Neurological Sciences (2019) 40:2549–2554
https://doi.org/10.1007/s10072-019-04005-z

ORIGINAL ARTICLE

Quality of life assessment in migraine and relapsing remitting multiple sclerosis: self-perceived health is similar

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Received: 27 April 2019 / Accepted: 5 July 2019 / Published online: 17 July 2019

Abstract

Objective The aim of this study was to compare self-perceived health between migraine and early stages of relapsing-remitting multiple sclerosis (RRMS) and to explore whether and how accurate those health domains predict overall quality of life.

Methods Ninety patients aged 18–55 years were enrolled in this cross-sectional study. Thirty follow-up outpatients were recruited with migraine (with or without aura), 30 patients with RRMS, and 30 healthy subjects. They were asked to complete the Health status questionnaire (SF-36) and Personal Wellbeing Index (PWI).

Results Patients with RRMS and migraine had significantly worse self-reported health regarding role limitation due to physical problems and general health than the healthy control group. Additionally, migraine patients had more bodily pain, while RRMS patients expressed more difficulties regarding physical functioning. Differences between migraine and RRMS patients were not significant. Hierarchical regression analysis revealed that role limitation due to physical problems, mental health, and general health represents significant predictors of overall quality of life.

Conclusions Migraine may affect quality of life similarly to early stages of RRMS. Bio-psycho-socio-medical understanding of the two diseases and their impact on patients QoL should be reconsidered.

Keywords Quality of life · Migraine · Relapsing-remitting multiple sclerosis

Introduction

Health is not only an absence of disease or disability but according to the World Health Organization (WHO) a complete physical, mental, and social well-being [1]. Therefore, quality of life (QoL) is an individual's perception of life in the context of the culture and values system they live in, as well as in relation to their goals, expectations, standards, and concerns. [2]. On the other hand, health-related quality of life (HRQoL) constitutes only one part of QoL, as it includes the individual's satisfaction with his/her health status and emotional response he/she gives to his/her health status [3, 4].

Multiple sclerosis and migraine significantly affect QoL, interfering with a patient's ability to work, pursue leisure activities, and execute daily life tasks [5–9]. Moreover, MS patients with comorbid migraine have worse scores than those without role limitation due to physical problems, bodily pain, and health perception subscales [10]. Both MS and migraine have a pervasive impact on person's quality of life and for that reason, maintenance of quality of life and functionality is the focus of treatment, instead of complete recovery [11–13].

Although different studies have investigated QoL in MS patients and migraine, results may vary across regions, cultures, and health care systems [14–17]. The objective of this study was to compare self-perceived health between migraine and early stages of RRMS patients using the Croatian version

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of SF-36 and to explore whether those health domains predict overall quality of life and to what extent.

Methods

Study design

This single-center, cross-sectional study was carried out at the Neurology Department of the General Hospital in Zadar, Croatia, between 2010 and 2012. The study protocol was approved by the local Ethics Committee and all participants signed a written informed consent. The study was conducted in accordance with the World Medical Association Declaration of Helsinki [18]. The study has not been registered as it was an observational investigation.

Participants

Since both RRMS and migraine affect young and working people, targeted population included 18–55 years old Croatian patients of both genders with early stage RRMS diagnosed according to the 2010 revised Mc Donald criteria [19] or patients diagnosed with migraine according to the ICHD-II criteria [20]. Minimal sample size with $\alpha = 0.05$, 95% statistical power, and large effect size $d = 0.8$ is 42 participants in each group [21]. However, 90 patients were recruited in this pilot study: 30 consecutive outpatients with an early stage of RRMS, immunomodulatory therapy, Kurtzke Expanded Disability Status Scale (EDSS) ≤ 2.5 (mild disability in one or minimal disability in two functional systems), and no history of migraine; 30 consecutive outpatients suffering from migraine either with or without aura; 30 healthy participants representing the control group composed of healthy family members and hospital personnel matched by age, gender, and level of education. Exclusion criteria for RRMS patients were active disease or relapse and for migraine patients acute migraine attack. Specific exclusion criterion for healthy control group was being diagnosed with any chronic illness at the time of enrollment. Exclusion criteria for all participants were represented by other severe physical or mental disease (e.g., depression, anxiety) and alcohol/drug abuse. Patients or subjects not able to answer the questionnaire were not enrolled (Fig. 1).

