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The impact of Sjögren's disease on health related quality of life and its relationship with socioeconomic variables in Argentina

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Abstract

Objectives

To describe Health-related quality of life (HRQol) in adult patients with Sjögren disease (SD) and analyze its association with clinical manifestations, and socioeconomic condition.

Methods

Patients with diagnosis of SD fulfilling classification criteria 2002/2016 were included in a multicentric, cross-sectional study. For assessment of HRQoL, SF-36 questionnaire was used; eight multiple linear regression models were performed.

Results

252 patients were included, 98,38% were female, mean age of 52,64 years (± 14,84). The mean SF-36 domains values were: general health 48,84 (± 22,24), physical role functioning 43,06 (± 42,71), body pain 52,87 (± 25,92), physical functioning 64,34 (± 26,81), vitality 45,93 (± 20,83), social functioning 62,10 (± 27,36), emotional role functioning 51,72 (± 43,24) and mental health 57,10 (± 21,19). The most frequent variables associated independently with all SF-36 domains were: fatigue, xerostomy, depression and anxiety. Statistically significant differences between public and private centers were observed in the following domains: physical role functioning [34,93 (± 41,86) vs 54,41(± 41,39)], body pain [48,96 (± 26,91) vs 58,73 (± 23,15)] and emotional role functioning [46,81 (± 44,14) vs 59,48 (± 41,33)]. Statistically significant differences among patients with lower and those with full or higher secondary education level, in physical role functioning [36,65 (± 41,25) vs 47,29 (± 43,18)] and body pain [47,71 (± 42,39) vs 56,45 (± 52,33)] were found.

Conclusion

We found a negative impact of SD in HRQoL, being xerostomy and fatigue the most frequent manifestations associated to the different domains of the SF-36.

INTRODUCTION

Sjögren disease (SD) is a chronic systemic autoimmune disorder, which is associated with lymphocytic infiltration of exocrine glands and epithelium, a feature that is considered the histological hallmark of the disease. [1]

It is more common in women, with an approximate female/male ratio of 9–10: 1, between 40–60 years of age. [2]

The main clinical manifestations of exocrine glandular involvement includes xerophthalmia, xerostomia, xeroderma, xerovagina and xerotrachea.[3]

Although glandular involvement can be associated with local complications, its main importance lies in the impact that causes at psychosocial level and quality of life of patients.[3]

Classically, it has been described that approximately 30% of patients will develop extraglandular involvement. However, more recent studies, with patients followed for periods up to 75 months, report that 92% of individuals develop systemic activity.[4,5]

Health-related quality of life (HRQoL) is a dynamic and multidimensional concept, which includes physical and psychological health, level of independence, social ties, its relationship with the most outstanding elements of the environment, as well as its relationship with disease, damage and treatment. This dynamic concept is the result of experiences, present circumstances, and future expectations. [6,7]

An international publication reported a relationship between SD and significant deterioration in HRQoL, related to glandular and extraglandular manifestations, comparable with data reported from rheumatic diseases considered more severe, such as rheumatoid arthritis (RA), among others.[8]

In developing countries with poor health care systems, it is expected that HRQoL could be worse in patients suffering SD. There are scarce data from Latin America and no study carried out in different centers from Argentina assessing the HRQoL in SD, so we performed a study to evaluate the HRQoL in patients with SD and to analyze it association with clinical manifestations and with socioeconomic condition. Our hypothesis is that patients with SD will have deleterious HRQoL with even poorer results in those patients with extraglandular involvement and lower socioeconomic condition.

