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**Quality of life in patients with multiple sclerosis and their caregivers in  
Colombia: one-year follow-up**

**Calidad de vida en pacientes con esclerosis múltiple y sus cuidadores en  
Colombia: un año de seguimiento**

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Todos los autores participaron en la escritura del manuscrito.

**Introduction.** Multiple Sclerosis (MS) is a chronic inflammatory demyelinating disease associated with neurological disability. Clinical features include: motor function, cerebellar and visual, sensory disturbances and psychiatric comorbidities. There is little literature available on the quality of life of patients and their caregivers.

**Objective.** Assess the quality of life of patients with MS and their caregivers in Colombia, since there is no information on the subject in this particular population to establish comprehensive management plans.

**Materials and methods.** Was used the questionnaire MusiQol, CareQol and depression of Beck. A prospective analytical observational protocol was designed to include patients aged 18 to 65 years with diagnosis of Relapsing-Remitting MS (RR) between October 2014 and 2015 at the San Ignacio University Hospital. Quantitative variables, Spearman correlations. Data analysis with Student T-Test and Mann-Whitney U.

**Results.** 55 patients with MS RR In 27%, chronic fatigue was the most common comorbidity. The MusiQol revealed a good basal quality of life, which remained at similar levels in the follow-ups of 6 months and 12 months. Quality of life was good during the study, since there were no statistically significant differences between baseline and follow-up MusiQol scores A good quality of life was observed in caregivers.

**Conclusions.** The quality of life of a number of Colombian patients diagnosed with MS was very good. This positive result was also observed in caregivers, as demonstrated by the results of CareQol. We also observed and indicated an inversely proportional correlation between the EDSS and the quality of life indexes.

**Key words:** multiple sclerosis; patients; quality of life; caregivers; Colombia.

**Introducción.** La esclerosis múltiple (EM) es una enfermedad desmielinizante inflamatoria crónica asociada a discapacidad neurológica, afecta: función motora, cerebelosa, visual, sensorial y psiquiátricas como depresión, ansiedad e irritabilidad. Hay escasa literatura disponible sobre la calidad de vida (CV) de pacientes y sus cuidadores.

**Objetivo.** Evaluar la CV de los pacientes con EM y sus cuidadores en Colombia, no hay información sobre el tema en esta población en particular para establecer planes de manejo integral.

**Materiales y métodos.** Se utilizó el cuestionario MusiQol, CareQol y de depresión de Beck. Se diseñó un protocolo observacional analítico prospectivo para incluir pacientes de 18 a 65 años con diagnóstico de EM recurrente-remitente (RR) entre octubre de 2014 y 2015 en el Hospital Universitario San Ignacio. Se evaluaron variables cuantitativas, correlaciones de Spearman. El análisis de datos con prueba t de Student y Mann-Whitney U.

**Resultados.** 55 pacientes diagnosticados con EM RR. En el 27%, la fatiga crónica fue la comorbilidad más frecuente. El MusiQol reveló una buena CV basal, que se mantuvo en niveles similares en los seguimientos de 6 y 12 meses. La CV fue buena durante el estudio, no hubo diferencias estadísticamente significativas entre las puntuaciones MusiQol basales y de seguimiento. Se observó una buena CV en los cuidadores

**Conclusiones.** La CV de una serie de pacientes Colombianos con diagnóstico de EM fue muy buena, así como en los cuidadores, como lo demuestran los resultados de CareQol. Observamos una correlación inversamente proporcional entre el EDSS y los índices de CV.

**Palabras clave:** esclerosis múltiple; pacientes; calidad de vida; cuidadores; Colombia.

Multiple sclerosis (MS) is a chronic inflammatory demyelinating disease of the central nervous system (CNS) associated with neurological disability (1).

Clinical features frequently include the involvement of motor, cerebellar and visual function, as well as sensory alterations and sphincter dysfunction (1,2).

MS is associated with psychiatric comorbidities; clinical studies list depression, present in up to 50% of patients, as well as other frequent psychiatric symptoms including anxiety, irritability and lability. The prevalence of anxiety in this pathology is 36% (3).

