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Original Article

Physiotherapy Section

Psychometric Evaluation of Hindi Version of Fatigue Pictogram in Individuals with Breast Cancer: A Cross-sectional Study

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ABSTRACT

Introduction: Cancer Related Fatigue (CRF) is the most prevalent and distressing symptom among women with Breast Cancer (BC) which is underestimated and undertreated by healthcare professional. Barrier to under-reporting and under treatment of CRF include more focus on patient survival, busy clinical settings with patient overload, and lengthy CRF evaluation tools. Fatigue Pictogram (FP) is a brief, valid and reliable Fatigue Screening Tool (FST) which can be promptly administered in busy clinical settings. There is lack of brief, easily applicable FST in Hindi language which can be promptly administered in busy Oncology Clinics.

Aim: To evaluate the psychometric properties of Hindi version of FP among women with BC.

Materials and Methods: The present cross-sectional study was conducted in two phases. In phase 1, original English version of FP underwent forward and backward translation and a prefinal Hindi version of FP was created. The prefinal version was then pilot tested on 10 women with BC. In phase 2, psychometric properties of final Hindi version of FP were evaluated. Criterion validity was evaluated on a sample of 101 women with BC by testing against Hindi version of Fatigue Severity Scale (FSS-H) and test-retest reliability was evaluated on a sample of 50 BC survivors by administering Hindi version of FP on two occasions. Data analysis was carried out using Statistical Package for Social Sciences (SPSS) version 24.0. FP has two items (Item A and Item B) which evaluate two dimensions of CRF (severity and impact of fatigue on activity level), and has no overall cut-off score, therefore, both the items of FP were separately evaluated for psychometric properties. Spearman's rho Correlation Coefficients (r) were calculated for establishing criterion validity of Hindi version of FP and Spearman correlation coefficient, and Wilcoxon signed-ranks test were calculated to evaluate test-retest reliability of each item separately.

Results: Validity testing revealed a moderate positive correlation between Item A and FSS-H ($r=0.680$, $p<0.001$) scores and item B and FSS-H ($r=0.643$, $p<0.001$) scores. Reliability testing revealed a highly significant correlation between the Hindi version of FP scores on two occasions for both the Items ($r=0.901$, $p<0.001$ for Item A, and $r=0.917$, $p<0.001$, for Item B).

Conclusion: Despite high prevalence rate, CRF is understated and undermanaged symptom. Acceptable criterion validity and excellent test-retest reliability support the application of Hindi version of FP as a FST in Hindi speaking individuals with BC.

Keywords: Fatigue pictogram, Cancer related fatigue, Hindi translation, Validation

INTRODUCTION

The CRF is subjective, frequent, frustrating side-effect of cancer and its treatment, affecting day to day life of individuals with cancer [1]. CRF exerts a profound negative effect on physical, physiological, social, cognitive and role functioning of individuals with cancer. CRF adversely affects emotional wellbeing, return to work, quality of life and overall survival of individuals with BC [2-6]. CRF has an estimated pooled prevalence of 52% across different cancer types [7]. When compared to general population, chronic fatigue is reported seven times more prevalent in individuals with cancer, and is rarely relieved by rest or sleep [8]. In BC, CRF has prevalence up to 60% which, to a varying degree, may persist for many years after completion of anti-cancer treatment [9,10]. Kaur N et al., reported clinically significant fatigue in 38% participants and an overall prevalence of 60% in a sample of 230 Indian BCS [10]. National Comprehensive Cancer Network has defined CRF as "a distressing, persistent, subjective sense of physical, emotional, and/or cognitive tiredness or exhaustion related to cancer or cancer treatment that is not proportional to recent activity and interferes with functioning" [11]. Evidence-based guidelines on CRF recommend routine fatigue screening using valid assessment tools, and further evaluation and treatment of people having moderate to severe fatigue [11].