MATERIALS AND METHODS

A multicenter, and cross-sectional study was conducted. Patients with SD fulfilling the American -European 2002 [9] / ACR-EULAR 2016 [10] classification criteria (American College of Rheumatology - European League Against Rheumatism), older than 18 years, that agreed to participate and signed an informed consent form treated in 11 rheumatology public or private centers from Argentina, were included during three consecutive years. Patients with diagnosis of another associated autoimmune rheumatic disease, uncontrolled chronic diseases (heart, kidney and liver failure, liver cirrhosis, chronic lung disease,

neuropsychiatric or dermatological chronic diseases, peripheral vascular disease, neoplasms except lymphoma associated with SD, and uncontrolled hypothyroidism or diabetes, as well as transplant patients) were excluded.

Dependent variable:

HRQoL: was measured by self-administered questionnaire SF-36, in its validated Spanish version for Argentina, at a site visit.[11] It evaluates the quality of life in the last four weeks, and includes eight domains with different items: Physical Functioning (10 items), Physical Role (4 items), Bodily Pain (2 items), General Health (5 items), Vitality (4 items), Social Functioning (2 items), Role Emotional (3 items), Mental Health (5 items). The questionnaire is scored from 0 to 100. It is considered that the higher the score, the better the state of health.

Independent variables:

Sociodemographic variables

sex, age at the time of evaluation in years, educational level (complete secondary school or higher vs incomplete secondary school or lower; in Argentina complete secondary school corresponds to twelve years of education) and type of medical care (public vs private). In Argentina the site of medical care can give an approximation of the socioeconomic condition, as well as educational level.

Variables specifically related to the disease:

1. Disease duration at inclusion in the study, measured in years.
2. Xerophthalmia, xerostomia, xeroderma, xerovagina, fatigue. These were measured through patient's visual analogue scales (VAS), from 0 to 100 mm, considering last week as the time frame.
3. Systemic clinical manifestations that were present in the previous 4 weeks: parotid swelling, inflammatory arthralgia (as defined by EULAR Sjögren’s syndrome disease activity index (ESSDAI))[12], arthritis, myalgia, Raynaud 's phenomenon, polyneuropathy, cutaneous vasculitis, lung involvement, lymphoma, renal involvement, anemia of chronic disorders, and neutropenia, once other causes have been ruled out. The last 4 weeks were considered, since it is the time period evaluated by the SF-36.
4. Treatment: artificial tears and/or ocular gel, treatment with saliva substitutes, secretagogues, hydroxychloroquine, immunosuppressants, and biological agents.

Comorbidities- possible confounders:

The presence of the following possible confounders were considered: depression (measured by the Patient Health Questionnaire 9: PHQ-9, in its Spanish version validated for Argentina) [13–15)], anxiety (measured by the self-administered questionnaire Generalized anxiety Disorder 7: GAD-7 in its Spanish version validated for Argentina)[15], osteoarthritis, fibromyalgia; smoking, alcoholism and arterial hypertension (assessed by the WHO STEPS questionnaire, Spanish version for Argentina)[16], and level of physical activity (through the International Physical activities Questionnaire: IPAQ in its Spanish version validated for Argentina)[17,18].

SAMPLE SIZE CALCULATION:

Sample size was based on the desired confidence interval for the estimation of the mean of the population under study, considering each domain of the SF-36. Half-width of the interval of 5 points, and the results of standard deviations for each domain, reported in HRQoL studies in SD, were considered. For sample size calculation, it was considered the larger standard deviation reported in previous studies on SD (Physical Role: SD ± 42.9), this implied the larger number of patients to include: 280 patients.[19]

STATISTIC ANALYSIS:

Continuous variables were reported as mean and standard deviation or median and interquartile range, depending on their distribution and sample size. Categorical variables were reported in percentages. Initially, bivariate analysis was performed between each independent variable and the dependent variable (each domain of the SF-36). An explanatory model of multiple linear regression was built with each domain of the SF-36, taken as dependent variable. The variables that in the bivariate analysis showed a $p <= 0.20$ were progressively entered in the multivariable model. The final models included only the variables that were significantly and independently associated with the dependent variable and those that produced a confounding effect. The presence of differences in the HRQoL subscales was evaluated according to educational level and care site. In the cases in which significant differences were found, a multivariable linear regression model was generated for each case. The analysis was performed with STATA 12.

