Feasibility and Validity of a One-Item Fatigue Screen in a Thoracic Oncology Clinic

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Introduction: Fatigue is one of the most common symptoms in patients with advanced cancers. Despite its high prevalence, it is often unrecognized and undetected. This study assessed the feasibility and validity of a one-item fatigue scale (OIFS) in an outpatient oncology clinic.

Methods: Over a 3-month trial period, all patients in a thoracic oncology clinic were screened for fatigue with a one-item, 0 to 10 scale. Over a second trial period, an additional sample of 100 clinic patients completed validated measures of fatigue, including the Functional Assessment of Chronic Illness Therapy-Fatigue Scale (FACIT-F) and Fatigue Symptom Inventory (FSI), in addition to the OIFS.

Results: During the initial trial period, more than 95% of patients (574 of 600) had a documented OIFS score on their first clinic visit. Data from the second cohort of patients revealed that the OIFS had good test-retest reliability (r = 0.88) and was highly correlated with the FSI severity scale (0.87) and the FACIT-F (0.75). Receiver operating characteristic analysis showed the OIFS had good discrimination compared with the FACIT-F (area under the curve = 0.87). Sensitivity and specificity of several OIFS cutoff scores were compared, and scores between 3 and 5 were found to be optimal.

Conclusions: The use of a one-item scale to screen for fatigue is feasible in an ambulatory clinic setting. This scale had convergent validity with other measures of fatigue and was able to identify cases feasible in an ambulatory clinic setting. This scale had convergent validity and validity of a one-item fatigue scale (OIFS) in an outpatient oncology clinic.

Fatigue is one of the most prevalent and distressing symptoms among patients with cancer. Cancer-related fatigue (CRF) differs from the fatigue experienced by healthy people because it is unrelied by rest or sleep.1 The National Comprehensive Cancer Network (NCCN) defines CRF as “a persistent, subjective sense of tiredness related to cancer or cancer treatment that interferes with usual functioning.”2 Estimates of the prevalence of CRF range from 60% to 90%.3-5 Fatigue is the most common side effect in patients undergoing chemotherapy or radiation.6 Although fatigue is a common symptom at the time of cancer diagnosis, it increases in prevalence and intensity with therapy and cancer progression.7 A study of more than 3000 cancer patients demonstrated that nearly twice as many patients reported fatigue as pain.8 Studies show the prevalence of fatigue in ambulatory patients with advanced-stage lung cancer is as high 81.5%.9

CRF is very distressing to patients as it interferes with their ability to remain functionally independent and active.10 Multiple studies have shown that fatigue negatively affects enjoyment and quality of life (QOL). The studies performed by the Fatigue Coalition illustrate the impact of fatigue on QOL.3,11 More than 75% of the cancer survivors in this study experienced fatigue at least a few days of the month while receiving chemotherapy. Of these patients, 91% reported that fatigue prevented them from experiencing a normal life, and 88% responded that it caused them to alter their daily routine.11 A similar study found that most patients ranked fatigue as the side effect that most affected them during therapy, significantly more than nausea, hair loss, or pain.12

Despite its prevalence and impact, cancer-related fatigue is often overlooked in clinical practice because oncology clinicians tend to focus their limited time discussing anti-cancer therapy with their patients. There are many patient and clinician barriers to effective communication about fatigue.13 One of the most widely recognized obstacles is that cancer patients often fail to communicate their fatigue because they believe it is unrelieved by rest or sleep.1 The NCCN guidelines recommend screening every patient at regular intervals for fatigue as part of the vital signs.2 They recommend screening with the question, “Since your last visit, how would you rate your worst fatigue on a scale of 0

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to 10?” Scores on this scale are given corresponding categorical descriptions: no fatigue (0), mild fatigue (1–3), moderate fatigue (4–6), and severe fatigue (7–10). Although the NCCN recommends this screening tool at each initial visit and at regular intervals, few data exist on the feasibility or validity of this screening.

Any screening tool for CRF must be easy to administer in an ambulatory practice and be clinically meaningful. A one-item scale for fatigue could easily be incorporated in any clinical setting. Support for the use of a 0-to-10-point scale to rate fatigue levels can be derived from studies of other instruments. The Brief Fatigue Inventory (BFI) is a validated nine-item instrument for assessing fatigue in cancer patients that includes three one-item, 0 to 10 severity scales.16 Scores of seven or greater on both “usual level of fatigue during the past 24 hours” and “worst level of fatigue during the past 24 hours” were associated with greater interference in functioning, increased symptom distress, and decreased QOL.16,17 Similarly, a score of seven or greater on the one-scale for fatigue is associated with functional impairment assessed by the Medical Outcomes Study Short Form 36 (MOS-SF-36).18

There have been no studies validating the feasibility or utility of implementing an OIFS into routine clinical care. The goal of this study was to assess the feasibility and validity of the OIFS in a busy outpatient oncology clinic. Because of the high prevalence of fatigue among patients with lung cancer, we choose a thoracic oncology clinic as our population to investigate the practicability of the rapid one-item screen. To investigate the scale’s validity, we also performed comparisons to published validated instruments for convergent and divergent validity and its ability to discriminate differences in functional abilities.