Scarce literature is available on the relationship between caregiving family members and the patient, their attitude toward the disease, and the impact in the quality of life of both patient and caregiver. There are no studies in Colombia that show the current situation of quality of life in patients with MS and their caregivers. Some studies show a direct link between the severity of the patient's case and the quality of life of the caregiver (1-3). Furthermore, time and money expenses, along with leaves from work, end up affecting the entire family nucleus and thereby worsening disease progression. In addition, quality of life varies among countries where patients are evaluated, according to sociodemographic factors such as socioeconomic background, level of education, and marital status, which certainly can modify the progression of the disease. A recent multicentric study in Austria, Poland and Germany showed that each region's unique factors, access to healthcare, beliefs and customs play a decisive role in the quality of life of MS patients, varying drastically among assessed countries (4). For these reasons, there is a need for studies on the quality of life of Colombian MS patients, as there is no information on the matter for this particular population. Collecting data on how these factors affect

MS patients is required to establish integral management plans to educate patients and their caregivers based on the needs identified in this study (4-6).

#### Materials and methods

To evaluate the quality of life of patients with MS and their caregivers in Colombia, through MusiQol and CareQol respectively. Since there is no information on the subject in this population to establish comprehensive patient-caregiver management plans.

In order to measure the quality of life of patients with relapsing-remitting MS in Colombia and diagnosed using criteria described in McDonald (2010), we used the MusiQol and CareQol questionnaire scores to classify patients and caregivers, respectively. We also sought to collect demographic data including gender, age, ethnicity, level of education, and marital status of patients and their caregivers; to measure disability with the EDSS (Expanded Disability Severity Scale); to analyze disease-modifying drug therapy adherence and frequency of use; and to analyze the frequency of depression among patients under study according to the Beck Depression Inventory. A prospective analytical observational protocol was designed to include patients aged 18 to 65 who met 2010 McDonald criteria for relapsing-remitting MS, with EDSS scores for multiple sclerosis between 0 and 6.5, who had been undergoing treatment with a disease-modifying drug for the last 6 months. Patient exclusion criteria included associated neurological pathologies or systemic diseases, history of alcohol or drug abuse, and MS relapse during the month prior to evaluation. Between October 2014 and October 2015, we collected data from patients with relapsing-remitting MS at the San Ignacio University Hospital who met the aforementioned inclusion criteria while failing to do so with exclusion criteria. A



limitation of the study is the small sample-size, which could make results uncertain. In order to participate in the study, all patients signed an informed consent form approved by the Ethics Committee of the Universidad Javeriana. Patients accepted into the study filled out a form to collect their demographic information, time of disease course, disease-modifying drugs taken, and drug treatment adherence. We assessed their level of disability at the beginning of the study using the EDSS; quality of life using the MusiQol questionnaire scale; and depression using the Beck Depression Inventory. We collected demographic data from caregivers as well, and assessed their quality of life using the CareQol questionnaire scale. Patient follow-up was performed 6 and 12 months after their inclusion in the study, using the EDSS, MusiQol and Beck Depression Inventory scales; caregiver follow-up was performed at the same intervals using the CareQol tool.

The MusiQol score quantifies the quality of life an MS patient. The score is directly correlated with the quality of life, i.e.: the higher the score, the higher the quality of life of a patient. MusiQoL comprises 31 items that describe nine dimensions. Each dimension is named according to its constitutive items, as follows: activities of daily living (ADL, 8 items), psychological well-being (PWB, 4 items), symptoms (SPT, 3 items), relationships with friends (RFR, 4 items), relationships with family (RFa, 3 items), relationship with the healthcare system (RHCS, 3 items), sentimental and sexual life (SSL, 2 items), coping (COP, 2 items) and rejection (REJ, 2 items). Each item was answered using a six point Likert scale, where 1 = 'never/not at all', 2 = 'rarely/a little', 3 = 'sometimes/somewhat', 4 = 'often/a lot', 5 = 'always/very much', 6 = 'not applicable'. The negatively worded item scores were reversed so that higher

scores indicated a higher level of HRQoL. For each patient, the score of each dimension was obtained by computing the mean of the item scores of the dimension. If fewer than half of the items were missing, the mean of the non-missing items was substituted for the missing items. All dimension scores were linearly transformed to a 0-100 scale. A global index score was computed as the mean of the dimension scores.

The MusiQoL questionnaire allows for evaluation of quality of life, providing a global assessment score; however, it can also be used to measure a variety of specific dimensions . Evaluated domains are: Activities of Daily Living, Psychological Well-Being, Symptoms, Relationships with Friends, Relationships with Family, Relationships with Healthcare System, Sentimental and Sexual Life, Coping, and Rejection.

