A Comparison of Fatigue Scales in Postpoliomyelitis Syndrome

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Objective: To examine the applicability and validity of traditional fatigue questionnaires in postpoliomyelitis syndrome (PPS) patients with disabling fatigue.

Design: Cross-sectional study. PPS and disabling fatigue were ascertained according to published criteria. Descriptive- ness was determined using the McNemar test, and interscale z-score agreement was estimated with Pearson’s coefficients.

Setting: PPS clinic.

Participants: Fifty-six survivors of poliomyelitis: 39 met criteria for PPS, 25 of whom met criteria for disabling fatigue.

Interventions: Not applicable.

Main Outcome Measures: The Fatigue Severity Scale (FSS), visual analog scale (VAS) for fatigue, and Fatigue Impact Scale (FIS).

Results: Twenty-four patients scored 50% or higher on the scale range for FSS, compared with 19 patients for VAS for fatigue ($P=0.042$), and 7 patients for FIS ($P<0.001$). Scores for patients with disabling fatigue averaged 81.5%, 62%, and 40.9% of the scale range for FSS, VAS for fatigue, and FIS, respectively. Agreement was moderate between the FSS and VAS for fatigue ($r=0.45$, $P=0.02$), but low between FSS and FIS ($r=0.29$, $P=0.15$), and FIS and VAS for fatigue ($r=0.20$, $P=0.33$). Two sample t tests showed significant differences between those with disabling fatigue and those without, based on FSS scores ($t=3.8$, $P<0.001$), but not for VAS for fatigue or FIS scores.

Conclusions: FSS was the most descriptive of the instruments tested. Scores generated by the scales were not interchangeable. Of the 3 scales, FSS seemed to be the most informative for the clinical assessment of fatigue in patients with PPS.

Key Words: Fatigue; Poliomyelitis; Postpoliomyelitis syndrome; Rehabilitation.

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POSTPOLIOMYELITIS SYNDROME (PPS) is the term used to describe the new onset of progressive fatigue, pain, muscle weakness, atrophy, and functional loss that starts decades after recovery from poliomyelitis.1 Fatigue, defined as the subjective lack of physical or mental energy,2 is among the most debilitating symptoms of PPS. Fatigue is typically the earliest symptom, worsens over time, and often leads to severe incapacitation. In the 1985 National Survey of 676 polio survivors, 91% of the participants reported new or increased fatigue, 41% said fatigue significantly interfered with working, and 25% stated fatigue hindered with daily self-care activities.

Despite extensive research, an effective pharmacologic therapy to reduce fatigue in PPS patients is lacking. A shortcoming in previous PPS trials for fatigue has been the lack of diseasespecific outcome tools that could allow researchers to more accurately measure changes in fatigue intensity occurring over time.3-14 Because of this, investigators have employed fatigue questionnaires that had been developed and validated on subjects with a variety of other disorders, including multiple sclerosis (MS), chronic fatigue syndrome, and others. It is likely that the use of such instruments in PPS clinical trials is not devoid of problems. Although these instruments have established psychometric properties, they were designed to study other conditions and may fail to capture important characteristics of the fatigue unique to patients with PPS.

In the present study, we compared 3 traditional fatigue scales in order to determine which instrument would most accurately reflect symptom intensity in PPS patients suffering from disabling fatigue. In addition, we examined the magnitude of agreement between scales when administered to patients within a short period of time. Although these scales work as constructs to measure fatigue as an independent variable, we found that their scores were inconsistent and not interchangeable. This is in agreement with a previous investigation that indicates caution is needed when selecting outcome tools to measure fatigue during longitudinal studies with PPS patients.15 This becomes especially important if employing multiple outcome measures to assess end-point changes in symptom-targeted research. Further defining the limitations each scale carries, how well they overlap when applied concomitantly, and how these assessment tools complement each other may lead to improved research design and assist investigators with selecting the proper measures for fatigue in future PPS studies.