Two types of scales are available to evaluate CRF- unidimensional, and multidimensional scales. Unidimensional scales evaluate CRF in terms of its severity and existence e.g., brief fatigue inventory, Wu cancer fatigue scale, FSS. Multidimensional fatigue scales measure the impact of fatigue on other domains such as physical, emotional and cognitive function in cancer patients e.g., the multidimensional fatigue inventory-20, piper fatigue scale revised, FP. Most of the fatigue scales are validated in mixed population, while some like Wu fatigue scale, piper fatigue scale revised, multidimensional fatigue symptom inventory-short form, and cancer-related fatigue distress scale have been validated in BC patients [12]. However, among a wide array of symptoms related to cancer or its treatment, CRF is often given less importance by the patient themselves and often overlooked and undertreated by healthcare professionals [13-16]. Busy clinical settings and heavy patient case load, extensive length and complexity of the valid fatigue assessment tools has been cited as the reason for less reporting of CRF in clinical settings by healthcare professionals [16].

Literature evidence shows that addition of pictures can enhance the comprehension of written medical instructions and symptom reporting by patients [17]. FP having two questions with pictures to rate the intensity and impact of fatigue [Table/Fig-1] has good applicability in such busy clinical settings and in patients with lower reading and comprehensive skills [18].

A few CRF assessment tools like multidimensional fatigue inventory 20, functional assessment of chronic illness therapy-fatigue scale, FSS have been translated in to Hindi language and validated for use in Hindi speaking patients [19-21]. However, these tools have multiple items to evaluate different aspects related to fatigue, and take longer to administer. FP has only two items, therefore, takes

[Table/Fig-1]: Fatigue Pictogram [18].

less time to administer and pictorial illustrations make it easy to understand and respond for patients [18]. Original English version of FP has been translated in to Portuguese language [22]. However, there is no study on its validation in any of the Indian languages. Hindi is the official language of the Government of India and is one of the most widely spoken languages worldwide. According to Government of India data, 43.63% of the people in India speak Hindi [23]. A Hindi translation and validation of the FP can provide a brief, easy to administer FST for clinicians across the world treating Hindi speaking individuals, research trials involving Hindi speaking participants. Therefore, the present study aimed to evaluate the psychometric properties of Hindi version of FP among women with BC. The study is a part of PhD thesis work on women with BC and none of the data related to current manuscript has been published anywhere.

MATERIALS AND METHODS

The present cross-sectional study was conducted in Department of Radiation Oncology, Pt. BD Sharma PGIMS Rohtak and College of Physiotherapy, Pt. BD Sharma PGIMS, Rohtak, between July to December, 2024. Ethical approval for the study was obtained from Institutional Ethical Committee, Amity University (AUUP/IEC/DEC/2022/), Noida and Biomedical Research Ethics Committee, Pt. BD Sharma PGIMS/UHS, Rohtak (No. BREC/23/113). The study is registered with Clinical Trial Registry of India (CTRI/2023/04/051543). Informed consent was obtained from all study participants. The permission to use, translate, and validate the Hindi version of FP was obtained by contacting the primary developer of the tool.

As per recommendations for performing linguistic translation and cultural adaptation of an outcome measure, a sample size with ratio of at least 10 participants for each scale item (respondent-to-item ratio) is considered methodologically adequate to assess the validity of a translated tool. A sample size ≥50 is considered acceptable to establish test-retest validity of a translated tool [24-26]. FP is a two-item tool. However, to evaluate its criterion validity, Hindi version of FP and Hindi version of FSS were administered simultaneously on 101 women with BC. For test- reliability testing, Hindi version of FP was administered on 50 BC survivors on two occasions at an interval of 10-14 days. Nineteen BC survivors participated in validity as well as reliability testing, hence the final Hindi version of FP was administered on 132 women with BC.

Inclusion and Exclusion criteria: Eligibility criteria were diagnosed cases of BC who were on active anti-cancer treatment or completed it, aged 18 years or above, having Hindi as their native language and who could comprehend and answer the FSS-H questionnaire and Hindi version of FP items. Subjects having psychiatric illness, communication impairment or who could not read and respond to FSS-H questionnaire and Hindi version of FP questions were excluded.

