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Comparison of the Quality of Life of Patients with Multiple Sclerosis and the Healthy Population with Special Reference to the Impact of Fatigue, the Frequency of Relapses and the Use of Immunotherapy

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#### **ABSTRACT**

**Background:** The aim of this study was to compare the quality of life of patients with multiple sclerosis and the healthy population. Another aim of this study was to determine the impact of pathological fatigue, the number of relapses and the effect of immunotherapy on the level of satisfaction with the quality of life among the sick population.

**Methods:** The study included 30 patients diagnosed with relapsing-remitting multiple sclerosis and 30 healthy subjects. Basic data were taken from the archives of the clinic for neurology, and patients were examined according to the Modified Fatigue Impact Scale and SF36-v2 questionnaires.

**Results**: This study showed that patients with multiple sclerosis have a poorer quality of life compared to the healthy population (p=0.002), Among the patients, the level of satisfaction with the quality of life differed significantly depending on fatigue, the number of relapses in the last year and immunotherapy. It was found that patients with more relapses in the last year were more dissatisfied with the quality of life compared to patients with one or no relapses (p=0.048). Moreover, research has shown that patients who suffer from increased fatigue have a poorer quality of life, in contrast to patients with a normal level of fatigue (p=0.007). Finally, patients receiving immunotherapy have a better quality of life compared with patients not receiving it (p=0.033).

**Conclusion:** Those with multiple sclerosis have a significantly lower level of satisfaction with the quality of life. Patients with more relapses in the last year, those who suffer from increased fatigue and those who do not receive immunotherapy have a poorer quality of life.

**Key words**: relapsing-remitting multiple sclerosis; quality of life; fatigue; MFIS; SF36-v2

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#### INTRODUCTION

Multiple sclerosis (MS) is chronic, inflammatory, demyelinating and neurodegenerative disease of the central nervous system, which most commonly occurs in young adulthood. It is a heterogeneous, multifactorial and immune-mediated disease affected by genetic and environmental factors. The pathological feature of MS is the formation of demyelinating lesions in the area of white and gray matter of the brain and spinal cord. Clinical manifestations and the course of MS are heterogeneous (1).

Relapsing-remitting multiple sclerosis (RRMS) is the most common form which affects 80-85% of patients. It is manifested by a sudden deterioration (relapse), followed by recovery. Relapse should not be accompanied by fever or infection, and relapse should be followed by prolonged remission and recovery. When we talk about MS in general, we usually mean the RRMS form. New patients are mostly between the ages of 20 and 40, and women are more likely to become sick.

Primary-progressive multiple sclerosis (PPMS) is a more severe form of MS, characterized by the gradual, progressive development of ailments, without relapse and with an accumulation of neurological deficit. It affects the sexes equally and mainly affects those over the age of 40.

Secondary-progressive multiple sclerosis (SPMS) is a form of RRMS progression in 25-40% of patients after 20 years or more. Relapses are much more severe; remissions are shorter or absent.

Progressive relapsing multiple sclerosis (PRMS) is the rarest form and is characterized by a progressive course with more acute relapses (2).

MS can cause a variety of symptoms, including sensory disturbances, visual disturbances, muscle weakness, depression, coordinating and speaking disorders, severe fatigue, cognitive impairment, balance problems, overheating and pain. In severe cases, it causes reduced mobility and disability (3).

Although the physical disability of MS is of great importance, quality of life measurements is considered increasingly important in terms of assessing disease progression and assessing the treatment and care provided to patients with MS (4).

The aim of this study was to compare the quality of life of people with MS with the healthy population.

## PARTICIPANTS AND METHODS

#### **Participants**

The study included 30 patients diagnosed with RRMS (McDonald criteria in 2010), who were treated at the Clinic of Neurology of the University Clinical Hospital Mostar during the period from June 1, 2019 to June 1, 2020, and had an EDSS of 0-5.0 (mobile patients). Moreover, 30 healthy subjects of appropriate age and sex participated in the study. The study excluded patients with a score greater than 5 on the Expanded Disability Status Scale (EDSS), patients with established cognitive impairment, and those who, in addition to MS, suffered from other serious diseases.

