Short Form 36 (SF-36) health survey questionnaire in health-related quality of life assessment in patients with inflammatory myopathies

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Abstract

Objective

Patients with idiopathic inflammatory myopathies (IIM) experience significant impairment in their health-related quality of life (QoL); however, there are currently no validated measures to assess QoL in these patients. This study aims to examine the measurement properties of short form (SF)-36 in QoL assessment of adults with IIM.

Methods

FORWARD is a U.S.-based databank collecting biannual patient-reported data on rheumatic diseases, including sociodemographics, symptoms, treatment and health-care utilisation. SF-36 produces physical (PCS) and mental (MCS) component scores, ranging 0-100 with higher scores indicating a better QoL. Discriminant and construct validity were assessed using proportion of a priori hypotheses. Responsiveness was assessed using linear mixed models.

Results

A total of 168 patients with IIM were included (77.3% female, 78.5% White), with an average (±standard deviation [SD]) age of 54.3 (±13.8). Mean SF-36 PCS and MCS were 36.5 (±11.2) and 47.0 (±12.0), respectively. The majority of a priori hypotheses for construct and discriminant validity were met for PCS and MCS. PCS was different between those with low vs. high physical function, disease activity, fatigue and pain, while MCS was different between patients with and without depression and anxiety, and low vs. high fatigue and pain levels ($p<0.0001$). PCS and MCS had moderate to strong correlations with pain, fatigue, physical function, disease activity, and health satisfaction. Longitudinal changes in these parameters were also significantly associated with changes in PCS and MCS over time.

Conclusion

SF-36 demonstrated adequate discriminant and construct validity and responsiveness for health-related QoL assessment in patients with IIM.

Key words

myositis, inflammatory myopathies, quality of life, FORWARD, autoimmune diseases, rheumatic disease

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Introduction

Idiopathic inflammatory myopathy (IIM) is a group of autoimmune diseases characterised by chronic skeletal muscle inflammation presenting as muscle weakness (1). Due to chronic multi-system manifestations of IIM, which include skin rashes, interstitial lung disease, inflammatory arthritis, Raynaud's phenomenon, and myocarditis, these patients frequently experience a combination of physical, emotional, and social limitations (2). Clinical manifestations such as chronic weakness, fatigue, and pain significantly impact patients' overall quality of life (QoL) (2). Depending on severity, patients with IIM may suffer from increased dependence, social isolation, and emotional distress, further worsening their QoL (1, 2).

Traditionally, outcomes in rheumatic diseases have been assessed by provider-driven tools such as physical exam and laboratory tests; however, in the last years, there has been an increased focus on understanding the disease experience from the patient's view through patient-reported outcome measures (PROMs) in addition to the provider-driven tools. The Centers for Medicare and Medicaid Services and Food and Drug Administration (FDA) have strongly advocated for the incorporation of PROMs in both clinical practice and research (3).

The Short Form 36 (SF-36), developed in 1992, is a PROM that is frequently used to assess health-related QoL. It contains 36 questions divided into 8 domains of health: physical functioning, physical limitation, bodily pain, general health, vitality, social functioning, emotional limitation, and mental health. The SF-36 questionnaire has two components: the physical component summary (PCS) and the mental component summary (MCS). Each component has a score ranging from 0 to 100 with higher scores indicating a better health state, while the lower scores indicate poor QoL (4). The SF-36 has been used to assess QoL in a wide range of diseases including rheumatoid arthritis, schizophrenia, and asthma (5, 6, 7). Several studies in IIM utilised SF-36 to assess QoL and demonstrated a significantly lower health-related QoL in patients with dermatomyositis (DM) and polymyositis (PM) compared to healthy controls (8) and general population (9). Despite common utilisation of SF-36 in patients with IIM, the validity of this tool has not been previously examined. In this study, we aim to assess the measurement properties of SF-36 in adults with IIM using a prospective nation-wide cohort.

Materials and methods

Study population and variables

FORWARD is the largest patient-reported national research database for adult rheumatic diseases in the U.S. The registry includes data from patients with lupus, psoriatic arthritis and spondyloarthropathies, among others. Patients are recruited from rheumatology clinics, provide informed consent and typically complete surveys semi-annually (10). The FORWARD registry procedures were approved by the Via Christi Institutional Review Board. All patients with IIM who had available data on SF-36 in FORWARD registry were included in the study.