PATIENTS AND METHODS

Study Population

Feasibility Study

From April 2004 until July 2004, all ambulatory patients seen in the thoracic oncology clinic at a Massachusetts General Hospital were asked about their level of fatigue, regardless of type of malignancy, stage of disease, or duration of illness. Data on fatigue screening were collected over a 3-month period, beginning on the first day of the screening program. The study was conducted with approval and monitoring of the internal review board. Patients were not required to provide informed consent for participation.

Cross-Validation Study

We obtained additional internal review board approval for the cross-validation study on a second cohort of patients. An additional sample of 100 patients presenting to the thoracic oncology clinic between October 2004 and December 2004 were recruited to participate in this study. Based on prevalence estimates of fatigue in thoracic oncology patients, a sample size of 100 patients was expected to yield sufficient cases of fatigue to examine sensitivity and specificity and cutoff scores for the OIFS. All patients presenting to the clinic, regardless of type of malignancy, stage of disease, or duration of illness were eligible to participate. Participants in this study were required to read English. The medical assistants informed patients that completion of the questionnaires served as implied consent.

Procedure

Feasibility Study

A physician and nurse manager trained the medical assistants who escort patients from the waiting room to the examination room and assess vital signs. The training consisted of a 1-hour program reviewing CRF and the NCCN guidelines. The medical assistant placed posters with information about CRF, including a visual analogue fatigue scale, in each examination room.

The medical assistants were instructed to ask, “How would you rate your fatigue on a scale of 0 to 10 with 0 being ‘no fatigue’ and 10 being the ‘worst possible fatigue’?” The medical assistants recorded the OIFS with the vital signs in the medical record for oncologist to review before entering the patient room.

Cross-Validation Study

The medical assistants recruited patients to complete a packet of self-report questionnaires while waiting for their clinic appointment. During the study period, the medical assistants gave all patients presenting for appointments the questionnaire packet, which included a cover letter from the director of thoracic oncology clinic explaining that the purpose of the questionnaires was to better understand CRF. The medical assistant continued recruitment until 100 questionnaire packets were completed.

Assessments

Cross-Validation Study

The participants in the cross-validation study were asked to complete the FACIT-F, the FSI, and the Hospital Anxiety and Depression Scale (HADS). The medical assistants also administered the OIFS in an identical fashion as the feasibility study.

The FACIT Measurement System is a group of questions that measure health-related QOL among cancer patients. The FACIT-F subscale is a 13-item questionnaire that assesses fatigue and its impact on function. The response format consists of a five-point Likert scale to assess fatigue during the preceding week. FACIT-F scores range from 0 to 52, with higher scores representing lower levels of fatigue. Scores less than 30 are considered indicative of clinically significant fatigue.19

The FSI is a 14-item self-assessment tool to measure the intensity and duration of fatigue and its affect on QOL.20 The questionnaire includes multiple response formats including four questions with an 11-point scale ranging from 0 to 10 (anchored by “not fatigued at all” to “as fatigued as I could be.”) There are also seven questions inquiring about the interference of fatigue on activity and function and three questions to assess the duration and pattern of fatigue. A higher score on the FSI is indicative of greater levels of fatigue. The FSI does not have defined cutoff criteria for
identifying clinically significant fatigue. The severity scale of the FSI was used in all analyses.

The depression subscale of the HADS was used to assess depression among study participants. The HADS is a self-assessment 14-item questionnaire that has been well tested in cancer patients. It consists of two seven-item sub-scales assessing depression and anxiety in the preceding week. The scale is considered appropriate for cancer patients because of the lack of items regarding somatic symptoms, which can confound the identification of psychiatric issues.21 The format consists of four responses that quantify the degree to which a particular emotion is experienced by the patient. The score on each subscale ranges from 0 to 21 and a score greater than 11 is considered to be consistent with definitive depression or anxiety.

Analyses

Convergent validity between the one-item fatigue screen and the two validated measures of cancer-related fatigue was analyzed by using Spearman correlations. As a measure of divergent validity, scores on the one-item fatigue screen were correlated with depression scores on the HADS.