ETHICAL ASPECTS

The project was approved by the Research Ethics Committees (CEI) of the participating centers. This research complies with all relevant legislation and regulations that the CEIs adhere to, which were in force at the time of the execution of this research, in accordance with the Declaration of Helsinki. Informed consent was obtained from the participating

patients. The confidentiality of personal information was respected, ensuring that the information obtained was not used to the detriment of the study subjects.

RESULTS

Sociodemographic variables

The total of 252 patients from 11 centers were included. Five centers were public and six were private. Regarding the sociodemographic characteristics of the population (Table 1), 98.38% of the patients were female, with a mean age of 52.64 years (± 14.84), the mean duration of the disease was 7.33 years (± 7.54) and 56.72% had completed secondary or higher educational level.

The mean's VAS of fatigue, xerophthalmia and xerostomia were: 48.9 (± 33.3), 56.9 (± 30. 56), 56.7 (± 35), respectively; while the presence of arthralgias in the month prior to the evaluation was the most frequent systemic manifestation (Fig. 1). Regarding treatment, 87.14% used artificial tears, 48.96% ocular gel, 22.68% saliva substitutes, 18.49% pilocarpine, 62.76% immunomodulatory treatment with hydroxychloroquine and 17.23% treatment with immunosuppressive drugs/biologic agents.

Comorbidities-possible confounders

The frequency of depression according to the different categories was: absent: 33%; mild: 25%, moderate: 20%, moderately severe: 15% and severe: 7%.

The frequency of anxiety according to the different categories was: absent: 36%, mild: 29%, moderate: 20%, severe: 15%. The rest of comorbidities variables are described in Table 2.

Health-related quality of life

A pronounced deterioration was observed in all the domains of the SF-36, with the Physical Role being the one with the lowest score (43.06 ± 42 .71) (Table 3).

General health

Results of bivariate analysis are shown in Suplementary table S1.

In the multivariate analysis, fatigue and anxiety (mild, moderate and severe) were significantly and independently associated with deterioration in general health scale (Table 4A).

Physical role

Results of bivariate analysis are shown in Suplementary table S2.

In the multivariate model, an independent and significant association was found with: xeroderma, fatigue, age and depression (Table 4A).

Bodily Pain

Bivariate analysis is shown in supplementary table S3.

The different work activities, taking unemployment as the reference category, and physical activity showed a positive statistically significant association with bodily pain (Table 4A).

Vitality

Bivariate analysis is shown in supplementary table S4.

In the multivariate analysis, the presence of fatigue, fibromyalgia, depression (all categories), mild and moderate anxiety, physical activity, as well as the occupations: student, administrative employee, and housewife showed an independent and significant association with impairment of this scale. (Table 4A)

Social function

Bivariate analysis is shown in supplementary table S5.

In the multivariate analysis, the presence of xerostomia, fibromyalgia, anxiety (all categories), moderate, moderately severe, severe depression, and age, showed a significant and independent association with this scale (Table 4B).

Mental health

Results of bivariate analysis are shown in supplementary table S6.

In the multivariate analysis, the variables anxiety depression and arthralgia showed an independent and significant association (Table 4B).

Physical function

Results of bivariate analysis are shown in supplementary table S7.

The following variables remained significantly, negatively and independently associated in the multivariable analysis: fatigue, moderate, moderately severe and severe depression, fibromyalgia and osteoarthritis; in contrast, severe anxiety and the following occupation categories (considering unemployment as the reference category) were independently and significantly associated with better Physical Function: professional, student, teaching profession, merchant, administrative employee, housewife (Table 4B).

Emotional Role

Results of bivariate analysis are shown in Supplementary table S8.