Demographic data collected include IIM subtype [DM, PM, immune-mediated necrotizing myositis (IMNM), overlap myositis (OM), anti-synthetase syndrome (ASyS), and inclusion body myositis (IBM)], time since symptoms onset (years), age, sex, race/ethnicity (White, Black, Hispanic or Asian), history of smoking, Body Mass Index (BMI), education level (years), and total annual income ($). Patient-reported outcomes collected and used in our study include the SF-36 PCS and MCS (0-100 points, with higher points indicating better physical and mental health, respectively), pain visual analogue scale (VAS, range 0-10, with higher score indicating worse pain), fatigue VAS (0-10, with higher score indicating worse fatigue), patient global disease activity (0-10 points, with higher score indicating worse disease activity), health assessment questionnaire II (HAQ-II, 0-3 points, with higher score indicating more disability), health satisfaction Likert scale (0-4 points, with higher score indicating more satisfac-

tion), and Polysymptomatic Distress Scale (PSD, 0-31 points, higher score indicates more pain-related symptoms) (11). Comorbidities included fibromyalgia, overlap disease, osteoarthritis, Raynaud's, self-reported current depression, self-reported current anxiety, history of hypertension, myocardial infarction, depression, cancer, renal disease, pulmonary disorder, gastrointestinal disorders, cardiac condition and the rheumatic disease comorbidity index (RDCI, range 0-9, higher score indicates more comorbid conditions). Data about therapies included the use of non-steroidal anti-inflammatory drugs (NSAIDs), glucocorticoids, disease-modifying anti-rheumatic drugs (DMARDs), and biologics use in the last six months. All of these variables including diagnosis and medication information in the FORWARD databank were patient reported.

Statistical analyses

The baseline patient characteristics were reported using descriptive statistics. Analyses were conducted using complete case approach whereby only participants with no missing data on variables of interest were included. Histograms of SF36-PCS and MCS from the baseline visit were plotted to examine the visual distribution of scores. Ceiling effect was calculated as proportion of patients scoring between 95 and 100 on the 100-point scale. Floor effect was calculated as proportion of patients scoring between 0 and 5 on the 100-point scale.

Discriminant validity was assessed based on proportion of a *priori* hypotheses that were met. Confirmation of ≥75% of the hypotheses support the validity (12). *A priori* hypotheses for discriminant validity of SF-36 PCS were statistically significant differences in SF-36 PCS between patients who have low vs high physical function (HAQ-II <1 *vs*. ≥1), patient global disease activity (<3.5 *vs*. ≥3.5), fatigue (<4.5 *vs*. ≥4.5) and pain levels (<2.5 *vs*. ≥2.5). Cut-points for subgroups were selected based on the median scores for these instruments in the study cohort to separate the lower from higher levels of the measured construct. A priori hypotheses for discriminant validity of SF-36 MCS were statistically significant differences in SF-36 MCS between patients who report current depression vs those who do not, those who report anxiety vs not, patients with low vs high fatigue (<4.5 *vs*. ≥4.5) and pain levels (<2.5 *vs*. ≥2.5). All subgroups were compared using student t-test from the first study visit in FORWARD registry (baseline visit).

Similarly, construct validity was assessed based on proportion of a *priori* hypotheses that were met. *A priori* hypotheses reflected the expected relationships between SF-36 and other outcome measures and were generated based on the investigators' experience with using these tools and the expertise in conducting similar psychometric studies as well as prior literature. Pearson correlation was performed to assess the cross-sectional correlation between SF-36 subdomains and the other measures at baseline except health satisfaction scale for which Spearman correlation was used due to ordinal data. Correlations were interpreted as weak for r between 0-0.3, moderate for 0.3-0.7, and strong >0.7 (13).

Responsiveness was assessed using linear mixed models with a patient-level random intercept. Dependent variables were the SF-36 PCS and MCS, while independent variables included pain level, fatigue level, patient global disease activity, HAQ-II, and PSD. Covariates were age, sex, and obesity. These variables were selected based on the expected significant longitudinal relationship between QoL and these constructs. Models were fit using the 'lme4' package with R version 4.4.1. *P*-values were calculated using the 'lmerTest' package through Satterthwaite's degrees of freedom method (14, 15).

