Subjective symptom impact on quality of life in patients with myotonic dystrophy

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Abstract

Background: Although functional impairment in patients with myotonic dystrophy is an important determinant of quality of life (QoL), it is possible that QoL could further be influenced by the subjective evaluation of symptoms. The aim of this study was to investigate the subjective symptom impact on the QoL, after controlling for functional impairment. Methods: Eligible patients with myotonic dystrophy type 1 (DM1) were recruited from four hospitals in Japan. Subjective symptom impact across four domains (muscle weakness, fatigue, pain, and myotonia) and overall QoL were evaluated using the Individualized Neuromuscular Quality of Life (INQoL) questionnaire. Functional impairment was assessed using the modified Rankin scale. Results: Eighty-six patients with DM1 were included in this study. On multiple regression analysis, a portion of the variance in the overall QoL was significantly accounted for by demographic variables and functional impairment (adjusted R2 = 0.32). In addition to these variables, subjective symptom impact (muscular weakness, fatigue, and myotonia) explained additional variance in the overall QoL (adjusted R2 = 0.80). Difficulties in activities of daily living and participation caused by each symptom consistently predicted overall QoL across three symptom domains (muscular weakness, fatigue, and myotonia). Conclusions: Subjective symptom impact needs to be considered, in addition to functional impairment, when evaluating the QoL of patients with DM1.

Background

Myotonic dystrophy type 1 (DM1) is the most common muscular dystrophy in adults, and is characterized by various symptoms, including progressive muscular weakness, fatigue, and myotonia [1]. These symptoms of the disease often influence patients' lives, including daily activities and social participation, which negatively impact quality of life (QoL) [2, 3]. Generally, the severity of symptoms of the disease is considered as the strongest predictor of QoL [4]. Functional impairment is one of the major factors that affect activities of daily living and social participation in neuromuscular disorders; however, psychosocial and subjective factors also have a substantial contribution on QoL [5-8].

Recently, patient-reported outcomes have increasingly been considered as important factors in clinical trials [2, 9]. Although the severity of symptoms have been well-studied in neuromuscular disorders, the impact of subjective assessment of difficulties in activities and participation and the importance of these difficulties on patients' assessment of their QoL has not been well investigated. As well, the assessment of symptoms by a clinician and the subjective evaluation of symptoms by patients may differ [10]. Therefore, patients' QoL could be affected by subjective evaluation of symptom severity and limitations in activities and restriction in participation associated with muscular diseases [11, 12]. Consequently, patients with similar severity of symptoms, their QoL may differ depending on the limitations and restrictions experienced and the importance of these activities and of participation for an individual. Therefore, the subjective feature of the disease burden may affect variability in QoL among patients with DM1. As such, in the current study, we examined the hypothesis that the subjective symptoms impact will explain QoL after controlling for functional impairment.

Methods

Participants

Patients were recruited from four hospitals in Japan (Toneyama National Hospital, Aomori National Hospital, Osaka University Hospital, and Yokohama Rosai Hospital). The eligibility criteria for patients were as follows: genetic or clinical diagnosis of DM1; age ≥18 years; and provision of informed consent, after the procedures had been fully explained. Because the data were collected as part of a larger study, some of the data included in the analysis overlapped with those from our previous study [13].

Ethics, consent and permissions

Informed consent was obtained from all patients participated in this study. This study was conducted in accordance with the World Medical Association's Declaration of Helsinki and was approved by the institutional review board at each institution.

Measures

Subjective symptom impact and QoL

The subjective burden of symptoms and quality of life were measured using the Japanese version of the Individualized Neuromuscular Quality of Life (INQoL) [13, 14] which includes common symptoms of neuromuscular diseases, i.e., muscular weakness, pain, fatigue, and myotonia. Each symptom domain is evaluated on three scales: a. severity of the symptom, b. difficulties caused by the symptom, and c. the importance of the difficulties caused by the symptom to the person. Symptom scores range from 0 to 100, and indicate subjective impact of each symptom. A higher score indicate greater symptom impact.

The QoL index is calculated from Life domain scales of the INQoL including aspects of independence, social relationships, emotions, and body image, apart from symptom scales. Thus, the QoL index represents a patient’s overall QoL on a scale of 0 to 100. A higher score is indicative of worse QoL.