In the multivariate analysis, a statistically significant and independent association was found with fatigue and depression in all categories. (Table 4B)

HRQoL: CARE CENTERS

Patients attending public centers and with lower educational levels had worse scores on the Body Pain and Physical Role domain compared to those treated in private centers and with higher educational levels. Patients treated in the public centers showed worse scores in Emotional Role scale, all these differences were statistically significant (Table 5).

Bivariate and multivariate analyzes were performed to evaluate the main clinical manifestations associated with each condition.

Physical role-public centers

In the multivariate model of patients seen in public centers, the following variables presented a significant, independent, and negative association: fatigue, depression (all categories); while a positive and independent association was observed with occupations: student and teaching profession. Table 5

Physical role- private centers.

The multivariate model for private centers showed a significant and independent association with all categories of depression, with fibromyalgia, xeroderma and cutaneous vasculitis. Table 5.

Physical role-educational level less than complete secondary school

Regarding patients with a lower educational level, depression was the only variable that remained associated in the robust multivariate regression analysis. Table 5.

Physical role-educational level greater than or equal to complete secondary school

A multivariate model performed in patients with a higher educational level showed a significant and independent association with fatigue, depression, fibromyalgia and cutaneous vasculitis. Table 5.

DISCUSSION

In our study, a negative impact was observed on HRQoL assessed through the SF-36 questionnaire in patients with SD. As expected, Physical Role domain was the one most

affected. Xerostomia and fatigue were the clinical manifestations most frequently associated with a reduced HRQol. On the other hand, depression and anxiety showed a significant and independent association with a worse HRQoL. Assuming educational level and care center (public versus private) as surrogates of socioeconomic status, patients with lower educational level attending public centers presented a significantly lower HRQoL on both, Physical Role and Body Pain domains. On the other hand, patients attending public centers also scored worse on the Emotional Role domain.

Regarding general population from Argentina, Augustovski y col. observed better results than in our study, in all domains of SF-36. They included 2.638 subjects from the general population and found these HRQoL domain results: physical functioning 89.07 (± 14.40), physical rol 83.71 (± 30.37), body pain 80.57 (± 22.04), general health 71.47 (± 16.49), vitality 62.63 (± 19.77), social function 81.14 (± 22.53), emotional roles 78.90 (± 33.16), and mental health 67.34 (± 18.96).[11] While in our study, we found results markedly lower than those reported in the general population of Argentina: *physical functioning 64,34 (± 26,81), physical rol 43,06 (± 42,71), body pain 52,87 (± 25,92), general health 48,84 (± 22,24) vitality 45,93 (± 20,83), social functioning 62,10 (± 27,36), emotional role functioning 51,72 (± 43,24) and mental health 57,10 (± 21,19).*

As in our work, studies performed in other populations have also reported a decrease in HRQoL in this group of patients. [20–27]Segal et al. (2009)[20] in the US, Liu et al. (2017) in China [21], and a multicentric study by Dias et al. (2021)[22], found a decrease in all SF-36 domains in SD patients, when compared with healthy controls. Segal et al.'s publication also reported that the Physical Role was the most significantly affected, with fatigue and depression emerging as the most commonly independently associated variables, in line with our analysis findings.[20]

The systematic review published by Miyamoto et al. (2019) concluded that patients with SD have a significant decrease in HRQoL, this reduction is associated not only with symptoms such as sequelae, pain, and fatigue, but also with alterations in the autonomic response, physical function and activity levels, among others.[23]

Studies focused on symptoms of oral and ocular dryness have shown their significant impact on HRQoL; however, multivariate analysis of global studies showed that fatigue and pain could be better predictors of HRQoL. [23]

The publications reported by Lee (2016)[24] and Koh (2017)[25] in the Korean population, as well as the brief report reported by Tarn[26], evaluated HRQoL in patients with SD using the EQ5D tool, showing worse HRQol in these patients and found that EULAR Sjogren's Syndrome Patient Reported Index (ESSPRI) behaved as an independent predictor.[27]

