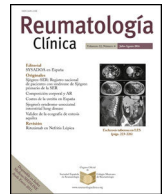




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Original Article

Quality of life in Ecuadorian patients with rheumatoid arthritis: A cross-sectional study[☆]

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ABSTRACT

Objectives: To evaluate health-related quality of life (HRQoL) and associated clinical, demographic and socioeconomic factors in a cohort of Ecuadorian patients with rheumatoid arthritis (RA).

Patients and methods: A cross-sectional descriptive study evaluating (HRQoL) with the Spanish version of the Quality of Life Rheumatoid Arthritis (QoL-RA) instrument in patients diagnosed with RA according to the criteria of the American College of Rheumatology and the European League Against Rheumatism. In addition, the following data were obtained: age, sex, marital status, socioeconomic stratum, comorbidities, disease duration, medication, rheumatoid factor positivity, disease activity using the simplified disease activity index and physical functionality measured with the modified Health Assessment Questionnaire (MHAQ).

Results: A total of 163 patients were assessed, the mean score of the QoL-RA scale was 6.84 ± 1.5 points. The highest measurements were obtained in the domains of interaction (8.04 ± 1.9) and support (8.01 ± 2). The factors that were associated with the overall quality of life assessment were: functionality measured with MHAQ ($r = -.70$; $P < .001$); disease duration in years ($r = -.178$; $P < .05$); and disease activity (mean difference of 1.5; 95% CI: 1.09–1.91).

Conclusion: The patients evaluated had a good to moderate HRQoL. The domains related to support and social life were those with the highest scores and the lowest scores were related to pain and nervous tension. Functionality, duration, and disease activity were statistically associated with HRQoL.

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Calidad de vida en pacientes ecuatorianos con artritis reumatoide: un estudio transversal

RESUMEN

Objetivos: Evaluar la calidad de vida relacionada con la salud (CVRS) y los factores clínicos, demográficos y socioeconómicos asociados en una cohorte de pacientes ecuatorianos con artritis reumatoide (AR).

Pacientes y métodos: Estudio descriptivo transversal que evaluó la CVRS con la versión en español del instrumento *Quality of Life–Rheumatoid Arthritis* (QoL-RA) en pacientes con diagnóstico de AR según los criterios del Colegio Estadounidense de Reumatología y de la Liga Europea Contra el Reumatismo. Adicionalmente, se obtuvieron los siguientes datos: edad, estado civil, sexo, estrato socioeconómico, comorbilidades, duración de la enfermedad, medicación, positividad de factor reumatoide, de ACPA, actividad de la enfermedad mediante el índice de actividad de la enfermedad simplificado y funcionalidad física medida con MHAQ.

Palabras clave:

Artritis reumatoide

Calidad de vida

Apoyo social

Desenlaces comunicados por los pacientes

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Resultados: Se evaluaron un total de 163 pacientes con AR, la puntuación media de la escala QoL-RA fue de $6,84 \pm 1,5$ puntos. Las medias más altas se obtuvieron en los dominios de interacción ($8,04 \pm 1,9$) y apoyo ($8,01 \pm 2$). Los factores que estuvieron asociados con la valoración global de la calidad de vida fueron: funcionalidad medida con MHAQ ($r = -0,70$; $p < 0,001$); duración de la enfermedad en años ($r = -0,178$; $p < 0,05$) y actividad de la enfermedad (diferencia de medias de 1,5; IC 95%: 1,09-1,91).

Conclusión: Los pacientes evaluados tuvieron una CVRS de buena a moderada. Los dominios relacionados con soporte y vida social fueron los mejor puntuados y los más bajos los relacionados con dolor y tensión nerviosa. La funcionalidad, la duración y la actividad de la enfermedad estuvieron estadísticamente asociadas a la CVRS.

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Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease which mainly occurs in the joints and incurs different degrees of deformity, including functional disability of varying levels, leading to a poorer health-related quality of life (HRQoL) compared with the general population, and also to premature death.^{1,2}

Several studies have demonstrated that the impact of RA on physical and mental status is considerable and this confirms that HRQOL is a vital goal in the management of these patients.^{3,4} In addition to this, many patients attach a higher value HRQOL than to disease-related variables, and the assessment of the medical status only in terms of disease activity may therefore not reflect the health triggers that are of interest to patients.³

In this regard, guidelines created by the American College of Rheumatology (ACR),⁵ the European League against Rheumatism (EULAR)⁶ and the National Institute for Health and Clinical Excellence of England⁷ recommend that the HRQOL in patients with RA be periodically assessed.