To evaluate diagnostic utility of the OIFS, analyses compared OIFS scores of patients with significant fatigue versus those without significant fatigue as measured on the FACIT-F. The FACIT-F was used as the criterion measure because it has a validated cutoff score for designating significant fatigue.19 In a receiver operating characteristic analysis, the calculation of the area under the curve was used to quantify the diagnostic utility of the OIFS across the full range of scores. Area under the curve values ≥0.80 are considered good, and values ≥0.90 are considered excellent.22 Based on the cutoff scores recommended by the NCCN, the validity of several candidate OIFS cutoff scores were evaluated by calculating the sensitivity and specificity of these scores compared with the FACIT-F.

RESULTS

Feasibility

In 2004, 640 new patients were seen in the thoracic oncology clinic. The breakdown of these new patients by disease was approximately 58% non-small cell lung cancer, 6% small cell lung cancer, 10% esophageal cancer, 2% mesothelioma, and 15% other (thyroid cancer, thymic malignancies, adenoid cystic carcinoma, other solid tumors, or pathology unknown). The age of these patients ranged from 25 to 91 years old, with a median of 65 years old. Women and men compromised 47% and 53% of the population, respectively.

During the 3-month study period, 600 patients participated in 1418 visits to the thoracic oncology clinic. The number of visits per patient ranged from one to 13, with a median of two. The medical record contained a documented fatigue score for 96.6% of the visits. The data from the first visit of the 600 different patients show that the medical assistants screened 574 of the patients (95.6%) for fatigue. The numbers and percentage of patients reporting each level of fatigue on their initial screen is shown in Table 1. The mean OIFS score for all patient visits was 3.4, with a standard deviation of 3.2.

Cross-Validation

Population Description

The mean FACIT-F score for the population was 36.45 (±12.11), and 30.1% of patients had FACIT-F scores of 29 or less, meeting criteria for fatigue. Twenty-seven patients (27%) were currently working, and the mean number of hours was 32.9 (±2.58). A few patients reported functional impairments: inability to walk two blocks (15.3%), climb stairs (18.9%), do housework (13.8%), and complete their activities of daily living (8.2%). Four patients (4%) reported that their fatigue interfered with their ability to make medical appointments.

Test-Retest Reliability

As a measure of test-retest reliability, we compared scores on the OIFS obtained by the medical assistants as part of the vital signs with the same question in written form as one of the items of the FSI in the questionnaire packet. In these two forms, the one-item scale had a test-retest reliability of \( r = 0.88 \).

Fatigue Scores

The screening scores from the 100 participants on the cross-validation study were similar to the scores obtained in the pilot screening study and suggest a representative sample. The mean fatigue score was 3.5 ± 2.8. The distribution of categorical scores was also similar, with 30.9% reporting no fatigue, 25.5% reporting mild fatigue, 26.6% reporting moderate fatigue, and 17.0% reporting severe fatigue.

Correlations with Other Instruments

The OIFS was correlated with the severity scale of the FSI at 0.87 (\( P < 0.001 \)) and the FACIT-F at −0.75 (\( P < 0.001 \)), as shown in Table 2. This correlation is in the range of the two validate instruments correlating with each other, −0.87 (\( P < 0.001 \)). Less robust correlations were found with the depression scale of the HADS and the OIFS (0.56; \( P <

### Table 1. Distribution of fatigue scores in the feasibility sample analyzing the first observation per patient

<table>
<thead>
<tr>
<th>Fatigue score</th>
<th>Fatigue category</th>
<th>Patients reporting score</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>None</td>
<td>207 (36.1)</td>
</tr>
<tr>
<td>1</td>
<td>Mild</td>
<td>19 (3.3)</td>
</tr>
<tr>
<td>2</td>
<td></td>
<td>32 (5.6)</td>
</tr>
<tr>
<td>3</td>
<td></td>
<td>37 (6.4)</td>
</tr>
<tr>
<td>4</td>
<td>Moderate</td>
<td>41 (7.1)</td>
</tr>
<tr>
<td>5</td>
<td></td>
<td>74 (12.9)</td>
</tr>
<tr>
<td>6</td>
<td></td>
<td>41 (7.1)</td>
</tr>
<tr>
<td>7</td>
<td></td>
<td>45 (7.8)</td>
</tr>
<tr>
<td>8</td>
<td>Severe</td>
<td>54 (9.4)</td>
</tr>
<tr>
<td>9</td>
<td></td>
<td>10 (1.7)</td>
</tr>
<tr>
<td>10</td>
<td></td>
<td>14 (2.4)</td>
</tr>
</tbody>
</table>

Values are \( n \) (%).
Classification Agreement with the FACIT-F

The area under the receiver operating characteristic curve (Figure 1) was 0.87, indicating the OIFS discriminates effectively between those with and without significant fatigue. The sensitivity and specificity of several candidate cutoff scores indicated that OIFS scores between 3 and 5 had adequate sensitivity (>0.85) and specificity (>0.61) for use in this population (Table 3).