## Methods

Basic information regarding patients was taken from the archives of the neurology clinic. were subsequently examined, **Patients** according to the Modified Fatigue Impact Scale (MFIS) and SF36-v2 questionnaires. The MFIS is a modified form of the Fatigue Impact Scale, based on items derived from interviews with MS patients concerning how fatigue impacts their lives. This instrument provides an assessment of the effects of fatigue in terms of physical, cognitive and psychosocial functioning. The full-length MFIS consists of 21 items, while the abbreviated version has five items. The SF-36v2 asks 36 questions to measure functional health and well-being from the patient's point of view. It is a practical, reliable



and valid measure of physical and mental health that can be completed in 5 to 10 minutes.

## Statistical analysis

Continuous data were shown as mean and standard deviation, while categorical variables were shown as frequencies and percentages. Differences in categorical variables were tested by the chi-square test and Fisher's exact test. Student t-test for independent samples, and Mann-Whitney U test were used to analyze the differences between continuous variables. Relationship between variables were tested by using Spearman correlation coefficient. The probability level of p<0.05 was taken as statistically significant. **SPSS** statistical software, version 17, was used for all statistical analyses (SPSS Inc., Chicago, IL, USA).

#### **RESULTS**

A statistically significant difference according to the MFIS (fatigue) criterion was observed by comparing the group of patients with MS and the healthy population, matched by age and sex, so that the group of patients had a significantly higher level of fatigue than the group of healthy participants. In addition, MS patients had a poorer level of satisfaction with the quality of life compared to their healthy counterparts (Table 1).

Table 1. A comparison of the level of fatigue and the level of satisfaction with the quality of life between those with MS and the healthy population

	Group					
	Patients with MS		Healthy population		t	p
	X	SD	X	SD		
MFIS	45.87	15.122	31.83	12.855	3.873	<0.001
SF36	22.23	10.887	14.67	6.110	3.320	0.002

Among the sick population, this study showed that patients suffering from increased fatigue have a poorer quality of life than patients with normal levels of fatigue (Figure 1).

When discussed the number of relapses in the last year, we found a statistically significant, yet weak, positive relationship between the number of relapses of MS in the last year and the level of satisfaction with the quality of life (Table 2).

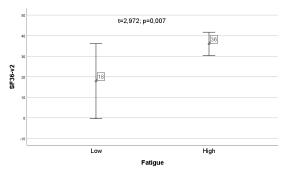


Figure 1. A review of the impact of fatigue on the level of satisfaction with the quality of life in patients with a normal level of fatigue and those who suffer from increased fatigue

Table 2. Relationship of the number of relapses of MS in the last year and the level of satisfaction with the quality of life

	The number of relapses of MS in the last year:		
	ρ	p	
SF36	0.364	0.048	

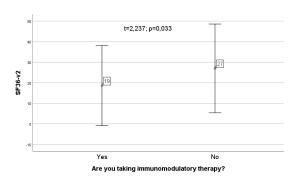


Figure 2. A review of the impact of immunomodulatory therapy on the level of satisfaction with the quality of life among patients receiving immunomodulatory therapy and those not receiving it



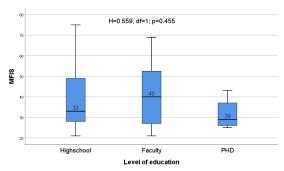


Figure 3. Demonstration of the influence of the level of education of MS patients on the level of satisfaction with the quality of life

Patients who did not take immunomodulatory therapy had a significantly poorer quality of life (Figure 2).

Among patients with MS, there was no statistically significant difference in the level of satisfaction with the quality of life regarding the level of their education (Figure 3).

Moreover, no statistically significant difference was observed in the quality of life of patients according to their employment status (Figure 4).