METHODS

Research Participants

We conducted this study under a protocol approved by the local institutional review board. Following the subject’s consent, we carried out a detailed clinical evaluation to confirm the diagnosis of PPS, to discern the presence or absence of disabling fatigue, and to exclude confounders. We ascertained PPS according to a slightly modified version of the diagnostic criteria recommended by the International March of Dimes16: (1) unequivocal remote history of paralytic poliomyelitis followed by total or partial recovery, (2) an interval of 10 or more years...
years (instead of usually ≥15y) of stable function after best recovery, (3) onset of new symptoms, such as progressive weakness and atrophy of previously affected or clinically unaffected muscles, muscle and/or joint pain, and fatigue, that are not otherwise explicable and lead to gradual functional decline. In the absence of a criterion standard, we ascertained patients with disabling (severe) fatigue based on their responses to the following statements of a structured questionnaire:

1. Fatigue was the most or among the most debilitating symptoms experienced (as opposed to not being the most or among the most debilitating symptoms),
2. Fatigue was present daily or on most days of the week (as opposed to not being felt daily or in most week days), and
3. Fatigue restricted the capacity of patients to carry out desired daily activities at home or work (as opposed to not restricting).

Because many patients with pain may verbalize that they feel tired and need rest, we paid particular attention to this aspect. We excluded patients having pain as their primary symptom and made sure pain levels were similar between groups.

In addition to medical interview and clinical and neurologic evaluations, we conducted a battery of laboratory tests (blood, urine, cardiogram) to help screen out covert confounders, including anemia, electrolyte imbalances, hepatic or renal insufficiency, thyroid dysfunction, urinary infection, cardiac arrhythmias, vitamin deficiencies, or autoimmune processes. Because sleep and mood disorders can induce excessive daytime fatigue (generally expressed as chronic tiredness), we also screened patients with the Epworth Sleepiness Scale (ESS) and the Beck Depression Inventory—II (BDI-II). The ESS is a commonly used tool to assess for symptoms and risk factors for excessive daytime sleepiness based on a 3-point rating scale for 8 categories. The BDI-II construct correlates with the depression criteria of the Diagnostic and Statistical Manual of Mental Health Disorders, 4th Edition, and is routinely used as a screening method for depression.

Fatigue Questionnaires

To assess objectively fatigue in the study population, we used 3 traditional questionnaires: the Fatigue Severity Scale (FSS), the visual analog scale (VAS) for fatigue, and the Fatigue Impact Scale (FIS). The FSS and VAS for fatigue, but not the FIS, have been used in previous PPS studies. The FSS consists of a questionnaire in which subjects rate their fatigue level along a numeric list of 9 statements. Each statement is rated from 1 (strong disagreement) to 7 (strong agreement). Responses to the questions are then averaged (minimum and maximum score range, 1–7) to reflect the subject’s overall level of fatigue. In a previous study in patients with PPS, an average FSS score of 3.3 (about 50% of the scale value) or higher was shown to correlate with moderate to severe fatigue. In the present study, we used absolute FSS scores in addition to averaged scores (provided within parentheses in the Results section).

The VAS for fatigue is a modification of the VAS for pain. The VAS for fatigue is simple, practical, reproducible, and fast, with scores ranging from 0 (no fatigue) to 10 (worst fatigue) to reflect the severity of fatigue. It can be used to measure fatigue changes over short time intervals (minutes, hours, days), or to closely estimate average intensity changes over longer time periods (weeks, months). In a previous study with PPS patients, a mean VAS for fatigue score of 4.4 (about 50% of the scale value) indicated severe fatigue. The FIS (developed for patients with MS) is structured around 40 independent symptom-based questions, each rated on a scale of 0 (no problem) to 7 (extreme problem) to reflect severity. The total FIS score is the sum of responses to all 40 entries: minimal score of 0 (no fatigue), maximum score of 160 (extreme fatigue). In a previous study with MS patients, an FIS score of 80 (50% of the scale value) or higher correlated with moderate to severe fatigue. To our knowledge, FIS has not yet been tested in patients with PPS.