DISCUSSION

Over the last few years, there has been a marked improvement in pain management based on the development of pain as the “fifth vital sign.” It is routine practice for all cancer patients to be screened for pain at each outpatient encounter and during each inpatient hospitalization. The implementation of this practice has broken down many of the barriers to communication about pain between patients and clinicians.

Like many cancer-related symptoms, fatigue often goes unrecognized and untreated in cancer patients. The first step toward improving the recognition of CRF is to routinely inquire about it in clinical practice. Although the FSI and FACIT-F are well-validated tools for measuring fatigue in a research setting, they are not practical as a screening modality. Treating physicians cannot immediately use the information elicited from the FSI and the FACIT-F because the data must be analyzed and cannot immediately be given to the physician.

Although the NCCN guidelines advocate routine screening with a one-item scale, there are limited data to support the feasibility of this recommendation. Based on a routine screening rate of more than 96%, our pilot screening study establishes the feasibility of screening for fatigue in a busy ambulatory oncology clinic. The results also confirm the magnitude of the burden of CRF. Roughly half of the patients in this study reported fatigue levels of 4 or higher, consistent with other reports of fatigue among patients with lung cancer. The NCCN recommends that patients with a fatigue score of 4 or greater undergo further evaluation to determine the etiology and potential therapies for CRF. This study uncovered a widespread, unrecognized burden among our thoracic oncology patients.

Our data provides cross-validation for the one-item scale for use in clinical practice. The OIFS was highly correlated with the two validated measures of fatigue, the FACIT-F and the severity scale of the FSI. It should be noted that the correlation of the OIFS and the FSI severity scale is partially because of the OIFS being included as one of the four items of the scale. The one-item scale was less strongly correlated with the HADS depression scale, suggesting that depression is a related but distinct construct. This correlation was weaker than the correlations of the FSI and FACIT-F with depression and is similar to the mean for correlations of fatigue and depression instruments.

The OIFS was also effective in identifying patients who met FACIT-F criteria for fatigue. Examining the sensitivities and specificities of the different possible cutoff points; the optimal cutoff score is between 3 and 5. The lower the number chosen as a cutoff, the less likely that a possible case of fatigue will be missed but the greater the burden in further evaluating fatigue among the false positives. These data support the NCCN recommended cutoff score of 4.

Although this study provides preliminary evidence regarding the feasibility and validity of a rapid screen for fatigue in a specific population of ambulatory oncology patients, further studies are needed to support these findings. One of the limitations of this study is that we did not collect demographic information from the study participants. This was an observational study, and we have limited information on the patients who were screened, other than they were being evaluated for a thoracic malignancy. We are not able to describe the correlation of medical variables with fatigue or to control for confounders of fatigue such as stage of disease.

![Figure 1](image-url)
and chemotherapy. Although these relationships are important, this analysis was beyond the scope of this preliminary psychometric study and has been previously described in lung cancer patients.9 Another limitation is that this study was performed at a single academic institution and may not be generalizable to a community setting. However, the OIFS was quite easy to administer by medical assistants with limited patient experience. We therefore feel that most clinical settings would be able to administer the screening tool. Although we did assess the reliability of the OIFS, we administered the scale in a written and oral form, rather than repeating the oral scale. However, because the reliability was quite robust at \( r = 0.88 \), we do not believe that this method was particularly problematic.

There is a growing body of literature for interventions to treat and prevent CRF. There are data to support the use of erythropoietic agents, exercise, and attention to emotional distress to improve CRF.2 6–4 0 Screen for CRF will identify patients who are most likely to benefit from targeted interventions for fatigue. In addition, a screening program will identify patients who may be eligible for clinical trials to assess therapies for fatigue.

Based on these data, the Massachusetts General Hospital Cancer Center has now adopted a policy for fatigue screening at each outpatient encounter. This information is included in the vital signs, which are provided to the clinician along with the pain score. We have also increased our educational programs for patients and staff on CRF and have developed a CRF clinic to assist with fatigue management. Although identifying fatigue as the “sixth vital sign” may increase the detection and recognition of this common and distressing symptom among our patients, further studies on the clinical utility of screening and the impact of screening on the behavior of oncology providers and fatigue outcomes are needed.

REFERENCES