A total of 132 women with BC, who spoke Hindi as native language were enrolled in the study using convenient sampling method. Participants were informed about the study and a written informed consent was obtained. At first assessment, the demographic characteristics were recorded and all subjects were asked to mark their responses on Hindi version of FP. For establishing criterion validity, Hindi version of FP and FSS-H was administered simultaneously on a sample of 101 women with BC who were either undergoing active anti-cancer treatment (BC patients) or completed it (BC survivors). For test-retest reliability testing, 50 BC survivors were included, assuming that fatigue (severity and impact on activities) will be stable during a period of 10-14 days in BC survivors, who were not on any active anti-cancer treatment. For evaluating test re-test reliability, Hindi version of FP was administered on two occasions by the same assessor, first, in person at the time of enrolment in study and second, at home, 10-14 days after the first administration using telerehabilitation services in College of Physiotherapy, Pt. BD Sharma PGIMS, Rohtak, India.

Fatigue Pictogram (FP): FP is a simple, brief, and easy to understand FST for individuals with cancer. It has two questions/items to evaluate two dimensions of fatigue - physical tiredness (Item A) and activity level (Item B) over last one week [Table/Fig-1]. Each question has five illustrations with descriptors to rate the intensity ('not at all tired', 'a little bit tired', 'somewhat tired', 'moderately tired' and 'extremely tired'), and impact of fatigue ('I can do everything I normally do', 'I can do almost everything I normally do', 'I can do some of the things I normally do', 'I do what I have to do', and 'I can do very little'). FP is an ordinal scale with responses ranging between 0-4, and does not have an overall score or cut off score. FP has demonstrated good validity and reliability and had comparable properties when administered face-to-face or by phone [18]. In a feasibility study, numeric rating scale and FP have been found equally applicable for screening fatigue in cancer outpatient care [27].

Fatigue Screening Scale (FSS): FSS is a valid and reliable self-report fatigue questionnaire developed by Krupp LB et al., commonly used to assess fatigue in chronic diseases [21]. FSS is a nine-item scale used for evaluating physical aspect of fatigue and how fatigue affects motivation, exercise capacity, physical functioning, sustained functioning, performing duties, hindering work, family, and social life. Each item is a short statement which is rated on a Likert scale with responses ranging from one ("completely disagree") to seven ("completely agree"). The minimum possible score is nine and the highest is 63. A total score of 36 (out of 63) or a mean score of 4 is considered indicative of significant fatigue which needs further evaluation. FSS has been used in different patient populations, including individuals with cancer. FSS has been translated in to multiple languages including Arabic, Dutch, and Finnish, Gujarati, Punjabi, Hindi, Kannada and Bangla and Tamil, and is widely used in clinical practice and research. Hindi version of FSS (FSS-H) has been found to have high internal consistency and validity in detecting fatigue in a group of patients with Parkinson's disease [28].

Study Procedure

The study was conducted in two phases.

Phase 1: In phase 1, translation and construction of FP into Hindi language was done as per standardised guidelines for performing linguistic translation and cultural adaptation of an outcome measure [24-26]. The original English version of FP (text part) was forward translated in to Hindi language by two independent, bilingual translators (a retired rehab professional with post graduate degree in occupational therapy and a Hindi language academician with post graduate degree in Hindi language, working in Government Institution) which resulted in two forward translated Hindi versions of FP (FP-H1 and FP-H2). Both the versions were reviewed by a review committee and a mutually agreeable synthesised version of the FP-H12 was created. The synthesised Hindi version (FP-H12) was translated back to English (FP-HB1, FP-HB2) by two bilingual,

independent translator (academicians in Government Institutions, one being of English language and both having PhD degrees). Both back-translations were compared by a review committee regarding any ambiguities and discrepancies of format and wording, similarity in meaning, and whether the content of translated versions was representative of the original FP. Review committee included translators, a methodist, a bilingual medical cancer expert and one of the authors (SM) of this study. After review by committee, a prefinal Hindi version of FP was created which was pilot tested on ten Hindi speaking BC survivors in Outpatient Department (OPD), Department of Radiation oncology, Pt. BD Sharma, PGIMS Rohtak, India, to evaluate its clarity and understandability. No changes were required after pilot testing. The approval for Hindi version of FP was obtained from the primary developer (Fitch) of FP.