The presence of pain, fatigue, and to a lesser extent anxiety, were significantly correlated with the decline in HRQoL, in agreement with our findings.[24–26]

Pain and fatigue have shown to negatively impact quality of life of these individuals, regardless of disease activity, age, educational level, marital status, work disability, and fibromhyalgia.[22]

The strengths of our study include its multicenter design and the inclusion of a substantial number of patients representative of the local population, recruited from both public and private healthcare centers. Additionally, all participants completed a validated self-reported questionnaire, which provided additional insights into patient perspectives. However, our study has some limitations. We did not have a control group; nevertheless, there is published data on general population in Argentina that can give a good idea to compare with. Another limitation of this study is the potential for selection bias, as it was conducted in Rheumatology reference centers, and may have included mostly well-managed patients with a higher level of disease awareness. Also, disease activity was not assessed using ESDDAI and ESSPRI as they were not widely validated and adapted for Argentina at the time the protocol was designed.[28, 29] Finally, given the complexity and economic instability of Argentina and the lengthy time required to enroll patients, income level or other proxies for socioeconomic condition were not adequate at the time of the analysis, so we considered site of care and educational level as an approximation. We estimate that the lower scores on the Physical Role and Bodily Pain domains observed in patients treated in the public centers with a lower educational level, as well as on the Emotional Role scale, could reflect the negative impact of a worse socioeconomic condition on the disease.

CONCLUSION

We found a decrease in the score of all the SF-36 questionnaire domains. The most frequent manifestations of disease associated independently to the different domains of the SF-36 questionnaire were fatigue and xerostomy. Subjects with lower educational level and treated in public centers presented significant lower scores in physical role functioning and body pain scales.

We anticipate that the findings of our study will contribute significantly to the existing body of knowledge regarding the adverse effects of SD on HRQoL. This contribution aims to enhance the understanding of the disease and its multifaceted nature.

Declarations

Funding Declaration

The study had no funding.

Author Contribution

All authors have made substantial contributions to the conception, interpretation of data; substantively revised the work, have approved the submitted version, and have agreed both to be personally accountable for the author's own contributions and to ensure that questions related to the accuracy or integrity of any part of the work, even ones in which the author was not personally involved, are appropriately investigated, resolved, and the resolution documented in the literature.

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Data Availability

All the data generated is available if neccesary

References

1. Baldini C, Talarico R, Tzioufas AG, Bombardieri S. Classification criteria for Sjogren's syndrome: a critical review. J Autoimmun. 2012;39(1–2):9–14. 10.1016/j.jaut.2011.12.006. Epub 2011 Dec 30. PMID: 22209352.
2. Qin B, Wang J, Yang Z, Yang M, Ma N, Huang F, Zhong R. Epidemiology of primary Sjögren's syndrome: a systematic review and meta-analysis. Ann Rheum Dis. 2015;74(11):1983–9. 10.1136/annrheumdis-2014-205375. Epub 2014 Jun 17. PMID: 24938285.
3. Kassan SS, Moutsopoulos HM. Clinical manifestations and early diagnosis of Sjögren syndrome. Arch Intern Med. 2004;164(12):1275-84. 10.1001/archinte.164.12.1275. PMID: 15226160.
4. Brito-Zerón P, Ramos-Casals M. Evolución y pronóstico del paciente con síndrome de Sjögren primario [Prognosis of patients with primary Sjögren's syndrome]. Med Clin (Barc). 2008;130(3):109–15. Spanish. Doi: 10.1157/13115353. PMID: 18261383.
5. Ramos-Casals M, Brito-Zeron P, Solans R, et al. Systemic involvement in primary Sjogren's syndrome evaluated by the EULAR-SS disease activity index: analysis of 921 Spanish patients (GEAS-SS Registry). Rheumatology. 2013;53(2):321–31.