Statistical Analysis

In the present survey, we evaluated the applicability of each scale by examining the relationship between fatigue scores and presence or absence of disabling fatigue. We examined the proportion of patients with disabling fatigue who scored 50% or higher on the scale range as an objective indicator of severe fatigue, using the McNemar test. To determine concurrence between scales we used Pearson correlation coefficients. To assess for comparability between groups across the 3 scales, we employed a 2-sample t test for continuous variables, and the chi-square or the Fisher exact test for categoric variables. Absolute scores for each scale were normalized into transformed z scores for graphical comparison and analysis. In addition, to verify the scales’ ability to distinguish subjects with disabling fatigue from those without, we conducted a discriminant analysis and a follow-up logistic regression to determine the scales’ ability to predict disabling fatigue.

RESULTS

In total, 56 patients (22 men, 34 women) were recruited as part of a larger outpatient study in a metropolitan area. Age varied from 31 to 88 years (median, 59y; mean, 59.9y). Of the 56 patients, 39 fulfilled the adopted diagnostic criteria for PPS, and 25 of the 39 also had disabling fatigue according to definition. Mean age at acute poliovirus infection was 6.4 years, (median, 5y; range, 9mo to 23y). Time from acute infection to maximal recovery was 1 to 26 years (median, 4y; mean, 7y). Among the 25 PPS patients with disabling fatigue, 7 were men and 18 were women (age range, 47–81y; mean, 58.9y; median, 59y). All 25 patients in this group completed the fatigue measures.

Twenty-four of 25 PPS patients scored 50% or higher on the scale range for the FSS, compared with 19 of 25 for the VAS for fatigue (P=.042), and 7 of 25 for the FIS (P<.001). The mean absolute fatigue score among PPS patients with disabling fatigue was 51.4 (averaged score, 5.7; 81.5% of scale value), 6.2 (62% of scale value), and 65.6 (40.9% of scale value) for the FSS, VAS for fatigue, and FIS, respectively. The FSS was the most accurate of the 3 tools: 24 of 25 (96%) subjects scored at or above the value set for disabling fatigue (ie, ≥50% of the scale range), compared with 19 of 25 (76%) subjects for the VAS for fatigue, and 7 of 25 (32%) patients for the FIS (fig 1). Using transformed z-score equivalents of the FSS set value (z = −2.07) as a primary reference, absolute scores for the VAS for fatigue and FIS were 2.6 and 9.6, respectively. This indicated that in order to match the percentage inclusion equivalent of the FSS, patients needed to score at least 2.6 on the VAS for fatigue, and 9.6 on the FIS (see fig 1). The correlation was moderate between the FSS and the VAS for fatigue scores (r = .45, P = .02), but low between the FSS and FIS (r = .29, P = .15) and the FIS and VAS for fatigue (r = .20, P = .33).

Correlation coefficients between the fatigue scales and the questionnaires assessing depression (BDI-II) and excessive daytime sleepiness (ESS) were low (r = .21), suggesting that PPS fatigue is not simply a direct result of depressed mood or poor sleep.

Results from the 2-sample t tests revealed significant differences between those with disabling fatigue and those without on the FSS (t = 3.8, P < .001). Direction of effect confirms that
those with disabling fatigue tended to score higher on the FSS than those without (mean difference for FSS, 13.54). No significant differences were observed between the groups on the VAS for fatigue and FIS (fig 2). A discriminant analysis was conducted to assess the scales’ ability to distinguish people with disabling fatigue from those without. The overall Wilks Λ was significant (Λ=.637, χ² test=16.5, P=.001), thereby indicating that overall predictors differentiated among those with and those without disabling fatigue. Combined, the scales correctly classified 72% of the cases. As an alternative, a logistic regression was conducted to evaluate the scales’ contribution in predicting disabling fatigue. The criterion used was the presence of disabling fatigue, for which the FSS, VAS for fatigue, and FIS were used as predictor variables. Results revealed that the Hosmer-Lemeshow statistics were not significant, indicating a good fit of the overall model to the data (χ² test=1.9, P=.984). Results also showed that the FSS was a significant predictor of disabling fatigue for the sampled population (Wald χ² test=8.044, P=.005), whereas the VAS for fatigue and the FIS were not (Wald χ² test=.39, P=.532; Wald χ² test=1.20, P=.273, respectively).