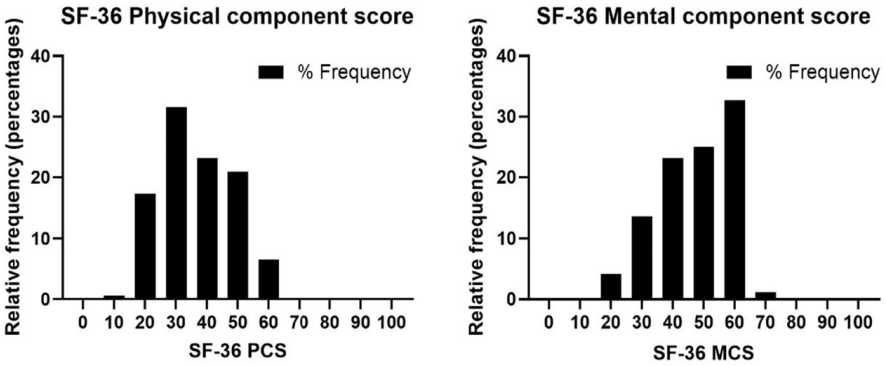

Fig. 1. Histograms of SF-36 PCS and MCS for examination of floor and ceiling effects.

Results

Participant characteristics

FORWARD registry included a total of 210 patients with IIM. Of whom, 42 did not have SF-36 data available; therefore, the remaining 168 patients (77.3% female) who had SF-36 data were included in the study. The average age of the group was 54.3 years (± standard deviation [SD]) (±13.8) (Supplementary Table S1). Race/ethnicity of patients included White (n=132), Black (n=10), Hispanic (n=9), Asian (n=2), American Indian (n=1) and unknown (n=14). IIM subtypes included DM (n=62), PM/IMNM (n=59), OM (n=2), ASyS (n=1), IBM (n=5) and unspecified myositis (n=39). The patients who did not have SF-36 data (n=42) were slightly older, had higher levels of pain and were more likely to have non-White race compared to those with SF-36 data (n=168), while their fatigue levels, education, IIM subtype, sex distribution, symptom duration and patient global disease activity were comparable.

Distribution, ceiling and floor effect of SF-36 PCS and MCS

Mean SF-36 PCS and MCS (SD; range) were 36.5 (11.2; 14.5 - 60.5) and 47.0 (12.0; 17.0 – 67.1). No floor or ceiling effect was observed (Fig. 1).

Discriminant validity of SF-36 PCS and MCS

All *a priori* hypotheses were met for both PCS and MCS. The SF-36 PCS

Table I. Comparison of SF-36 PCS and MCS across different subgroups of patients with IIM at baseline.

Groups	SF-36 PCS				Groups	SF-36 MCS			
	Mean (SD)	CI for mean difference	t (df)	*p*-value		Mean (SD)	CI for mean difference	t (df)	*p*-value
HAQ-II <1 (n=81)	44.4 (8.9)	-17.7 to -12.7	11.9 (166)	<0.0001*	Depression (n=47)	36.8 (11.3)	-17.9 to -11.0	8.2 (162)	<0.0001*
HAQ-II ≥1 (n=87)	29.2 (7.5)				No depression (n=117)	51.3 (9.7)			
Patient global <3.5 (n=82)	43.1 (9.9)	-15.7 to -10.1	9.1 (166)	<0.0001*	Anxiety (n=37)	36.1 (11.1)	-18.1 to -10.3	7.2 (163)	<0.0001*
Patient global ≥3.5 (n=86)	30.2 (8.3)				No anxiety (n=128)	50.2 (10.4)			
Fatigue <4.5 (n=82)	42.8 (9.9)	-15.6 to -10.1	9.2 (164)	<0.0001*	Fatigue <4.5 (n=82)	52.0 (9.7)	-13.2 to -6.5	5.8 (164)	<0.0001*
Fatigue ≥4.5 (n=84)	29.9 (7.9)				Fatigue ≥4.5 (n=84)	42.2 (12.2)			
Pain <2.5 (n=72)	42.5 (10.4)	-13.7 to -7.6	6.9 (164)	<0.0001*	Pain <2.5 (n=72)	52.0 (9.3)	-12.0 to -5.1	4.9 (164)	<0.0001*
Pain ≥2.5 (n=94)	31.9 (9.3)				Pain ≥2.5 (n=94)	43.4 (12.3)			

*Statistically significant according to the Bonferroni adjusted *p* value of 0.006 for multiple comparisons.
SD: standard deviation; CI: Confidence interval; df: degrees of freedom.

Table II. A priori and observed correlations between SF-36 PCS and MCS and other outcome variables.