6. Lin X-J, Lin IM, Fan S-Y. Methodological issues in measuring health-related quality of life. Tzu Chi Med J. 2013;25(1):8–12.
7. Measuring Healthy Days. Population Assessment of Health-Related Quality of Life. Centers for Disease Control and Prevention. National Center for Chronic Disease Prevention and Health Promotion. Division of Adult and Community Health. 2000: https://www.cdc.gov/hrqol/pdfs/mhd.pdf
8. Strömbeck B, Ekdahl C, Manthorpe R, Wikström I, Jacobsson L. Health-related quality of life in primary Sjögren's syndrome, rheumatoid arthritis and fibromyalgia compared to normal population data using SF-36. Scand J Rheumatol. 2000;29(1):20 – 8. 10.1080/030097400750001761. PMID: 10722254.
9. Vitali C, Bombardieri S, Jonsson R, et al. Classification criteria for Sjögren's syndrome: a revised version of the European criteria proposed by the American-European Consensus Group. Ann Rheum Dis. 2002;61:554.
10. Shiboski CH, Shiboski SC, Seror R, et al. 2016 American College of Rheumatology/ European League Against Rheumatism Classification Criteria for Primary Sjögren's Syndrome: A consensus and data-driven methodology involving three international patient cohorts. Arthritis Rheumatol. 2017;69:35–45.
11. Augustovski FA, Lewin G, Elorrio EG, Rubinstein A. The Argentine-Spanish SF-36 Health Survey was successfully validated for local outcome research. J Clin Epidemiol Dec. 2008;61(12):1279–84.
12. Seror R, Bowman S, Brito-Zeron P, et al. EULAR Sjögren's syndrome disease activity index (ESSDAI): a user guide. RMD Open. 2015;1:e000022.
13. Bonicatto S, Gargoloff P, Tutor C, et al. Diagnóstico de alteraciones mentales en atención primaria. Adaptación de un procedimiento de tamizaje. Acta Psiquiátr Psicol Am Lat. 1999;45:223–34.
14. Kroenke K, Spitzer R, Williams JB. The PHQ9. Validity of a brief depression se verity measure. J Gen Intern Med. 2001;16:606–13.
15. GAD 7. PHQ 9. Http://www.phqscreeners.com/
16. Manual de Vigilancia STEPS de la OMS. Www.who.int/chp/steps/manual/es/index3. Html.
17. de Cuestionario. Actividad Física. IPAQ. Argentina. 2002.
18. Guidelines for Data Processing and Analysis of the International. Physical Activity Questionnaire (IPAQ). Short and Long Forms. 2005.
19. Meijer JM, Meiners PM, Huddleston Slater JJ, et al. Health-related quality of life, employment and disability in patients with Sjogren's syndrome. Rheumatol Sep. 2009;48(9):1077–82.
20. Segal B, Bowman SJ, Fox PC, Vivino FB, Murukutla N, Brodscholl J, Ogale S, mclean L. Primary Sjögren's Syndrome: health experiences and predictors of health quality

among patients in the United States. Health Qual Life Outcomes. 2009;7:46. 10.1186/1477-7525-7-46. PMID: 19473510; PMCID: PMC2693523.