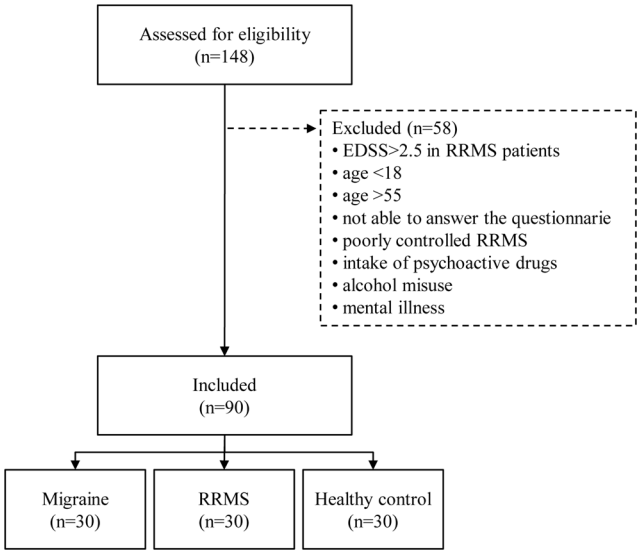

Fig. 1 Participants' flow diagram

Instruments

Health status was measured multidimensionally by the Croatian version of the Health status questionnaire (SF-36). SF-36 is a short multifunctional health questionnaire comprising 36 questions [22]. It represents a theoretically based and empirically authenticated operationalization of two general health concepts—physical and psychological health—and their two general manifestations, functioning, and wellbeing. Hence, the four types of scales or conceptually diverse health measurements relative to the following health assessments or indicators are as follows: (a) functioning on the level of behavior, (b) estimated wellbeing, (c) limitations to the social life and realization of central life roles, and (d) personal self-assessment of the overall health. At the manifestation level, each questionnaire item relates to one of the following eight health indicators: physical functioning (PF) (10 items); role limitation due to physical problems (RP) (4 items); bodily pain (BP) (2 items); perception of general health (GH) (5 items); vitality and energy (VE) (4 items); social functioning (SF) (2 items); role limitation due to emotional problems (RE) (3 items); mental health (MH) (5 items); changes in health (CH) as one item refers to changes in health over the last year (five levels from "how much the condition is better than a year ago" to "how much the condition is worse than a year ago"), not expressed as a scale, but still useful for the evaluation of the average change in the health status over a period of 1 year prior to monitoring, and was presented separately from results on 8 dimensions. A Croatian translation of SF-36 was validated on general Croatian population and proved good metric characteristics [23].

Overall quality of life was measured by the Personal Wellbeing Index—Adult Questionnaire (PWI-A), which represents a multidimensional measure of subjective quality of life. It includes seven items which measure satisfaction on seven life domains: standard of living, health, achievements in life, close relationships, safety, community connectedness, and future security. Answers are given on an 11-point Likert scale where 0 stands for "not satisfied at all" and 10 means complete satisfaction. Overall, the index (PWI) is calculated as an arithmetic mean of the results across the seven domains. These results were transformed and presented as percentage of scale maximum (%SM), and range 0–100 %SM [24].

Statistical methods

Minimum sample size was calculated by G*Power software, ver.3.1.9.4 [21]. Statistical significance was set at $p < 0.05$ and all confidence intervals were given at 95% level. In all instances, we used two-tail tests. The main analysis was done by hierarchical regression analysis (HRA). Multicolinearity of independent and confounding variables was tested by tolerance, variance inflation factor (VIF), and eigenvalues/condition numbers. Independence of residuals was tested by the Durbin-Watson test. Normality of distributions was analyzed by the Shapiro-Wilk test. Statistical data analysis was done by SPSS software for Windows, version 20.0, SPSS Inc., Chicago, IL, SAD.

Results

Participants' characteristics are reported in Table 1. After adjusting for age, gender, and level of education, the differences in SF-36 subscales results between patients with migraine and RRMS were not statistically significant (Table 2). Patients with migraine had significantly worse HRQL than healthy control regarding the role limitation due to physical problems, bodily pain, and self-perceived general health. The difference of means was 33%, 24%, and 23% respectively. Patients with RRMS had significantly worse HRQL than healthy participants considering physical functioning, role limitation due to physical problems, and general health; the difference between means was 24%, 33%, and 32% respectively. Overall, the differences between our three study groups were not significant on the SF-36 mental health dimension. On the physical health dimension, RRMS and migraine groups were very similar; however, both conditions scored significantly worse than the healthy control group.

After adjusting for age, gender, and level of education, two SF-36 summary scores, namely Physical and Mental health dimensions, were not significantly correlated among healthy participants ($r = 0.30$; $p = 0.125$). Yet, this correlation was significant in RRMS patients ($r = 0.64$; $p < 0.001$), and particularly high in migraine patients ($r = 0.81$; $p < 0.001$).