The CareQoL questionnaire allows for measurement and classification of the quality of life of MS caregivers into Excellent, Good, Fair, and Poor; the score is inversely proportional to the caregiver's quality of life, meaning that lower scores point out a better quality of life.

We evaluated continuous quantitative variables using mean, median, and handled categorical variables as relative and absolute frequencies. We performed Spearman correlations between age and questionnaire outcomes, and compared means and evaluated data distribution for continuous variables, including gender, marital status, occupation, and comorbidities using Student's t-test for those behaving normally and Mann-Whitney U-test for those with non-normal distributions. The Kolmogorov-Smirnov test has been used to test normality.

## Results

This study recruited 55 patients diagnosed with relapsing-remitting MS, following 2010 McDonald diagnostic criteria (1). Average age was 36.2 years, evidencing a 2.1:1 female-to-male ratio. 55% of subjects were of Mestizo (mixed race) ethnicity, while only 5% were Afro-Latin American. Marital status data show most subjects had stable relationships: 47% were married or living together, while only 13% were divorced. The most frequent level of education attained by subjects was high school, followed by undergraduate education, with 37% and 31% respectively. Found in 27% of subjects, chronic fatigue was the most frequently encountered comorbidity (table 1).

As for pathology-related variables, we observed that the average disease duration when entering the study was 4.8 years. Relapses per year averaged 1.1, with a median of 1. Average EDSS score was < 3 (better life quality) (table 2).

The most frequent drug therapy among subjects was high-dose interferon beta-1a (42%). Adherence to treatment was 100% (this parameter was established by asking the patients the treatment time and adherence to it). Average treatment duration at the beginning of the study was 44 months.

A discrete progression of disability was observed at the 6-month and 12-month follow-up visits, but only of one point in the mean (2.25 at 6-months and at 12-months).

Use of this instrument on our patients revealed a good baseline quality of life, with a mean of 84.1, which remained at similar levels in the 6-month and 12-month follow-ups (means of 84 and 87.7, respectively). The quality of life was

good during the study, as there were no statistically significant differences between baseline and follow-up MusiQoL scores ( $p = 0.59$ ).

The baseline quality of life of our patients' caregivers was good, with a mean of 32.5, remaining stable after 6- and 12-month follow-ups with means of 32.6 and 30, respectively (table 3). No statistically significant variation in the quality of life of caregivers were observed along the length of the study compared with baseline CareQoL scores ( $p = 0.07$ ); thus, quality of life remained stable for MS caregivers as well.

The CareQoL questionnaire also allows for evaluation of specific quality of life aspects of the caregiver dealing with MS, such as their perception of Global Health and Physical Burden, Social Impact, Emotional Impact, Need of Help, and Emotional Reactions (table 4). We observed a good quality of life in our patients' caregivers in almost every dimension mentioned above, as shown by mean values and baseline averages at the 6- and 12-month follow-ups. Only the Emotional Impact dimension of the caregivers' quality of life had high scores, both at the baseline and during follow-up.

Using the Beck scale we determined depression frequency, observing a 14% baseline evaluation score that increased significantly, reaching 22% ( $p = 0.047$ ) at the 6-month follow-up, decreasing to 9% after 12 months.

We observed a direct correlation between depression scores at the beginning of the study in MS patients with EDSS scores, as well as an inverse correlation of scores after one year with the patient's age (table 5). We also observed an inverse correlation between caregiver quality of life scores and patient disability at the beginning of the study.

## **Discussion**

Psychological stress in MS patients is significantly greater than in healthy control subjects, being an independent predictor of lower quality of life and work productivity, as well as greater costs for the society these individuals' quality of life has an effect upon. MS is the most frequently diagnosed demyelinating disease, affecting mostly a young, productive population; it causes a progressive neurological decline that leads to early disability and unfitness for work (9). Few studies have assessed the magnitude of such effect. Kobelt and colleagues studied 13,186 MS patients in nine European countries, reporting that between 33% and 45% of patients earned an early retirement pension (10). To this day, there is no data available on unemployment rates among MS patients that are fit for work, mostly due to studies focusing on establishing the proportion of economically inactive patients instead. A study (11) carried out in Australia observed that 50% of male and 75% of female subjects were economically unproductive. Studies show that approximately 50% of patients will require walking aids, psychological treatment, and rehabilitation, developing loss of productivity with a great economic impact in terms of health costs and work leaves (12).