Furthermore, given the importance of the HRQOL in the management of patients with RA, several factors associated with the disease which have a greater or lesser impact in HRQOL have been studied. These include age, gender, functionality, disease duration, disease activity, presence of comorbidities,³ and social and economic resources.⁸

In Ecuador, however, there are no available studies to assess the impact of RA in HRQOL, nor have factors relating to it been explored. These data are considerably important for constructing health policies focused on limiting the effects of RA on HRQOL, which improves the care to these patients and is also associated with a lower use of healthcare resources.

The aim of this study was to evaluate HRQOL and the clinical, demographic and socio-economic factors associated with an Ecuadorian cohort of patients with RA.

Patients and methods

A descriptive, cross-sectional study was conducted following authorization from a Bioethical Committee certified by the national healthcare authority with outpatients who had been diagnosed with RA who presented at the Rheumatology Service of the Hospital Carlos Andrade Marín, a benchmark Ecuadorian public healthcare hospital in the city of Quito. This was conducted consecutively between September and October 2016. To be eligible, the patients had to have a documented diagnosis of RA in keeping with the 2010 reviewed criteria of the ACR and the EULAR.¹

Patient data regarding age, civil status, gender, duration of the disease and medication were collected via interviews. To assess disease activity the Simplified Disease activity Index (SDAI) was used. This is one of the tools recommended by the ACR for clinical use in healthcare centres.⁹ These data, together with rheumatoid factor positivity, anti-citrullinated protein antibodies positivity and

history of comorbidities such as diabetes mellitus, hypertension, hypothyroidism and heart diseases were recorded in the patient's medical file.

Quality of life, socio-economic stratum and functionality were recorded by the researchers through specific forms created for the research.

Quality of life was measured with the Spanish version of the *Quality of Life-Rheumatoid Arthritis* (QoL-RA) tool validated by Danao et al., for the Hispanic population of the U.S.A.¹⁰ This is a scale of 8 items which measures physical ability, joint pain, interactions by family and friends, mood, nervous tension, arthritis and health. Each item is classified on a scale of zero to 10. The scores increase as quality of life gets better.

Socio-economic stratum was assessed with a tool developed by the National Institute of Statistics and Censuses of Ecuador.¹¹ This tool divides the socio-economic stratum into 5 categories: upper; upper middle; middle; lower middle and low.

Functionality was assessed with the *Modified Health Assessment Questionnaire* (MHAQ), which is a short version of the HAQ, with only 8 items that are classified on a scale of 0–3, validated into Spanish by Esteve-Vive et al.: the lower the score, the better the functional ability. The main advantage of this tool is its simplicity, which facilitates its systematic use in patient assessment and follow-up.¹²

Statistical analysis

All data were reviewed and fine-tuned prior to analysis by the SPSS version 24.0 (SPSS Inc., U.S.A.) statistical software package. Descriptive statistic, central tendency measures (means and standard deviations) were calculated for quantitative variables and frequencies, and percentages for categorical variables.

For the comparison of groups, the Student's *t*-test and one-way ANOVA were used, in accordance with the variable characteristics. In order to assess correlation between numerical variables the Pearson correlation coefficient was used, given the normal distribution of data, which were also assessed using the Kolmogorov–Smirnov tests with correction by Lilliefors and Shapiro–Wilk.

In the multivariate analysis a multiple linear regression model was made, using quality of life as the dependent variable measured with the QoL-RA and each one of its domains. The model included these variables: age in years, gender, civil status, socio-economic stratum, duration of RA in years, rheumatoid factor positivity, anti-citrullinated protein antibodies positivity, current therapy with biologics, presence of at least one comorbidity, disease activity and functionality. These variables were included because they had been reported in previous studies as the factors with the highest explanatory capacity of the quality of life profile in these patients,^{2,3,13,14} and it was anticipated that they would be clinically associated with quality of life. A *P* value of <0.05 was considered statistically significant.