Hierarchical regression analysis was conducted in order to determine whether health domains and presence of migraine or RRMS predict overall quality of life. In this model, sociodemographic data (gender and age) were entered in step 1 and neurological conditions were entered jointly in step 2. Finally, health domains were added in step 3. Tolerance and variance inflation factor (VIF) were used to check for multicollinearity. Tolerance values of less than 0.10 and VIF values greater than 10 typically indicate multicollinearity issues [25]. The Tolerance values ranged from 0.26 to 0.99 and the VIF values ranged from 1.01 to 3.87, thus suggesting that multicollinearity had no significant impact on any of the

Table 1 Demographic characteristics of the participants

	Migraine ($n = 30$)	Multiple sclerosis ($n = 30$)	Healthy control ($n = 30$)	*P*
Age, mean (SD) year	40 (7.5)	37 (9.7)	38 (6.8)	0.291
Gender, *n* (%)				
Male	8 (26.7)	8 (26.7)	8 (26.7)	
Female	22 (73.3)	22 (73.3)	22 (73.3)	0.749
Age by gender, mean (SD) year				
Male	39 (8.8)	35 (11.4)	35 (8.8)	0.573
Female	40 (7.1)	38 (9.2)	38 (5.8)	0.506
Education, *n* (%)				
Primary school	15 (50.0)	21 (70.0)	14 (46.7)	
High school	12 (40.0)	6 (20.0)	11 (36.7)	0.132
University	3 (10.0)	3 (10.0)	5 (16.7)	
Education by gender, *n* (%)				
Male				
Primary school	7 (87.5)	6 (75.0)	3 (37.5)	
High school	1 (12.5)	1 (12.5)	5 (62.5)	0.037*
University	0 (0.0)	1 (12.5)	0 (0.0)	
Female				
Primary school	8 (36.4)	15 (68.2)	11 (50.0)	0.210
High school	11 (50.0)	5 (22.7)	6 (27.3)	
University	3 (13.6)	2 (9.1)	5 (22.7)	

P statistical significance of the difference, all *P* values were two sided

Table 2 Health-related quality of life (SF-36) in early stage of RRMS, migraine, and healthy participants after adjustment for age, sex and education

	Migraine ($n = 30$) (MG)	Multiple sclerosis ($n = 30$) (MS)	Healthy control ($n = 30$) (HC)	P_1 (MG-MS)	P_2 (MG-HC)	P_3 (MS-HC)
Data are presented as mean (standard deviation) if not stated otherwise						
Health status (SF-36)						
Physical functioning (PF)	79 (26.8)	67 (27.4)	88 (20.8)	0.136	0.701	0.006
Role limitation due to physical problems (RP)	62 (39.2)	62 (41.5)	92 (19.0)	> 0.999	0.003	0.010
Role limitation due to emotional problems (RE)	73 (40.5)	68 (36.2)	82 (34.7)	> 0.999	> 0.999	0.592
Social functioning (SF)	68 (25.1)	77 (18.3)	76 (23.4)	0.349	0.570	> 0.999
Mental health (MH)	65 (16.6)	68 (14.5)	67 (16.7)	0.985	> 0.999	> 0.999
Energy, vitality (VE)	53 (19.5)	57 (18.1)	58 (16.5)	0.933	0.845	> 0.999
Bodily pain (BP)	56 (25.0)	66 (23.1)	74 (18.3)	0.102	0.006	> 0.999
General health	60 (20.1)	53 (20.4)	78 (12.8)	0.638	0.001	< 0.001
SF-36 Physical health dimension	64 (21.2)	63 (23.5)	83 (12.4)	> 0.999	0.001	0.002
SF-36 Mental health dimension	65 (21.5)	68 (18.9)	71 (19.8)	> 0.999	0.774	> 0.999

P_1, statistical significance of the difference between migraine and MS patients; P_2, statistical significance of the difference between migraine patients and healthy participants; P_3, statistical significance of the difference between RRMS patients and healthy participants, all P values were two sided, adjusted for age, sex, and level of education, and for multiple comparisons by Bonferroni correction

variables in the analyses. The Durbin-Watson test amounts to 1.215. Table 3 shows the results of the regression model on the overall QoL score.