The chronic and potentially disabling nature of MS constitutes a threat to the marital life of patients. The probability of remaining together on the long-term for an MS patient and his or her partner is 33%, compared to 53% of control subjects, according to a Danish study (13); greater divorce rates were observed in men, childless couples, and patients with onset before age 36. MS significantly affects the partner of an MS patient, when compared to the general population (14).

Individuals suffering from this disease progressively develop a compromise of functional capacity, due to fatigue. 55% of MS-diagnosed patients describe fatigue as one of the most severe symptoms experienced in the disease. This clinical feature increases the risk of developing depression, and affects day-to-day activities as well as social behavior and quality of life (15).

In short, quality of life of MS patients is affected by many reasons, when compared to the general population. Most published studies report a correlation between advanced disability and quality of life. The latter is not the sole important predictor of the affectation suffered by patients of this pathology (13).

In addition to the broad spectrum of symptoms, signs, and functional limitations found in MS patients and their families adjust and adapt to major lifestyle changes and many types of restriction. As the disease progresses, the patient loses autonomy and begins to require the presence of caregivers even during everyday activities. Recently, the role of caregivers in the management of long-term MS patients as well as the insult and suffering they are subject to has been gaining importance, as well as the analysis of the impact caregiver loss has on the patient's quality of life. Few studies have looked into the relationship between MS patient characteristics and caregiver attributes, which eventually determine the impact on the caregiver's quality of life. The above is essential for early identification of vulnerable caregivers at high risk of compromising their quality of life, a step prior to developing strategies to perform early interventions aimed to improve MS prognosis and avoid caregiver loss (16).

Moreover, this study used an assessment tool validated in over 14 languages, including Spanish (7); its use will enable determination of a baseline score and

assessment of responses to interventions, as well as which quality of life aspects therapeutic interventions have the greatest impact on.

International research reported a 2.1/1 female-to-male ratio. The low percentage of Afro-Latin American MS patients, only 5%, may be a consequence of the low frequency of MS in that population and/or a lower access to healthcare services. The most frequent comorbidity was chronic fatigue, observed in 27% of patients. Time of disease progression for our patients at the moment of inclusion into the study was 4.8 years in average, while 44 months was the average of the duration of treatment with a disease-modifying drug with a 100% adherence. This explains the high functionality associated to low disability at the beginning of the study that we evidenced in a mean score of 1 in the EDSS which experienced a discrete progression to a mean score of 2 by the end of the follow-up year.

However, the methodological design as well as the low prevalence of MS in Colombia, a total of 3,462 people diagnosed with multiple sclerosis were treated during the 2009-2013 period. The national prevalence for the period was 7.52/100,000, with the highest figures in Bogotá (16.25), where 1,213 patients were attended, followed by the departments of Quindío (13.03) and Risaralda (11.18). Our patient sample entered the study with an EDSS mean score of 1, indicating high functionality and limited disability. This may be due to a relatively short time of disease progression, averaging 4.8 years, but high levels of adherence to treatment with disease-modifying drugs may also play a role in this phenomenon.

The quality of life as measured through MusiQol questionnaire was very good, with a mean score of 84.1 and statistically insignificant variations at the 6- and

12-month follow-ups ( $p = 0.59$ ); these results can be explained by the functional status and low EDSS score of patients, an early start of disease-modifying drugs and perfect reported adherence to such treatment, all within a relatively short disease duration at the moment of study: 4.8 years in average at the beginning of the study. Although it is not the objective of this study, other factors such as greater access to information in relation to the disease through the Internet could influence the results.

Our patient sample displayed high quality of life, which remained stable throughout the time of study, as evidenced by baseline mean scores as well as 6- and 12-month follow-up observations

We measured the quality of life of caregivers employing the CareQol questionnaire, and report here a good quality of life with a 32.5 mean score; we observed no statistically significant variations ( $p = 0.07$ ) during follow-ups after 6 and 12 months, which is consistent with and explained by the good quality of life and low disability of patients. We also found an inverse correlation between lower quality of life scores in caregivers with a greater degree of disability in MS patients.

Depression was infrequent among our patients at the beginning of the study, with only 14% presenting this condition; despite increasing to 22% after 6 months ( $p = 0.047$ ), it remained low in comparison with data from other studies reporting depression in up to 50% of subjects. Our results are most likely due to the fact that our patients were in great functional status, as a direct relationship has been described between scores in the Beck Depression Inventory and the EDSS.