Functional impairment

We assessed functional impairment using the modified Rankin Scale (mRS) [15], which has previously been used as an index of functional impairment in neuromuscular disorders [13, 16]. The mRS was evaluated by each patient’s primary physician, with scores ranging from 0 (no symptoms) to 5 (severe disability).

Statistical analysis

Statistical analyses were performed using R 3.4.1 statistical software (R Core Team, Vienna, Austria). Associations between subjective symptom impact and QoL were evaluated using Pearson’s correlation coefficient. We used a two-step multiple linear regression model to assess the relative contribution of the subjective symptom impact to the overall QoL, after controlling for demographic variables (sex, age, years

of education, disease duration, and employment status) and functional impairment (mRS). Because this study did not aim to examine the association between QoL and the molecular pathophysiology of the disease, the number of CTG repeats was not included as an independent variable in multiple regression models. Significant contributing variables were further analyzed using multiple linear regression to evaluate which aspect of subjective evaluation (a. severity of the symptom, b. difficulties caused by the symptom, and c. importance of the difficulties caused by the symptom to the patient) explains QoL. In multiple regression analysis, we also calculated the variance inflation factor (VIF) to assess potential multicollinearity between the predictor variables, where a VIF >10 was indicative of multicollinearity between predictors, and a VIF of 5–10 suggestive of a multicollinearity problem. We applied a ridge regression analysis if the VIF indicated presence of multicollinearity among variables. The ridge regression is an alternative approach to ordinary least squares (OLS) regression when the predictor variables are strongly correlated. The significance level was set at a two-tailed $p < 0.05$.

Results

Eighty-six patients with DM1 were included in this study (Table 1), with the majority having genetically confirmed DM1 (n = 79; 92%). The overall QoL was significantly correlated to patients' subjective symptom impact (Table 2). Functional impairment was also moderately correlated with QoL ($r = 0.45$, $p < 0.001$).

Demographic variables and functional impairment were entered into model 1, with overall QoL being significantly explained by disease duration and functional impairment ($F = 7.7$, $p < 0.001$, adjusted $R2 = 0.32$ [95% CI: 0.12–0.42]). Longer disease duration and higher functional impairment resulted in lower QoL (Table 3). The subjective symptom impact was then added as a predictor variable (model 2), with the subjective impact in the domains of weakness, fatigue and myotonia explaining a significant proportion of the variance in overall QoL, even after controlling for demographic variables and functional impairment (Table 3). Model 2 explained 80% of the variance in overall QoL ($F = 35.9$, $p < 0.001$, adjusted $R2 = 0.80$ [95% CI: 0.69–0.83]), with higher subjective symptom impact in weakness, fatigue and myotonia resulting in lower QoL. The explained variance in the overall QoL was significantly increased after entering symptom impact ($F = 46.1$, $p < 0.001$, $\Delta R2 = 0.48$), with symptom impact variables (entered in model 2) explaining an additional 71% of the unexplained variance in QoL by the model 1 (*partial* $R2 = 0.71$ [95% CI: 0.56–0.76]). VIF values for multicollinearity were not greater than the threshold in either model 1 or 2 (VIF < 3.0).

We further analyzed which aspect of the symptom domains identified as significant predictors in model 2 contributed to the overall QoL. The overall QoL was significantly explained by different aspect depending on the domains (Table 4). Difficulties were a significant predictor of QoL in all three domains (weakness, fatigue and myotonia). In contrast, symptom severity was significant in the fatigue domain (standardized coefficient = 0.32), whereas the importance of the difficulties was significant in the weakness domain (standardized coefficient = 0.40). However, the VIF was indicative of multicollinearity among variables in weakness (VIF, 3.8–6.7) and fatigue (VIF, 4.1–5.5) domains, with large confidence intervals of coefficients

(Table 4). A problem of multicollinearity was also identified in the myotonia domain (VIF, 5.3–9.2), with large confidence intervals of coefficients and an association with overall QoL which was in the direction opposite to the bivariate correlation (e.g., myotonia, severity aspect). Analysis of outcomes using a ridge regression to reduce the influence of multicollinearity provided a similar pattern of coefficients for each item in the domains, although the magnitude of coefficients were reduced relative to the results of the OLS regression (Supplemental Table S1).