21. Liu Z, Dong Z, Liang X, Liu J, Xuan L, Wang J, Zhang G, Hao W. Health-related quality of life and psychological status of women with primary Sjögren's syndrome: A cross-sectional study of 304 Chinese patients. Med (Baltim). 2017;96(50):e9208. 10.1097/MD.0000000000009208. PMID: 29390343; PMCID: PMC5815755.
22. Dias LH, Miyamoto ST, Giovelli RA, de Magalhães CIM, Valim V. Pain and fatigue are predictors of quality of life in primary Sjögren's syndrome. Adv Rheumatol. 2021;61(1):28. 10.1186/s42358-021-00181-9. PMID: 34051867.
23. Miyamoto S, Valim V, Fisher B. Health-related Quality of Life and costs in Sjögren's' syndrome. Rheumatology (United Kingdom). 2019 Feb 15. 10.1093/rheumatology/key370
24. Lee J, Koh JH, Kwok SK, Park SH. The EULAR Sjögren's Syndrome Patient-Reported Index is an independent determinant of health-related utility values of Korean patients with primary Sjögren's syndrome. Clin Exp Rheumatol. 2016;34:6637.
25. Koh JH, Kwok SK, Lee J, et al. Pain, xerostomia, and younger age are major determinants of fatigue in Korean patients with primary Sjo¨ gren's syndrome: a cohort study. Scand J Rheumatol. 2017;46:4955.
26. Tarn J, Lendrem D, mcmeekin P, Lendrem C, Hargreaves B, Ng WF. Primary Sjögren's syndrome: Longitudinal real-world, observational data on health-related quality of life. J Intern Med. 2022;291(6):849–55. 10.1111/joim.13451. Epub 2022 Jan 24. PMID: 35018685; PMCID: PMC9305875.
27. Berg J, Lindgren P, Mejhert M, Edner M, Dahlstrom U, Kahan T. Determinants of Utility Based on the euroqol Five-Dimensional Questionnaire in Patients with Chronic Heart Failure and Their Change Over Time: Results from the Swedish Heart Failure Registry. Value Health. 2015;18:439–48.
28. Seror R, Ravaud P, Bowman SJ, et al. EULAR Sjögren's syndrome disease activity index: development of a consensus systemic disease activity index for primary Sjögren's syndrome. Ann Rheum Dis. 2010;69:1103–9.
29. Seror R, Ravaud P, Mariette X, et al. EULAR Sjögren's Syndrome Patient Reported Index (ESSPRI): development of a consensus patient index for primary Sjögren's syndrome. Ann Rheum Dis. 2011;70:968–72.

Tables

Table 1
Socio-demographic characteristics and comorbidities.

SOCIO-DEMOGRAFIC CHARACTERISTICS	n patients: 252
Age in years (mean ± SD)	52.6 ± 14.8
Gender (% female)	98.4
Time of evolution of the disease in years (mean ± SD)	7.3 ± 7.5
Site of care (%)	
Public	57.1
Private	42.9
SCHOLARSHIP (%)	
Incomplete primary	11.3
Complete primary	15.6
Incomplete secondary	16.4
Complete secondary	21.4
Incomplete tertiary	5.9
Full tertiary	9.7
Incomplete university	5
Full university	14.7
OCCUPATION (%)	
Unemployed	5.5
Professional	13.1
Student	1.3
Teacher	6.4
Merchant	5.5
Administrative employee	9.7
Housewife	39.8
Craft	9.3
Others / retirees	9.3

Table 2
Comorbidities/possible confounders

COMORBIDITIES/POSSIBLE CONFOUNDERS	n patients: 252
Osteoarthritis (%)	36.29
Fibromyalgia (%)	21.43
Depression (*PHQ9 categories*)	Absent: 33% Mild: 25% Moderate: 20% Moderately severe: 15% Severe: 7%
Anxiety (GAD7 categories)	Absent: 36% Mild: 29% Moderate: 20% Severe: 15%
Physical activity: IPAQ score [(METs-minutes/week. (Median, IQR)]	1113 (297–2376)
Tobacco (WHO STEPS)	
Current consumption (%)	8.4
Daily consumption (% of patients with current consumption)	76.2
Daily consumption time in years (mean ± SD)	14.4 ± 9.7
Cigarettes/day (mean ± SD)	5.1 ± 5.4
Others/day (mean ± SD)	0
Past consumption (%)	24.6
Time you stopped smoking in years (mean ± SD)	14.4 ± 10.9
Alcohol (WHO STEPS)	
Consumption in the last 12 months (%)	48.9
Daily (%)	7.1
5–6 days/week (%)	0.9
1–4 days/week (%)	18.6
1–3 days/month (%)	42.5