Phase 2: In phase 2, Hindi version of FP survey was administered on women with BC to evaluate its validity and reliability.

STATISTICAL ANALYSIS

Descriptive statistics was used for analysing the demographic data and finding frequency (%) of participant responses to each of the two items/questions of Hindi version of FP. Since both items of the FP (Item A and Item B) represents different construct and there is no overall/cut-off score of FP, each item was separately evaluated in statistical analysis for its psychometric properties. Statistical analysis was carried out using SPSS version 24.0, and p p≤0.01 were considered significant for all analyses. The Criterion validity of Hindi version of FP was evaluated against FSS-H scores, which has been validated for assessing fatigue in Hindi speaking population [28]. A positive correlation was expected between the scores of Hindi version of FP items and FSS-H scores. As FP and FSS are ordinal scales, with paired observations in the study, Spearman's rho Correlation Coefficients (r) were calculated for establishing criterion validity of Hindi version of FP against Hindi version of FSS. Test-retest reliability was estimated by administering the Hindi version of FP on two occasions, first at the time of enrolment in the study, and second 10-14 days after the first assessment. Spearman correlation coefficient and Wilcoxon signed-ranks test were calculated to evaluate test-retest reliability of each item separately. Hypothesis tested was that the fatigue (severity and impact on activities) will be stable during a period of 10-14 days in BC survivors, who were not on any active anti-cancer treatment. Correlation between Item A and Item B of Hindi version of FP was assessed by calculating Spearman's Correlation Coefficients (r). p≤0.01 was considered significant.

RESULTS

A total of 132 women with BC participated in the study. Demographic characteristics of the participants are presented in [Table/Fig-2]. Mean age of the participants was 53.6±11.87 years (ranging between 27 to 80 years). Mean BMI (Kg/m^2) of the participants was 25.96±4.28. Forty participants (30.3%) were BC patients (still undergoing active anti-cancer treatment), while 69.7% (n=92) were BC survivors (completed active anti-cancer treatment).

Variables		Frequency (Percent)
Age (years)	Mean±SD=53.6±11.87	-
BMI (Kg/m^2)	Mean±SD=25.96±4.28	-
Treatment status	Breast Cancer (BC) patients	40 (30.3%)
	Breast Cancer (BC) survivors	92 (69.7%)
Menopausal status	Pre-menopausal	28 (21.2%)
	Post-menopausal	104 (78.8%)

[Table/Fig-2]: Demographic characteristics of the participants.

The frequency of responses given by the participants to Hindi version of FP items is presented in [Table/Fig-3]. A higher percent of participants reported moderate {'Moderately tired', 48 (36.3%)} to extreme fatigue {'Extremely tired', 33 (25%)}, which was higher among BC patients when compared to BC survivors. Fatigue had mild ('I can do almost everything I normally do' and 'I can do some of the things I normally do') to moderate ('I do what I have to do') impact on day-to-day activity performance. A statistically significant positive correlation (r=0.716) was found between Item A and Item B responses [Table/Fig-4].

Items	No. of participants (N=132)	Percent (%)
Item A- Fatigue severity		
Not at all tired (0)	8	6.8%
A little bit tired (1)	25	18.9%
Somewhat tired (2)	18	13.6%
Moderately tired (3)	48	36.3%
Extremely tired (4)	33	25%
Item B - Impact of Fatigue on activities		
I can do everything I normally do (0)	2	1.5%
I can do almost everything I normally do (1)	28	21.2%
I can do some of the things I normally do (2)	24	18.2%
I do what I have to do (3)	63	47.7%
I can do very little (4)	15	11.4%

[Table/Fig-3]: Distribution of participant responses to Fatigue Pictogram (FP) items.