Table 1
Sociodemographic and clinical characteristics of the assessed patients.

| | |
|--|----------------------|
| Sex, n (%) | |
| Female | 132 (81) |
| Male | 31 (19) |
| Mean age in years (SD) | 55.69 (± 11.8) |
| Duration of disease in mean years (SD) | 12.72 (± 10.4) |
| Civil status, n (%) | |
| Single | 23 (14.1) |
| Married | 94 (57.6) |
| Divorced | 28 (17.1) |
| Living with a partner | 10 (6.1) |
| Widowed | 8 (4.9) |
| Socio-economic stratum, n (%) | |
| Upper | 2 (7.4) |
| Upper middle | 57 (35) |
| Middle | 60 (36.8) |
| Lower middle | 33 (20.2) |
| Lower | 1 (.6) |
| Disease activity by SDAI, n (%) | |
| Remission | 63 (38.7) |
| Low activity | 66 (40.5) |
| Moderate activity | 30 (18.4) |
| Severe activity | 4 (2.5) |
| Presence of comorbidity, n (%) | |
| Yes | 69 (42.3) |
| No | 94 (57.7) |
| Use of biologics, n (%) | |
| Yes | 18 (11) |
| No | 145 (89) |
| Extra-articular disease, n (%) | |
| Yes | 9 (5.5) |
| No | 154 (94.5) |

SDAI: Simplified Disease Activity Index.

Results

A total of 163 patients with RA were included in the study. The socio-economic characteristics of the population studied are contained in Table 1.

A diagnosis of hypothyroidism was reported in 40 patients (24.5%); hypertension in 32 (19.6%); dyslipidemia in 8 (4.9%) and diabetes mellitus in 5 (3.1%). Nine patients presented with a history of extra-articular disease: 6 with Sjögren's syndrome, 2 fibromyalgia, and one systemic lupus erythematosus.

The mean years of RA diagnosis was 12.72 ± 10.4 years. Regarding disease activity, 63 patients (38.7%) were in remission ($SDAI \leq 3.3$); 66 patients (40.5%) in low activity ($SDAI \leq 11$); 30 patients (18.4%) in moderate activity ($SDAI > 11$ and ≤ 26) and 4 patients (2.5%) presented with severe disease activity ($SDAI > 26$).

The mean score of the QoL-RA scale was 6.84 ± 1.5 points. The highest averages were obtained in the social interaction domains (8.04 ± 1.9) and support from family and friends (8.01 ± 2), whilst the lowest scores were in the nervous tension domains (6.00 ± 2.3) and joint pain (6.33 ± 2.0). The mean score of the MHAQ was 5.88 ± 5.18 (Fig. 1).

In Table 2, which shows univariate analyses we can see that only disease activity determined statistically significant differences in the quality of life averages. Meanwhile, according to the Pearson correlation, the functionality measured with MHAQ and the duration of the disease in years were significantly correlated with quality of life measured by the QoL-RA ($r = -.70$; $P < .001$ and $r = -.178$; $P < .05$, respectively).

In multivariate analysis contained in Table 3, functionality was assessed through the MHAQ and was associated in almost all quality of life domains covered by QoL-RA, except the domains of

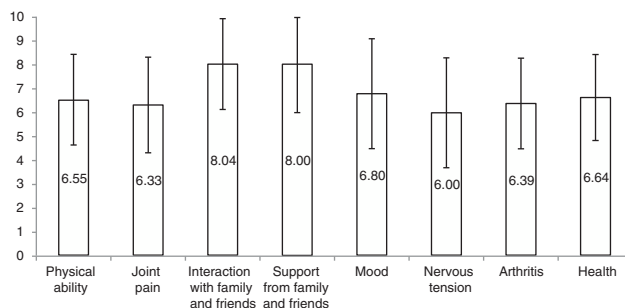


Fig. 1. Means and standard deviation of each domain from the QoL-RA scale.

interaction and nervous tension, with different levels of inverse correlation in each of them.

For its part, disease activity was one factor negatively associated with the domains of interaction, mood and nervous tension. Whilst there was a positive correlation of age with the domains of joint pain, nervous tension and arthritis. Disease duration was negatively correlated with the nervous tension domain.

The model presented the highest coefficient of determination for the domains of joint pain and arthritis ($R^2 = .52$), and the lowest value was ($R^2 = .10$) for the interaction dimension (Table 2).

