcomes (PROs) has gained renewed recognition, since care providers and policy makers are dependent on MID knowledge to guide clinical decisions (Johnston et al., 2015). The MID provides a threshold of the smallest change in symptom scores through patient report that would lead the patient or clinician to consider a change in care management (Schunemann & Guyatt, 2005). So, the next logical step for this validation is to determine the MID for SalFI from a larger number of subjects.

SalFI's relationship with objective measures of fatigue is also an important area to explore. Determining the predictive utility of SalFI in estimating functional performance status, would be clinically important. Previous report has suggested that subjective reports from patients often do not correlate with data obtained from objective measures, such as physical activity monitors (Wong et al., 2011).

Conclusions

CRF assessment is limited by the use of self-report instruments that lack objective assessment. The SalFI is a clinician-administered instrument developed for clinicians to objectively assess CRF. The study findings suggest that SalFI is a reliable and valid instrument to assess CRF. The SalFI can be administered in specialty institutions and community-based settings. Further validation of the SalFI in other clinical populations and in other languages is necessary to determine its clinical utility, especially in monitoring clinically-relevant toxicities related to standard and experimental cancer therapies.

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Table 1. Clinical and Demographic Characteristics of Sample.

Demographics	
	N=60
Age [mean (s.d.)]	65.43 (10.11)
Sex [n (%)]	
Male	47 (78.33)
Female	13 (21.67)
Race [n (%)]	
White	49 (81.67)
A.A./Black	7 (11.67)
Asian	2 (3.33)
Native American/Alaskan	1 (1.67)
Other	1 (1.67)
Ethnicity [n (%)]	
Hispanic/Latino	1 (1.67)
Not Hispanic/Latino	49 (81.67)
Unknown	3 (5.00)
Not Documented	7 (11.67)
Diagnosis [n (%)]	
Prostate Cancer	38 (63.33)
Pancreatic	4 (6.67)
Breast	8 (13.33)
Lung	5 (8.33)
Esophageal	2 (3.33)
Other	3 (5.00)

s.d., = standard deviation, A.A. = African American

Table 2. Fatigue scores

Questionnaire	Questionnaire Score Range	Time Point 1 [mean (SD)]	Time Point 2 [mean (SD)]	Time Point 3 [mean (SD)]
SalFI	0-34	3.91 (5.10)	3.87 (5.05)	4.09 (5.29)
Physical	0-14	1.93 (3.27)	1.87 (2.82)	1.48 (2.68)
Affective	0-14	1.03 (1.68)	1.02 (2.07)	1.08 (2.05)
FACT-F	0-52	42.09 (10.81)	40.65 (11.15)	39.57 (11.59)
rPFS	0-10	2.02 (2.20)	2.38 (2.42)	2.44 (2.41)

SD = standard deviation, SalFI – Saligan Fatigue Inventory, FACT-F = Functional Assessment of Cancer Therapy – Fatigue, rPFS = revised Piper Fatigue Scale

Table 3. Fatigue Scores of Metastatic vs Non-Metastatic Participants

	Questionnaire	Group	N	Mean (SD)	*p*-value
Time Point 1	SalFI	Non-Metastatic	39	2.46 (3.39)	0.01
		Metastatic	15	7.67 (6.81)	
	FACT-F	Non-Metastatic	39	44.10 (9.54)	0.03
		Metastatic	15	36.87 (12.45)	
	rPFS	Non-Metastatic	39	1.83 (2.06)	0.30
		Metastatic	14	2.55 (2.56)	
Time Point 2	SalFI	Non-Metastatic	41	2.83 (4.24)	0.01
		Metastatic	14	6.93 (6.09)	
	FACT-F	Non-Metastatic	39	42.98 (8.76)	0.01
		Metastatic	14	34.14 (14.52)	
	rPFS	Non-Metastatic	40	2.15 (2.31)	0.25
		Metastatic	14	3.02 (2.70)	
Time Point 3	SalFI	Non-Metastatic	38	3.18 (4.70)	0.01
		Metastatic	8	8.38 (6.16)	
	FACT-F	Non-Metastatic	38	41.21 (11.13)	0.03
		Metastatic	8	31.75 (11.11)	
	rPFS	Non-Metastatic	37	2.21 (2.39)	0.18
		Metastatic	8	3.47 (2.33)	