Variables	SF-36 PCS			SF-36 MCS		
	A priori hypotheses	SF-36 PCS	Met?	A priori hypotheses	SF-36 MCS	Met?
Symptom duration	Weak	-0.05	Yes	Weak	0.11	Yes
Age	Weak	0.12	Yes	Weak	0.21	Yes
Body mass index	Weak	-0.25	Yes	Weak	-0.01	Yes
Education level	Weak	0.17	Yes	Weak	0.21	Yes
Annual income	Weak	0.24	Yes	Weak	0.28	Yes
Pain level	Moderate	-0.56	Yes	Moderate	-0.43	Yes
Fatigue level	Moderate	-0.66	Yes	Moderate	-0.49	Yes
Patient global disease activity	Moderate	-0.66	Yes	Moderate	-0.43	Yes
HAQ-II	Strong	-0.79	Yes	Moderate	-0.30	Yes
Rheumatic disease comorbidity index	Moderate	-0.27	No	Moderate	-0.27	No
Health satisfaction	Moderate	0.66	Yes	Moderate	0.42	Yes

was significantly different between patients who have low vs high physical function (HAQ-II <1.5 *vs*. ≥1.5), patient global disease activity (<5 *vs*. ≥5), fatigue (<5 *vs*. ≥5) and pain levels (<5 *vs*. ≥5) (p<0.0001 for all) with lower SF-36 PCS scores in those with low physical function, high patient global disease activity, high fatigue and pain groups (Table I). The SF-36 MCS was significantly different between patients who report current depression vs those who do not, those who report anxiety vs not, patients with low vs high fatigue (<5 *vs*. ≥5) and pain levels (<5 *vs*. ≥5) (p<0.0001 for all) with lower MCS scores in patients with current depression, anxiety, those with high fatigue and pain levels.

Construct validity

All *a priori* hypotheses were met for both PCS and MCS except the correlation between rheumatic disease comorbidity index for both PCS and MCS. Correlations between rheumatic disease comorbidity index were estimated to be moderate with PCS and MCS; however, the analyses yielded weak correlations with both. SF-36 PCS had weak correlations with symptom duration, age, BMI, education level and total income, moderate correlations with pain and fatigue levels, patient global disease activity, and health satisfaction, and strong correlations with HAQ-II (Table II). SF-36 MCS had weak correlations with symptom duration, age, body mass index, education level, annual income and moderate correlations with pain and fatigue level, patient global disease activity, HAQ-II, and health satisfaction.

Responsiveness

After controlling for age, sex, and obesity, all parameters including pain level, fatigue level, patient global disease activity, HAQ-II, and PSD were found to be significantly associated with changes in PCS over time (p<0.0001) (Table IV). Similarly, after controlling for age, sex, and obesity, all parameters including pain level, fatigue level, patient global disease activity, HAQ-II, and PSD were found to be significantly associated with changes in MCS over time (p<0.0001) (Table III).

Discussion

In this observational study, SF-36 PCS and MCS had no floor or ceiling effect and demonstrated good construct and discriminant validity, and responsiveness in the assessment of health-related QoL of patients with IIM. There are currently no validated measures of health-related QoL in patients with IIM; therefore, this study serves an important need in the myositis field. As a widely available and free tool used in several diseases including rheumatoid arthritis, psoriatic arthritis and lupus, SF-36 could be used to monitor quality of life in routine clinical practice and clinical trials of patients with IIM. Further, using SF-36 can allow to compare the results of patients with IIM with other diseases (3).

The SF-36 PCS was able to differentiate patients with low vs high physical

Table III. Linear mixed models examining the relationship between longitudinal change in SF-36 PCS and MCS and other outcome variables after controlling for age, sex, and obesity.

Variables	SF36 PCS		SF36 MCS	
	Beta [CI]	*p*-value	Beta [CI]	*p*-value
Pain level	-1.68 [(-1.88) - (-1.47)]	<0.0001	-0.64 [(-0.91) - (-0.36)]	<0.0001
Fatigue level	-1.31 [(-1.51) - (-1.11]	<0.0001	-1.29 [(-1.54) - (-1.04)]	<0.0001
Patient global disease activity	-1.22 [(-1.42) - (-1.02)]	<0.0001	-1.01 [(-1.26) - (-0.76)]	<0.0001
HAQ-II	-8.16 [(-8.93) - (-7.39)]	<0.0001	-2.50 [(-3.61) - (-1.38)]	<0.0001
PSD	-0.56 [(-0.65) - (-0.47)]	<0.0001	-0.55 [(-0.66) - (-0.43)]	<0.0001