Correlation between item responses (Item A and Item B responses)		p-value
Spearman correlation coefficient (r)	0.716**	<0.001

[Table/Fig-4]: Correlation between Item A and Item B responses (n=132).
**Correlation is significant at the 0.01 level

The mean±SD score of FSS-H was 42.46±13.28. Correlation between Item A and FSS-H scores, and Item B and FSS-H scores, provided test for assessing concurrent criterion validity of Hindi version of FP. Results revealed a statistically significant, moderate positive correlation between Item A and FSS-H scores (r=0.680, p<0.001) and Item B and FSS-H scores (r=0.643, p<0.001, [Table/Fig-5]).

Correlation	Spearman correlation coefficient	p-value
Correlation between Item A scores and FSS-H scores	0.680**	<0.001
Correlation between Item B scores and FSS-H scores	0.643**	<0.001

[Table/Fig-5]: Correlations between Hindi version of Fatigue Severity Scale (FST) scores, and Hindi version of Fatigue Pictogram (FP) item scores (n=101).
FSS-H- Hindi version of Fatigue Severity Scale (FST)
**Correlation is significant at p<0.01

For test-retest reliability testing, fifty BC survivors were evaluated on two occasions at an interval of 10-14 days by the same assessor. The mean score of Item A of Hindi version of FP on 1st and 2nd visit were 2.44±1.07 and 2.34±1.06, respectively. The mean score of Item B of Hindi version of FP on 1st and 2nd visit were 2.30±1.02 and 2.34±0.98, respectively. A highly significant correlation was found between the FP-H scores at 1st and 2nd occasions for both the Items (r=0.901, p<0.001 for Item A, and r=0.917, p<0.001 for Item B) [Table/Fig-6].

Questions	Analysis (between 1st and 2nd assessment)		p-value
Question/Item A How tired have you felt over the past one week?	Spearman correlation coefficient	0.901**	<0.001
	Wilcoxon Signed Rank (z)	1.508	0.132
Question/Item B How much does feeling tired prevent you from doing what you want to do?	Correlation coefficient	0.917**	<0.001
	Wilcoxon Signed Rank (z)	0	1

[Table/Fig-6]: Test-retest reliability of Hindi version of Fatigue Pictogram (FP) (n=50).
**Correlation is significant at p<0.01

DISCUSSION

The symptom cluster literature in BC has revealed fatigue as the most prevalent and distressing symptom, adversely affecting functioning and quality of life of individuals with BC [29]. This emphasises the need to regularly evaluate CRF using valid, reliable tools. However, CRF is often overlooked and undermanaged by healthcare professionals, with commonly cited reasons being busy oncology clinical settings with patient overload, as well as the extensive length and complexity of valid fatigue assessment tools. Brief and easily comprehensible tools in local vernacular can have significant utility in busy oncology clinics. Present study aimed to evaluate the psychometric properties of Hindi version of FP among women with BC. The results of the study demonstrated that Hindi version of FP has satisfactory psychometric properties for screening fatigue in patients with BC. Hindi version of FP demonstrated good criterion validity and excellent test-retest reliability in patients with BC. It demonstrated comparable reliability when administered face to face or by teleconsultation, which makes it useful FST for patients from remote or distant areas.

A high percentage of participants reported moderate ('Moderately tired', 36.3%, n=48) to extreme fatigue ('Extremely tired', 25%, n=33), across all age groups, different BMI distribution, and menopausal status (Item A). This finding highlights high prevalence of clinically significant fatigue among women with BC. Previous research has also reported high prevalence of CRF in individuals with BC [9,10,30]. Mao H et al., reported that fifty six percent of BC survivors who received aromatase inhibitors, experienced moderate-to-severe fatigue [30]. Though the aetiology underlying CRF is still not well-understood, an array of biopsychosocial factors impacts and amplify CRF in individuals with cancer. BC and its treatment related side-effects contribute to CRF by causing inflammation, haematological compromise, cardiopulmonary toxicities and reduced metabolism. Emotional distress, depression, anxiety, pain, sleep disturbance, lack of support from family and friends, financial burden is also strongly linked to CRF [1,31,32].

