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Validation of the Lifeware Fatigue Instrument in Multiple Sclerosis Patients

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Background

Fatigue is one of the most common and bothersome symptoms of MS. It has been defined as a subjective lack of physical and/or mental energy that is perceived by the individual or caregiver to interfere with usual and desired activities.[1]

Numerous fatigue questionnaires have been introduced, but few have been validated.

Objective

The LIFEware system™[2] is a patient-reported measurement tool and includes a fatigue assessment that has been previously utilized in MS research.

LIFEware fatigue intends to measure the level of fatigability, a construct that assesses the limitations associated with fatigue.

This validation study aimed to investigate the utility of the single-item measure of LIFEware fatigue in a clinical sample.

Methods

- MS patients were extracted from the prospective, cardiovascular, environmental and genetic (CEG) study.
- LIFEware fatigue is part of the LIFEware System™ and is measured on a 1 to 7 scale with higher scores representing greater severity limitations associated with fatigue.
- Concurrent validity was evaluated using correlation analysis between LIFEware fatigue and the validated Fatigue Severity Scale (FSS).[3]
- Convergent validity was assessed by correlating the LIFEware fatigue score to measures conceptually related to fatigue, such as EDSS and depression as assessed by the Beck's Depression Inventory (BDI).[4]
- To assess divergent validity, we analyzed measures that were conceptually different from fatigue and are not, or only weakly, correlated with fatigue, such as Body Mass Index (BMI), age, and disease duration.
- Receiver operating characteristic (ROC) curve analysis was used with FSS fatigue to determine the optimal cutoff score, based on Youden's Index of LIFEware fatigue.
- Correlations were carried out using Spearman's rank coefficients. Group differences in means or medians were analyzed using Independent samples t-tests or Mann-Whitney U-tests, and Chi-square tests were carried out to investigate differences in frequencies. Associations between LIFEware and the FSS were visually evaluated using a scatterplot, and slope fit was determined using R^2 and regression analysis. ROC analysis was used to determine a LIFEware fatigue cutoff score to distinguish fatigued individuals.

Results

LIFEware fatigue correlated strongly (r=0.63) with the FSS (p<.001), indicating good concurrent validity. Construct validity was supported by correlations between LIFEware fatigue and EDSS (r=0.39, p<.001), BDI (r=0.38, p<.001), and by the weak correlations with BMI (r=-0.13), age (r=0.18), and disease duration (r=0.10, all p>.05). The FSS had similar correlations with both the convergent and divergent validity measures.

Table 1. Spearman's rank correlations validating LIFEware fatigue's convergent and divergent validity.

Correlations	LIFEware Fatigue	Fatigue Severity Scale
Convergent validity		
EDSS	0.39*	0.36*
BDI	0.38*	0.34*
Divergent validity		
BMI	-0.13	-0.07
Age (years)	0.18	0.10
Disease duration (years)	0.10	0.10

Legend: * = p<.001. FSS= Fatigue Severity Scale, EDSS= Expanded Disability Status Scale, BDI= Beck's Depression Inventory, BMI= Body Mass Index.

ROC analysis found a cutoff point of 5.0 on LIFEware fatigue had the highest optimal sensitivity (64.4%) and specificity (90.7%) to discriminate between fatigued and non-fatigued patients (Area Under the Curve [AUC]=0.83).

Table 2. Comparing patient-reported outcomes at baseline between patients with disability progression and those who remained stable

Demographics	All n=101	LIFEware Fatigue ≥5 (n=39)	LIFEware Fatigue <5.0 (n=62)	p
Age, mean (SD)	53.9 (12.1)	56.4 (11.6)	52.3 (12.2)	.098
Sex, female (%)	67 (66.3%)	30 (76.9%)	37 (59.7%)	.074
Race, Caucasian (%)	95 (95.0%)	38 (97.4%)	57 (93.4%)	.715
Age at MS onset, years (SD)	33.2 (9.9)	33.5 (10.4)	33.0 (9.7)	.780
Age at MS dx, years (SD)	37.0 (10.1)	38.9 (9.9)	35.9 (10.2)	.168
Disease duration, years (SD)	20.5 (10.8)	22.5 (12.1)	19.3 (9.7)	.152
EDSS, mean (SD)	3.9 (2.3)	4.7 (2.2)	3.3 (2.2)	.003
MS type, RRMS (%)	65 (64.4%)	21 (53.8%)	44 (71.0%)	.080

Legend: SD= standard deviation, dx=diagnosis, EDSS= Expanded Disability Status Scale, RRMS = relapsing-remitting multiple sclerosis.

Based on the ROC determined LIFEware fatigue cutoff of ≥5.0 and <5.0, there were no significant differences in age, disease duration, sex, race, or MS type between subjects who were classified as fatigued and those who were not. EDSS was significantly higher among fatigued patients.

Discussion & Conclusion

The self-reported single-question of LIFEware fatigue had good criterion validity as evidenced by a strong correlation with the validated and widely used FSS. Similarly, convergent validity was established by moderate correlations between LIFEware fatigue and fatigue-related constructs such as depression and EDSS. Divergent validity correlations between LIFEware fatigue and constructs that are not closely associated with fatigue, such as BMI, age, and disease duration were low. Together, these indicate that construct validity was achieved.

Furthermore, correlations between the convergent and divergent variables and fatigue were similar in magnitude between LIFEware fatigue and the FSS. These results suggest that LIFEware fatigue reliably measures a construct of fatigue.

To date, there is no gold standard to measure fatigue, although the FSS is the most commonly used fatigue scale in MS populations.[5] While the FSS is focused on measuring the severity of fatigue, LIFEware fatigue evaluates the level of limitation caused by fatigability.

The strong correlations but lower sensitivity between LIFEware fatigue and the FSS (r=0.67, p<0.001) among this MS sample, indicates both instruments measure a similar, but not identical construct.

The validity of LIFEware fatigue is sufficiently strong to utilize the instrument in research as well as in clinical settings, especially considering the minimal time needed. This makes the tool a useful screening measure to quickly distinguish fatigued patients from non-fatigued patients.

References

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