function, global disease activity, fatigue and pain levels. The SF-36 MCS was significantly different between patients with and without depression and anxiety, and those with low vs high fatigue and pain levels. These results were in concordance with a priori hypotheses and overall support the robust discriminant validity of both SF-36 subscales. In line with our findings, a longitudinal, cross-sectional analysis that assessed the validity, reliability and responsiveness of health-related QoL measures in rheumatoid arthritis (RA) using 3 generic (SF-36, EuroQol-5D and 15D) and 2 disease-specific measures (Rheumatoid Arthritis Quality of Life Scale and global Rheumatoid Arthritis scale score) demonstrated that the SF36 had a significant overall discriminant validity. Moreover, it had a significant discriminative ability between different DAS28 and VAS scores for arthritis activity and disability pension groups (16). SF-36 also demonstrated discriminant validity in patients with primary systemic vasculitis comparing different levels of vasculitis severity and in patients with different levels of depression and fatigue (17).

SF-36 PCS had a strong correlation with HAQ-II. This level of correlation was expected since physical function is a major determinant of both HAQ-II, and PCS is thought to be influenced the most by physical functional parameters (18). Pain level, fatigue level, patient global disease activity and health satisfaction had a moderate correlation with PCS as they are closely linked to physical health. As expected, MCS had a moderate level of correlation with pain level, fatigue level, patient global disease activity, HAQ-II and health satisfaction. The *a priori* hypothesis was not met for rheumatic disease comorbidity index for both PCS and MCS. This may be attributed to the fact that SF36 can be impacted by not only the number but also the type of the comorbid conditions in the rheumatic disease comorbidity index. Similar results were found in a French multicenter cross-sectional analysis that assessed the relationship between the QoL and comorbidities in patients with psoriatic arthritis (19). There was no significant association between either type or number of comorbid conditions and SF-36 PCS. With univariate linear regression analysis, there was an association between MCS and each of the five comorbidities included however, with multivariate regression analysis, and after adjusting for confounders, anxiety was the only comorbidity that was significantly associated with MCS, while depression, malignancy, cardiovascular, and pulmonary disease were not (19).

Responsiveness analysis showed that after controlling for age, sex, and obesity, SF-36 PCS and MCS were significantly associated with changes in pain and fatigue levels, patient global disease activity, HAQ-II, and PSD over time. Similar to the results observed in IIM, SF-36 had good responsiveness in other rheumatic diseases including RA, particularly in the physical role limitations subdomain (16). This was more prominent in patients who reported improvement of their symptoms over time versus patients who reported deterioration (16). Similar results were obtained in patients with lupus when the SF-36 was compared with the LupusQoL, a disease-specific QoL measure (20), as well as ANCA-associated vasculitis (21).

The major limitation of the study is the lack of laboratory or objective measures. Results are based on patient-reported outcomes alone. Including disease activity variables such as creatine kinase levels or muscle strength testing would strengthen our study. Cohort consisted of patients who agreed to fill out questionnaires twice a year. In addition, the FORWARD databank relies on volunteer physicians for recruitment of patients; therefore, a selection bias is likely. For example, patients with no SF-36 data were more likely to have non-White race, be older, and reported higher levels of pain compared to those who had SF-36 data in our study; therefore, the results may not be generalisable for the whole myositis population. In addition, since data is reported by patients, it can be subject to misclassification. For example, a high proportion of patients reported their myositis subtype as "unspecified", which suggests that a significant number of patients may not know their myositis subtype. However, the accuracy of the myositis diagnosis in FORWARD registry is thought to be high. A prior study on patients with rheumatoid arthritis showed approximately 99% agreement between the patient and physician provided diagnoses in FORWARD registry which could be applicable to patients with myositis. Strengths of the study include a relatively large sample size when compared with other psychometric studies and use of robust methodology, in line with COSMIN study design checklist. Further, linear mixed model was selected for responsiveness assessment due to its ability to integrate multiple covariates and possibility of being less impacted by outliers when compared with other types of analyses (23).

Conclusion

To our knowledge, there are currently no validated QoL measures in patients with IIM. SF-36 PCS and MCS components provide a comprehensive evaluation of QoL in a variety of rheumatic and non-rheumatic diseases. In this study, SF-36 showed overall adequate measurement properties with no floor or ceiling effect, good discriminant and construct validity, and responsiveness results in patients with IIM. SF-36 can be used to assess and monitor health-related QoL in clinical practice

and myositis clinical trials and could be included in the myositis core set measures. Our results serve as a bridge for a wider-scale studies with larger samples and pave the way to more in-depth comparison of SF-36 with other QoL measures in patients with IIM.

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