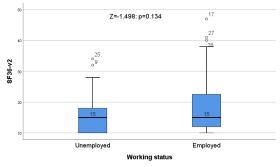


Figure 4. A review of the impact of the employment status of MS patients on the level of satisfaction with the quality of life

#### **DISCUSSION**

This study showed that those with MS have a poorer quality of life compared to the healthy population, and the main determinant of this quality is increased fatigue. Furthermore, among patients, the level of satisfaction with the quality of life differs significantly according to the impact of fatigue, the frequency of disease relapses in the last year and the use of immunomodulatory therapy.

This study showed that those with MS have a poorer quality of life compared to the healthy population. Due to a greater feeling of fatigue, sufferers need more rest and feel sleepier. In a study conducted by Kos et al., the level of fatigue in sick subjects was also significantly higher than the assumed value in healthy populations (5).

Furthermore, this study also found that patients who suffer from increased fatigue have a poorer quality of life, compared to patients whose fatigue is no different from the fatigue of the healthy population. This conclusion was also reached by Colbeck in her recent study (6).

In addition, this research found that patients with more relapses in the last year are more dissatisfied with the quality of life compared to patients with one or no relapses. The same results were obtained by a study conducted in Croatia. That study found that the number of relapses of MS in the last year negatively affected vitality and social functioning, and increased the impact of fatigue on cognitive functioning (7).

This study proved that MS patients, who do not receive immunomodulatory therapy, have a poorer quality of life compared to those who receive it. The study conducted by Boyko and Petrov demonstrated a significant and rapid relief of depression after 6 months of ocrelizumab treatment, which was associated with improved vitality index, general health, social relationships and an overall quality of life satisfaction (8). The same results were obtained by Pittion-Vouyovitch et al., whose study found that those with MS who do not receive immunomodulatory therapy have a poorer quality of life (9). In contrast, research conducted by Rupprecht et al. found that anxiety and fatigue impair the quality of life, but at the same time no statistically significant difference was found between the quality of life patients receiving immunomodulatory therapy and those not receiving it (10).



Secondary research results relate to the impact of education and employment status on the level of satisfaction with the quality of life.

Research showed that the degree of satisfaction with the quality of life does not depend on education or employment status. Other results were provided by a recent study conducted in Bosnia and Herzegovina, which found that higher levels of education and employment have a positive effect on the physical and mental components of the quality of life (11). According to this research, the patients' employment had a positive effect on the quality of life, as these patients are less restricted in performing daily activities compared to the unemployed. The same results were obtained by Meghan Beier et al., whose research showed that stress was related to work status, so that unemployed patients had significantly higher levels of stress and thus a lower level of satisfaction with the quality of life (12).

The main disadvantage of this research is the small sample size. The study only included patients diagnosed with RRMS, who were treated in an outpatient clinic over the last year, who are mobile, who do not have cognitive impairment and who, in addition to MS, do not have other serious diseases. Therefore, I would suggest that a larger number of patients be included in the next study, that they be observed over a longer period of time and that their level of satisfaction with the quality of life be compared with other clinical forms of MS.

#### **CONCLUSIONS**

Those with MS have a significantly lower level of satisfaction with the quality of life compared to the healthy population. Patients with more relapses in the last year, those who suffer from increased fatigue and those who do not receive immunotherapy have a poorer quality of life.

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#### CONFLICT OF INTEREST

Author RR declares that she has no conflict of interest; author SB declares that she has no conflict of interest; author IB declares that he has no conflict of interest; author KK declares that he has no conflict of interest, author JP declares that she has no conflict of interest; author AS declares that she has no conflict of interest.

#### AUTHORS' CONTRIBUTIONS

RR: acquisition of data, literature review, contribution to study conception and design, supervision, writing of the paper; IKS: contribution to study conception and design, literature review, supervision, interpretation of data, critical revision of the paper; DB: contribution to study conception and design, interpretation of data, literature review, supervision, critical revision of the paper.

# ETHICAL APPROVAL AND CONSENT TO PARTICIPATE

This research does not require an ethics review, as it was based on a retrospective review of the archives of the Student Office within the School of Medicine in Mostar. This study was based on the analysis of a dataset in which the data are anonymized. No identifier or group of identifiers, which would allow the release of private information to an individual, were provided in the manuscript.

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