Fatigue had significant mild ('I can do almost everything I normally do' and 'I can do some of the things I normally do', n=52, 39.4%) to moderate ('I do what I have to do', n=63, 47.7%) impact on performance of day-to-day life activities (Item B). Two constituent items of FP (Item A and Item B) evaluate two dimensions (intensity and impact on activities respectively) of fatigue which are theoretically related to each other. The results also revealed significant, strong positive correlation (r=0.716) between participant responses to Item A and Item B of Hindi version of FP indicating that higher level of fatigue had significant negative impact on activity level of the participants. Previous studies have reported significant negative impact of fatigue on functionality of women with BC [33,34]. Dodd MJ et al., in a longitudinal study on BC patients (n=112), who received adjuvant chemotherapy with or without radiation therapy, reported that women having higher scores in 'symptom cluster' of pain, fatigue, sleep disturbance and depression, had significantly poorer functional status and quality of life [34].

Criterion validity testing revealed a statistically significant, moderate positive correlation between FSS-H and Item A (r=0.680) scores, and FSS-H and Item B (r=0.643) scores, indicating that Hindi version of FP has good criterion (concurrent) validity. The reason for moderate correlation between Hindi version of FP and FSS-H scores might be twofold. First, Hindi version of FP has only two questions which evaluate only two dimensions of fatigue (severity of fatigue and its impact on activities). On the other hand, FSS is a nine-item scale which evaluates many aspects of fatigue like physical aspect of fatigue, and how fatigue affects motivation, exercise capacity, physical functioning, sustained functioning, hinderance in work, family, or social life of patients [21,28]. Second, two items of FP represent different constructs, therefore, are evaluated separately for psychometric properties, while FSS evaluates many aspects of fatigue altogether and gives an overall score.

Test- retest reliability testing revealed strong correlation between the scores of Item A (r=0.901, with no significant difference in ranks) and Item B (r=0.917, with no significant difference in ranks) at two occasions (1st and 2nd administration of Hindi version of FP over a period of 10-14 days), and in different settings (face to face and via teleconsultation), indicating that Hindi version of FP has an excellent test-retest reliability.

Original English version of FP has been translated in to Portuguese language and validated for use in Brazilian population also. In this study, to evaluate psychometric properties, Brazilian version of FP was administered on three group of participants- group having individuals with cancer, group having caregivers of individuals with cancer and group having healthy nursing students. Brazilian version of FP presented good convergent validity (r=0.418, p<0.001 for Item A, and r=0.425, p<0.001 for Item B) on testing against Beck Depression Inventory and divergent validity (r=-0.261, p<0.001 for Item A and r=-0.513, p<0.001 for Item B) on testing against Karnofsky performance status scale in patients with cancer group, but was not found valid for caregiver and student group. The test-retest reliability in group of patients with cancer was (r=0.543, p<0.05 for Item A and r=0.588, p<0.05 for Item B, with no significant difference in the ranks) [22].

CRF is one of the most frequent symptoms experienced by individuals across difference cancer types and treatment status. FP is a brief, simple to use, valid and reliable FST for individuals with cancer. A Hindi translation of FP can provide a brief FST for initial screening of CRF in busy clinical settings treating Hindi speaking individuals with BC. In this study, Hindi version of FP has been found to have acceptable criterion validity and excellent reliability, therefore, might be used by clinicians and researchers across the world treating Hindi speaking individuals with BC.

Limitation(s)

Though, the present study is the first study to evaluate and establish the psychometric properties of Hindi version of FP for use in Hindi speaking patients, the study had a few limitations also. The current study included women with BC only while prevalence rates, severity and dimensions of CRF vary in different cancer types. In the future, psychometric evaluation of the Hindi version of the FP may be conducted on individuals with other cancer types, involving participants of both genders and across multiple centres.

CONCLUSION(S)

The CRF is distressing and disabling symptom in patients with BC. Despite high prevalence rate, CRF is understated and undermanaged symptom. Self-report measurement tools are primarily used to evaluate severity and dimensions of CRF. Acceptable criterion validity and excellent test-retest reliability support the application of Hindi version of FP as a preliminary FST in Hindi speaking individuals with BC. Screening and treatment of CRF will have positive impact on quality of life of women with BC.

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