SD = standard deviation, SalFI – Saligan Fatigue Inventory, FACT-F = Functional Assessment of Cancer Therapy – Fatigue, rPFS = revised Piper Fatigue Scale

Appendix 1. The Saligan Fatigue Inventory

Saligan Fatigue Inventory (SalFI)

Directions: Each of the seven primary questions (*italicized*) should be asked exactly as written. Each question should elicit a detailed answer that will allow the interviewer to score the response. However, the use of follow-up questions may be needed; suggested follow-up questions are presented after the primary question. A total questionnaire score is obtained by summing all of the individual items. Higher scores indicate higher fatigue symptoms.

For each of the following questions, please circle the number which best describes the participants or their response for the past week. Please make every effort to answer each question to the best of your ability. Thank you very much!

1. *Did you have difficulty concentrating or collecting your thoughts in the past week*?

0	1	2	3	4	5	6
No Difficulty		Occasional		Moderate Difficulties		**Great Difficulty**

Examples of Follow-up Questions (as needed): How has your memory been this past week? Reading? Watching TV? Holding a conversation? Difficulty getting your thoughts started? How about making minor decisions? Have you been getting easily distracted?

2. *Did you have difficulty feeling motivated to start activities in the past week, including simple routine activities*?

0	1	2	3	4	5	6
No Difficulty		Slight difficulty		Difficulty with routine activities		**Unable to do anything**

Examples of Follow-up Questions (as needed): Did you notice feeling tired more easily? Has it been difficult to get started on things you need to do?

3. *Have you been feeling especially tense or irritable this past week*?

a. Patient Self Report:

0	1	2	3	4	5	6	7	8
None		Some Episodes Of Irritability		More Irritable than Usual		Frequently Irritable		**Irritable All the Time**

Examples of Follow-up Questions (as needed): Edgy? Worried a lot about things you don't ordinarily worry about? Unable to relax? Easily tearful? Startle easily? Restless?

b. Nurse Observation Only:

0	1	2	3	4	5	6	7	8
None		Looks Anxious, Worried, Or Tearful		Looks Irritable, Tense, Or Upset At Times During Interview		Looks Frequently Irritable, Tense, Or Upset During Interview		**Uncooperative**

4. *Did you feel fatigued this past week? If yes, how many times a week?*

0	1	2	3	4
No Fatigue	Fatigued, No Interference With Activities	More Fatigued than Usual ~once/day, 3x/week	Fatigued Most Days	**Fatigued all the Time**

Examples of Follow-up Questions (as needed): Do you feel heavy? Heaviness on limbs? Leaden? Weighed down? Unable to finish tasks (ex: cleaning, chores) because of being physically tired?

5. *Did you have difficulty performing activities this past week*?

0	1	2	3	4
No Difficulty	Feels Weak To Work Or Do Activities	Need To Push Self To Work Or Do Activities	Decrease In Actual Time Spent In Activities	**Stopped Doing Activities Or Work**

Examples of Follow-up Questions (as needed): Have you been working? Have you been social as when you feel well? Have you stopped doing anything you used to do?

6. *During the past week, did you have any heaviness in limbs, back or head: backaches, headache, muscle aches; loss of energy and fatigue*?

0	1	2
None	Any Clear-Cut Symptom	**General Symptoms**

7. **Nurse Observation Only:** slowness of thought and speech, impaired ability to concentrate, decreased motor activity

0	1	2	3	4
Normal Speech And Thought	Some Slowness with Response	Obvious Slowness with Response	Interview Difficult	**Complete Stupor**

SalFI [ ] **Score:**

End Time of Interview:_____