Discussion

The subjective symptom impact explained a significant proportion of overall QoL, after controlling for demographic variables and functional impairment, among patients with DM1. Our findings are in agreement with previous studies that have reported disease duration and functional impairment to be associated with QoL [17-19], although the relative contribution of these variables was limited when subjective symptom impact was explained in the present study. In fact, a substantial portion of QoL was explained, in our study group, by patients' subjective evaluation of the burden caused by muscular weakness, fatigue, and myotonia. Of these subjective factors, muscle weakness was the strongest predictor of QoL, within the domains examined in this study.

Most activities of daily living are strongly influenced by muscle weakness in patients with neuromuscular diseases, which naturally leads to worse QoL, with fatigue and myotonia having an effect on function in social participation and daily activities, to which muscle weakness also contributes [20]. Because QoL is a subjective phenomenon, patient evaluation of symptoms would comprise an important part of QoL in addition to objective assessment of the severity of the disease [2, 3]. As previously reported, the subjective evaluation of the symptom impact may also differ by symptoms [20]. Reducing the burden of these symptoms could be an important target for interventions to improve QoL in patients with myotonic dystrophy. Of note, pain was associated with QoL only in bivariate correlation, indicative that pain had a lower influence on QoL than other symptom domains evaluated (fatigue, weakness and myotonia), which is in agreement with previous studies [17, 21].

Difficulties caused by each symptom consistently predicted overall QoL across the three symptom domains, with resultant difficulties in activities of daily living directly influencing the physical and social components of QoL [2]. Therefore, improving the burden of fatigue, weakness and myotonia could improve a patient's QoL. However, careful interpretation of the strength of the influence of these symptoms on QoL due to the potential of bias from multicollinearity, even after applying a ridge regression. Further confirmation in future studies is necessary.

Our study suggest substantial influences of subjective symptom impact on QoL among patients with DM1, which might account for disparity between objective disease severity progression and QoL that has been reported in a few longitudinal studies [22-24]. It is possible that QoL and symptom impact could be influenced by a response shift phenomenon, defined as a change in internal standards [3, 25]. Patients' perceived impact of the disease is an important mediator of QoL, which may explain the noted variation

in QoL among patients with similar severity of a condition. In fact, disease perception is one of the determinants of coping and/or psychological distress [7, 26]. Therefore, although definitive evidence of the effectiveness of psychosocial interventions for patients with muscular diseases is unavailable [27], it is plausible to consider that psychosocial interventions, such as cognitive behavior therapy or neuropsychological interventions, could optimize QoL in these patients [28-30]. A recent randomized controlled trial for fatigued patients with DM1 showed cognitive behavioral therapy could increase patient's perceived capacity for activity and social participation, whereas there were no significant differences in disease burden and QoL between intervention and standard care group [31]. Although such results were affected by the fact that the intervention did not focused on subjective disease burden and QoL, more direct intervention may be needed [32].

Limitations

The limitations of our study should be acknowledged. First, although the INQoL covers the major components of QoL for patients with DM1, the relative importance of contributing factors could be affected by the underlying concept of QoL measured. Recently, the Myotonic Dystrophy Health Index, which measures the burden of disease in myotonic dystrophy, is available and has been validated in several languages [33-36]. The INQoL is rather a measure of how disease symptoms impact on the patient's perspective. The combination of the two instruments would be desirable to detect subjective experience of the disease in patients. Second, we could not examine environmental factors which would affect patients' QoL, such as social and welfare support which are known to have an impact on patients' QoL [6]. Third, cognitive impairment, awareness of the disease, and apathy, which are associated with disease severity, may partially moderate associations between subjective evaluation of disease impact and QoL [10, 37, 38].

Conclusions

Our findings indicate that subjective symptom impact affects QoL, in addition to functional impairment, among patients with DM1. Difficulties caused by DM1 symptoms are key predictor of QoL, in addition to severity of symptoms.

Declarations

Ethics approval and consent to participate

All procedures performed in studies involving human participants were in accordance with the ethical standards of the each institutional research committee and with the 1964 Helsinki declaration and its later amendments.

Consent for publication

Not applicable.

Availability of data and material

The datasets generated and/or analysed during the current study are not publicly available due to privacy constraints relating to the ethical approval but are available from the corresponding author on reasonable request.