Table 2
Univariate analysis of factors associated with quality of life in patients RA.

| Variable | Means | Mean difference (95% CI) | P |
|------------------------------|-------|---------------------------------|------|
| Sex | | .21 (-.36 to .80) | NS |
| Male | 7.02 | | |
| Female | 6.8 | | |
| Socio-economic stratum | | .23 (-.23 to .69) ^a | NS |
| Upper | 6.36 | | |
| Upper middle | 7.10 | | |
| Middle | 6.63 | | |
| Lower middle | 7.03 | | |
| Lower | 3.87 | | |
| Civil status | | -.24 (-.7 to .23) ^b | NS |
| Single | 7.03 | | |
| Married | 6.98 | | |
| Divorced | 6.43 | | |
| Living with a partner | 6.38 | | |
| Widowed | 6.56 | | |
| Presence of comorbidities | | -.05 (-.52 to .40) | NS |
| Yes | 6.80 | | |
| No | 6.86 | | |
| Disease activity | | 1.5 (1.09 to 1.91) ^c | <.01 |
| Remission | 7.76 | | |
| Low activity | 6.72 | | |
| Moderate activity | 5.47 | | |
| Severe activity | 4.53 | | |
| Rheumatoid factor positivity | | .21 (-.37 to .79) | NS |
| Yes | 6.88 | | |
| No | 6.67 | | |
| ACPA positivity | | .37 (-.30 to 1.04) | NS |
| Yes | 7.19 | | |
| No | 6.82 | | |
| Use of biologics | | .22 (-.51 to .95) | NS |
| Yes | 7.04 | | |
| No | 6.81 | | |

ACPA: anti-citrullinated protein antibodies; NS: not significant.

^a Mean difference when the socio-economic stratum is dichotomized in upper (upper, upper middle) versus middle and low (middle, lower middle and low).

^b Mean difference when the civil status in no partner (single, widowed and divorced) is dichotomized versus with a partner (married and living with a partner).

^c Mean difference when the disease activity in remission is dichotomized versus no remission.

Table 3
Multiple linear regression models for the factors associated with quality of life and each of its domains.

| | Associated factors | β | R ² |
|-------------------------------------|---------------------------------|------------------|----------------|
| Overall quality of life | Age | .207** | .60 |
| | MHAQ | -.461* | |
| | Duration of the disease | -.154* | |
| | Disease activity | -.282* | |
| QoL-RA domains | | | |
| | | | |
| Physical ability | MHAQ | -.626* | .39 |
| | Joint pain | Age | .230* |
| Interaction with family and friends | MHAQ | -.692* | |
| | Support from family and friends | Disease activity | .332 |
| Mood | MHAQ | -.694* | .48 |
| | Nervous tension | Disease activity | -.361* |
| Arthritis | Age | -.309* | |
| | Duration of the disease | .265** | .21 |
| | Disease activity | -.204* | |
| Health | Age | -.314* | |
| | MHAQ | .148** | .52 |
| | Disease activity | -.392* | |
| | MHAQ | -.365* | |
| | MHAQ | -.477* | .22 |

* $P < .01$.

** $P < .05$.

Discussion

The results obtained in this study indicate that, in general, quality of life for the patients who participated was from moderate to good, with a total mean score of 6.8 points. Despite the fact that in the literature a cut-off point has not been established within the scale to define good quality of life, the mean score found is similar to that reported in previous studies in the Latin population, that are ranged between 5.28 and 7.38 points.^{10,14–19}

The highest mean scores were obtained in the interaction (8.04 ± 1.9) and support (8.01 ± 2) domains, results which coincide with that reported in other studies conducted in the Spanish-speaking population with the same tool in Colombian,^{16–19} Cuban,¹⁴ and Latin patients resident in California¹⁰ and a sample of Spanish patients.¹⁵

In all of these studies the highest scoring domains are precisely those relating to support and social life. However, the mean scores of the overall QoL-RA and by domains are variable between the different studies: they are higher in the Colombian^{16–19} and Cuban¹⁴ populations and lower in the Spanish population and Latin residences in California.¹⁰ These data suggest that perception of quality of life of patients with RA is influenced by ethnic, social and cultural factors.