This one-year follow-up study revealed that the quality of life, as measured with the MusiQoL scale, of a series of Colombian MS patients who met 2010 McDonald diagnostic criteria was very good. Such positive outcome was also observed in our patient's caregivers, as evidenced by CareQoL scores. We also observe and report a correlation between greater patient disability scores, in the EDSS scale, with lower quality of life indexes in the CareQoL scale. These findings are consistent with a patient series with an average time of disease progression of 4.8 years, early treatment with disease-modifying drugs, proper adherence to therapy, and low disability.

#### **Interest conflict**

None

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**Table 1** Symptoms associated with relapsing-remitting multiple sclerosis, according to 2010 McDonald criteria; n = 55.

Comorbidities	Count	%
<i>None</i>	19	35
<i>Chronic fatigue</i>	15	27
<i>Anxiety</i>	9	16
<i>Depression</i>	4	7
<i>Insomnia</i>	2	4
<i>All of the above</i>	6	11

**Table 2** Descriptive statistics for disease-related variables; n = 55.

Variable	Average	Median	Min	Max
<i>Age</i>	<i>36.2</i>	<i>34</i>	<i>18</i>	<i>60</i>
<i>EDSS*</i>	<i>2</i>	<i>1</i>	<i>0</i>	<i>6.5</i>
<i>Time from MS diagnosis, in Years</i>	<i>4.8</i>	<i>4</i>	<i>0</i>	<i>13</i>
<i>Relapses Per Year</i>	<i>1.1</i>	<i>1</i>	<i>0</i>	<i>4</i>

\*EDSS: Expanded Disability Status Scale score

**Table 3.** Baseline, 6- and 12-month CareQol scores for the quality of life of caregivers; n = 55. (Values and interpretation: excellent: 20-29, good 30-39, fair: 40-50 and poor: >50)

CAREQOL SCORES	BASELINE	6 MONTHS	12 MONTHS	<i>p</i> value
<i>N</i>	55	55	55	
<i>mean</i>	32.5	32.6	30	0.07
<i>Min</i>	20	27	20	
<i>Max</i>	53.4	74	54.6	

\*T-test

**Table 4.** Baseline, 6- and 12-month CareQol dimension scores for the quality of life of caregivers. n = 55. (caregivers is the closest relative to the patient)

CAREQOL DIMENSIONS	BASELINE SCORE	6 MONTHS	12 MONTHS
	N=55	N=55	N=55
	Mean (min-max)	mean(min-max)	mean(min-max)
<i>Physical burden/Global health</i>	20 (20-52)	20 (20-60)	20 (20-52.5)
<i>Social impact</i>	20 (20-68)	21 (20-80)	20 (20-55)
<i>Emotional impact</i>	50 (20-86)	48 (20-90)	46.6(20-86)
<i>Need of help</i>	26 (20-60)	20 (23-73)	20 (20-73.3)
<i>Emotional reactions</i>	20 (20-90)	20 (20-70)	30 (20-60)

\* A direct correlation was observed between the depression scores at the start of the study in patients with MS with EDSS scores, as well as an inverse correlation of the scores after one year with the patient's age. We also observed an inverse correlation between the quality of life scores of the caregiver and the disability of the caregiver at the beginning of the study.

**Table 5.** Spearman's correlation between the patient and caregiver quality of life, and the depression scale and continuous variables of interest.

	Age <i>p</i> value	Correlation coefficient	EDSS <i>p</i> value	Correlation coefficient
<i>MusiQoL</i>				
<i>Initial</i>	0.518	0.089	0.181	-0.183
<i>6 Months</i>	0.159	-0.2.11	0.131	-0.226
<i>1 Year</i>	0.920	0.019	0.568	-0.109
<i>Beck</i>				
<i>Initial</i>	0.110	-0.218	0.048	0.267
<i>6 Months</i>	0.862	0.027	0.156	0.215
<i>1 Year</i>	0.022	-0.416	0.884	-0.028
<i>CareQoL</i>				
<i>Initial</i>	0.310	0.139	0.001	0.446
<i>6 Months</i>	0.562	-0.088	0.335	-.0145
<i>1 Year</i>	0.862	-0.029	0.410	0.136