Competing interests

The authors declare that they have no competing interests.

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Authors' contributions

HF was critically involved in the design, data collection, the analysis and interpretation of the data and wrote the draft of manuscript. HF, MPT, OI, and TM involved development of study concept. OI was critically involved in the design and interpretation of the data. TS, MPT, HT, TN, and TM were involved in the patient recruitment and the clinical assessments. All authors contributed intellectually to the data interpretation and approved the final manuscript.

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Not applicable.

Availability of Data and Materials

The datasets generated and/or analysed during the current study are not publicly available due we do not have approval to make the data publically available.

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Table 1: Demographic And Clinical Variables Of The Patients

Table 1. Demographic and clinical variables of the patients

	Mean (SD) or Number [%]
Sex (male/female)	39/47 [male 45.3]
Age	46.9 (10.9)
Years of education	13.5 (1.9)
Onset age	30.4 (13.3)
Disease duration (years)	16.3 (11.1)
Number of CTG repeats	689.8 (447.6)
Employment	32 [37.2]
Symptom impact	
Weakness	52.1 (26.2)
Pain	21.4 (27.4)
Fatigue	45.3 (27.1)
Myotonia	35.0 (30.3)
Oveall QoL	45.0 (22.6)

QoL: quality of life

Table 2: Correlations Between Subjective Symptom Impact And Overall Qol

Table 2. Correlations between subjective symptom impact and overall QoL

	Pain	Fatigue	Myotonia	Overall QoL
Weakness	0.53	0.70	0.54	0.84
Pain	-	0.63	0.58	0.64
Fatigue		-	0.62	0.76
Myotonia			-	0.63
Overall QoL				-

All coefficients were significant ($p < 0.001$)

QoL: quality of life

Table 3: Multiple Linear Regression Models Predicting Overall Qol In Patients

3. Multiple linear regression models predicting overall QoL in patients

tor variable	Model 1[a]		Model 2[b]	
	Standardized coefficient [95% CI]	P-value	Standardized coefficient [95% CI]	P-value
graphic variables and functional impairment				
	-0.01 [-0.19–0.17]	0.905	0.04 [-0.06–0.14]	0.438
	0.03 [-0.18–0.23]	0.795	0.02 [-0.10–0.13]	0.770
s of education	0.03 [-0.15–0.22]	0.725	0.00 [-0.10–0.10]	0.961
ase duration	0.38 [0.18–0.57]	<0.001	0.09 [-0.02–0.20]	0.129
oyment status	-0.14 [-0.34–0.07]	0.191	-0.09 [-0.21–0.02]	0.110
tional impairment	0.27 [0.06–0.49]	0.014	0.12 [0.00–0.24]	0.050
ctive symptom impact				
kness			0.40 [0.23–0.57]	<0.001
			0.10 [-0.04–0.23]	0.153
e			0.22 [0.06–0.38]	0.008
nia			0.20 [0.06–0.34]	0.005

7.7***, adjusted R^2 = 0.32 [95% CI: 0.12–0.42]

35.9***, adjusted R^2 = 0.80 [95% CI: 0.69–0.83]

< 0.001

nfidence interval

quality of life

Table 4: Multiple Linear Regression Models Predicting Overall Qol In Patients

ltiple linear regression models predicting overall QoL in patients

ariable	Weakness[a]		Fatigue[b]		Myotonia[c]	
	Standardized coefficient [95% CI]	P-value	Standardized coefficient [95% CI]	P-value	Standardized coefficient [95% CI]	P-value
ach						
y	0.08 [-0.14–0.31]	0.473	0.32 [0.03–0.60]	0.029	-0.31 [-0.68–0.05]	0.095
lties	0.40 [0.09–0.70]	0.011	0.44 [0.11–0.78]	0.010	0.75 [0.25–1.24]	0.003
ance	0.40 [0.12–0.67]	0.005	0.04 [-0.29–0.36]	0.832	0.21 [-0.24–0.66]	0.366

**, adjusted R^2 = 0.70 [95% CI: 0.58–0.77]

**, adjusted R^2 = 0.57 [95% CI: 0.41–0.66]

**, adjusted R^2 = 0.44 [95% CI: 0.27–0.55]

001.

nce interval

y of life

Supplementary Files

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