According to the data, both sociodemographic variables entered in step 1 do not predict QoL significantly. In step 2, nominal variables related to the presence of neurological

Table 3 Results of hierarchical regression analysis with PWI as criteria

Model	β	t	R	R^2	ΔR^2	ΔF
1						
Gender	− .014	− .138				
Age	− .174	− 1.681	.176	.031	.031	1.465
2						
Gender	− .004	− .044				
Age	− .176	− 1.709				
Migraine	− .107	− .913				
RRMS	− .239*	− 2.061	.273	.075	.044	2.127
3						
Gender	.031	.413				
Age	− .169*	− 2.207				
Migraine	.037	.388				
RRMS	− .131	− 1.280				
Physical functioning (PF)	− .097	− 1.185				
Role limitation due to physical problems (RP)	− .289*	− 2.393				
Role limitation due to emotional problems (RE)	.205	1.936				
Social functioning (SF)	− .111	− .832				
Mental health (MH)	.505*	3.553				
Energy, vitality (VE)	.063	.473				
Bodily pain (BP)	.119	.997				
General health (GH)	.347**	3.221	.756	.572	.498	11.924**

**$P < 0.01$; *$P < 0.05$

conditions explain 4.4% of the variance. However, the existence of RRMS predicts the criteria significantly in step 2 ($\beta = -.239$, $p < 0.05$), whereas in step 3, it does no longer significantly predict the QoL. Health domains entered in step 3 explained 49.8% of the QoL variance. Interestingly, after entering health domains in step 3, age became a significant QoL predictor ($\beta = -.169$, $p < 0.05$). Role limitation due to physical problems, mental health, and general health perception are the best QoL predictors, indicating that lower role limitations due to physical problems, higher levels of mental health, and more positive general health perceptions were associated with greater QoL. This model explained 57.2% of the QoL variance in total.

Discussion

This study showed that patients with migraine and RRMS had significantly worse health regarding role limitation due to physical problems and general health than healthy control subjects. It is possible that a perceived role limitation due to physical problems and lower general health emanates from physical impairment or disability. As anticipated, results indicate that migraine patients have more bodily pain while RRMS patients have more difficulties with physical functioning, compared with the healthy control group. This finding is in accordance with previous results, showing that migraine patients expressed the highest levels of bodily pain [26]. Interestingly, there were no significant differences in health between migraine and RRMS patients. Similar patterns regarding physical difficulties in migraine and RRMS patients were found, suggesting that both groups experience severe physical limitations and are confronted with various daily functioning difficulties as a result of disrupted health [9, 14].

Furthermore, our results revealed that health domains significantly predict QoL. As it can be seen in Table 3, role limitations due to physical problems, mental health, and general health represent significant QoL predictors. Similar findings were discovered in previous studies, indicating that mental health and patients' perceptions of own health are also important for overall QoL. In other words, overall wellbeing does not depend only on mere manifestation of handicap and impairment, but also on psychological and cognitive factors [27].

This study has some limitations, because it was conducted in a single center and the sample size is small. Minimal sample size required would be 42 participants in each group [21]. Instead, in this pilot research, 30 participants were enrolled in each study group and this might increase the likelihood of a type II error by skewing the results. In other words, there is a greater likelihood of assuming as true a false premise [28]. Nonetheless, given the sociodemographic characteristics of our participants, it may be concluded that they are representative of the MS and migraine population. Furthermore, this was a cross-sectional study and thus any conclusions regarding causality or directionality cannot be made. Finally, data were obtained using self-report measures. Even though both objective and subjective measures are considered to be valid and reliable, subjective measures contain a certain amount of bias which should be considered. These limitations warrant a collaborative study among Neurology Departments with a larger sample size. For this reason, we are launching a country-wide study on this topic.

Conclusion

The findings of the present pilot study involving migraine and RRMS patients indicate that health domains, such as role limitation due to physical problems and general health, tend to be lower in patients compared with a healthy control group. Moreover, the limitations due to physical problems, mental health, and general health significantly contribute to the overall QoL. Considering the variance of QoL explained by health domains, it might be concluded that subjective perception of individual's health regarding role limitation due to physical problems, mental health, and general health plays an important role in attaining higher levels of QoL and living a productive and fulfilling life in patients with migraine or RRMS. For that reason, assessment of health and quality of life should be included as a treatment evaluation method and in clinical trials to provide a complete view of patients' health status.

Acknowledgements The authors thank Prof. Claudio Baracchini, MD, Head of Stroke Unit and Neurosonology Lab, Department of Neuroscience, University of Padua School of Medicine, Padua, Italy. Iva Vranić, mag. psych. Josipa Erdeši, mag. psych.

Authors' contributions Klaudia Duka Glavor study design of the article, data collection, literature searches, writing the manuscript, approval of the final version.

Marina Titlić study design, supervisior of the research, approval of the final version.

Gorka Vuletić study design, statistical analysis and interpretation of results, approval of the final version.

Anamarija Mrđen study design (sample), interpretation of the results, comments on the draft paper.

Marina Maras Šimunić study design, literature searches, comments on the draft paper.

Compliance with ethical standards The study protocol was approved by the local Ethics Committee and all participants signed a written informedconsent. The study was conducted in accordance with the World Medical Association Declaration of Helsinki.

Conflict of interest The authors declare that they have no conflict of interest.

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