In addition to this, in this study MHAQ (higher scores) were identified for disease duration (higher years of disease) and disease activity (not obtaining remission) and associated with poorer quality of life scores. Age, for its part, was a factor positively associated with joint pain, nervous tension and arthritis domains: the higher the age the better the quality of life. No associations were found with gender, civil status, socio-economic stratum, presence of comorbidities, rheumatoid factor positivity, anti-citrullinated protein antibodies positivity and use of biologics.

With regard to physical functionality, our results match those reported by several authors, who found there was a correlation of the MHAQ with quality of life in patients with arthritis measured with several tools.^{2,13,19} With regard to age and disease duration, a systematic review which assessed the impact of RA on the HRQOL measured by the SF-36 tool and related factors, found that these were associated with the HRQOL in patients with RA.³ In this systematic review they also reported that the older the patient the

higher the quality of life score in the mental domain and the higher the overall score for the mental component, whilst the scores of physical function dropped.

Although it has been demonstrated that age has a negative impact on quality of life, it has been reported that in chronic clinical conditions such as chronic kidney disease²⁰ or chronic obstructive lung disease,²¹ the quality of life could be worse in younger patients. This fact could be explained by younger people's lower capacity for adaptation to the impact chronic diseases have on several aspects of life, such as personal relationships, employment, self-esteem and future plans.

It is important to note that, whilst in the present study no association was found with socio-economic stratum, other studies reported that this association was subrogated to economic satisfaction where patients who were financially dissatisfied obtained lower quality of life scores.^{2,22–24} This difference could be explained by the methodology used to define socio-economic strata and also because the patients assessed in this study belong to the public social security health system of Ecuador and were mostly classified as middle class. This is an important point since studies show that a lower level of socio-economic strata is associated with a poorer quality of life.

The key limitations of the study include the fact that the sample comprised of patients from a hospital located in the urban area of Ecuador, which could be interpreted as having major socio-economic differences and accessibility to healthcare services compared with all the other Ecuadorian patients. According to the stratification survey on socio-economic levels conducted by the Ecuadorian Institute of Statistics and Censuses, in Ecuador middle and lower middle class predominate,²⁵ whilst the cohort of patients assessed in this study were mainly from upper middle and middle social strata. Furthermore, we are aware that there are inequalities in access to healthcare services between the urban and rural population, which is reflected in the percentage of the population who are subscribed to at least one type of health insurance, and this is much higher in the urban than in the rural population.²⁶ These limitations could mean that the quality of life found in this study corresponds to a more privileged population sample with better access to healthcare services than the rest of the country. However, this study does include patients from a national benchmark hospital and they therefore represent the quality of life situation of a proportion of the population with RA resident in all provinces of Ecuador.

The study design is cross-sectional which prevents us from assessing the changes in quality of life as the disease progresses, and the factors impacting this change. Another limitation is the tool used to assess the HRQOL: although the QoL-RA has limited proof of validity of content and hypothesis according to a systematic review,²⁷ we decided to use it because it is an instrument which has been validated into Spanish in the Latin American population and this means that results are comparable with previous studies. Another aspect to consider in the interpretation of results of this study is that the comorbidities and extra-articular symptoms were collected from the medical histories when they were being described, and they may have been under represented.

In daily practice, RA patient management has been focused on improving clinical variables and for a long time assessment of disease activity was considered a more reliable tool than the perception of the patient on pain and their overall health status.¹ Growing emphasis on the patient's outlook on health when considering treatment options has resulted in the patient's assessment of health generally and their quality of life has become an essential part of daily practice and also a major trigger in clinical trials and observational studies.²⁸ This type of RA patient management in Ecuador should be heightened and this study, as the first of its

kind on quality of life and RA in Equator, provides a baseline for future research.

To conclude, the patients assessed had a good to moderate HRQOL. The domains related to support and social life were those which scored the highest, and the lowest were those related to pain and nervous tension. Physical functionality, duration and disease activity were statistically associated with the HRQOL.

Ethical disclosures

Protection of human and animal subjects. The authors declare that for this research no experiments have been carried out on humans or animals.

Confidentiality of data. The authors declare that they have adhered to the protocols of their centre of work on the publication of patient data.

Right to privacy and informed consent. The authors declare that no patient data appears in this article.

Conflict of interests

The authors have no conflict of interests to declare.

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