**DISCUSSION**

As shown, FSS was the strongest predictor of severe fatigue in the study sample. Our results indicated that scores on the FSS most closely agreed with the intensity of self-reported fatigue. All but 1 patient meeting the definition for disabling fatigue scored 50% or higher on the scale range for FSS. Our finding, however, should be taken with caution because of the strong resemblance between 2 of the 3 statements characterizing disabling fatigue and items 7 and 8 on the FSS form. The reliability of the FSS in patients with PPS has been carefully investigated by Horemans et al.15 In previous reports, too, mean FSS scores ranged from 4.8 to 6.4 (standard deviation range, 0.4–1.6), as expected for patients with severe fatigue.7,23-26 Overall, these findings may serve to guide investigators during the selection of measures for future PPS trials.

Fatigue has been examined in prior studies as well as in this one, and correlation between FSS and VAS for fatigue has been consistently moderate.21 The descriptiveness of VAS for fatigue, as compared with FSS, was considerably lower, although one can argue that the criterion set for the VAS for fatigue (≥5) may have been excessively stringent. As shown, descriptiveness seems to vary widely among scales and scores are not interchangeable, all probably reflecting the relative cohort specificity that the different fatigue forms tend to conserve.

Our study is the first to report on the application of the FIS in PPS patients. Notably, with few exceptions, FIS scores clustered below the mid-value range of the scale. Only 7 of the...
25 PPS patients with disabling fatigue scored 50% or higher on the FIS nominal scale value. In patients with MS, a distinct distribution occurred, with an absolute FIS score of 75 shown to represent the 75th percentile level for subjects with severe fatigue. When compared with severely fatigued MS subjects, PPS subjects with disabling fatigue scored surprisingly lower, suggesting that the FIS may have the strongest cohort specificity. More evidence comes from the study with outpatient hypertensive subjects, among whom significant fatigue was not present. An FIS score of 75 represented the 90th percentile among them. In subjects attending a clinic for chronic fatigue syndrome, an FIS score of 75 represented only the 25th percentile. Our results provide additional support to the notion of strong cohort specificity in the FIS.

Finally, fatigue scores were not interchangeable. An explanation for the variation is that the structure and attributes of each questionnaire differed remarkably. The weight of individual components of fatigue may have contributed to the significant interscale score deviations. The FSS assesses fatigue that is more neuromuscular in nature: 8 of the 9 entries on the FSS form directly refer to the assessment of physical fatigue. The VAS for fatigue has no identifiable domain. The FIS is more diversified, putting less emphasis on physical fatigue and more on other domains, including emotional, cognitive, and social elements of fatigue. Because the complications of poliovirus infection are primarily concerned with handicap caused by the loss of motor neurons, it is not surprising that tools designed to probe neuromuscular fatigue may have superior performance.

**CONCLUSIONS**

In patients with PPS, fatigue is an incapacitating symptom for which a plethora of conventional pharmacologic therapies have been tested and failed. A major road block in clinical research in PPS continues to be the lack of specific and sensitive measure tools. Among the traditional questionnaires tested in this investigation, the FSS seemed to be the most informative for the clinical assessment of PPS patients suffering from fatigue. However, the adequacy of FSS for longitudinal monitoring of PPS patients is still incompletely understood. Because laboratory tests for the objective assessment of fatigue are unavailable, fatigue scales are necessary. As such, caution is advised when selecting or combining scales to assess fatigue changes in PPS patients attending treatment centers or enrolling in clinical trials.

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