COMORBIDITIES/POSSIBLE CONFOUNDERS	n patients: 252
Less than once a month (%)	30.9
Average number of glasses/day when drinking alcohol (mean ± SD)	1.4 ± 1.1
Maximum number of glasses on the same occasion in the last 12 months	1.9 ± 1.4
High Blood Pressure (HBP) (WHO STEPS)	
Diagnosed last year by health professional (%)	22.8
Treatment or advice for HBP:	
Medication last 2 weeks (%)	24.4
Special diet prescribed by a doctor (%)	23
Advice or treatment to lose weight (%)	22.7
Advice or treatment to stop smoking (%) 4	4.9
Advice for exercising (%)	40.4
Visits to healers for hypertension (%)	0.4
Traditional or herbal medication for HBP (%)	4.3

SD: standard deviation, IQR: interquartile range.

Table 3
HRQOL results according to SF-36 domains.

SF-36 DOMAINS	SCORE (*mean ± SD)*	95% CI
GENERAL HEALTH	48.84 ± 22.24	46.08; 51.60
PHYSICAL ROLE	43.06 ± 42.71	37.79; 48.33
BODILY PAIN	52.87 ± 25.92	49.66; 56.08
VITALITY	45,93 ± 20,83	43.31; 48.55
SOCIAL FUNCTION	62,10 ± 27,36	58.71; 65.49
MENTAL HEALTH	57.72 ± 21.19	54.44; 59.76
PHYSICAL FUNCTION	64,34 ± 26.81	61.02; 67.66
EMOTIONAL ROLE	51.72 ± 43.24	46.38; 57.06

SD: standard deviation.

Table 4: Multivariate analysis between each domain of sf-36 and clinical manifestations and comorbidities

Table 4
A: SF-36 domains 1–4

SF-36 SCALES	β coefficient	95%CI	*p value*
GENERAL HEALTH [1]			
Xerostomia	-0.11	-0.19; -0.02	0.015
Fatigue	-0.14	-0.22; -0.06	< 0.01
Age	0.19	0.02; 0.35	0.02
Time of disease evolution in years	-0.37	-0.70; -0.04	0.03
Anxiety	-18.27	-24.26; -12.28	< 0.01
Mild	-18.90	-25.78; -12.01	< 0.01
Moderate	-26.96	-34.48; -19.43	< 0.01
Severe			
PHYSICAL ROLE [2]			
Xeroderma	-0.21	-0.39; -0.02	0.03
Fatigue	-0.22	-0.41; -0.04	0.02
Age	-0.43	-0.75; -0.12	< 0.01
Depression			
Mild	-21.90	-34.95; -8.85	< 0.01
Moderate	-30.99	-45.07; -16.90	< 0.01
Moderately Severe	-38.30	-54.57; -22.02	< 0.01
Severe	-48.70	-69.81; -27.58	< 0.01
BODILY PAIN[3]			
Xerostomia	-0.14	-0.23; -0.56	< 0.01
Arthralgia	-5.86	-11.09; -0.63	0.03
Artificial tears use	7.82	0.33; 15.31	0.04
Depression			
Mild	-11.18	-18.01; -4.35	< 0.01
Moderate	-24.59	-32.32; -16.85	< 0.01
Moderately severe	-31.22	-39.82; -22.63	< 0.01
Severe	-26.28	-38.11; -14.45	< 0.01

SF-36 SCALES	β coefficient	95%CI	*p value*
Fibromyalgia	-11.32	-18.18; -4.46	< 0.01
Gender	21.40	2.52; 40.30	0.03
Occupation			
Professional	16.26	3.16; 29.37	0.02
Student	37.81	12.40; 63.22	< 0.01
Teacher	17.67	3.13; 32.20	0.02
Merchant	4.11	-11.93; 20.15	0.61
Administrative employee	16.32	2.94; 29.70	0.02
Housewife	11.88	0.18; 23.59	0.05
Craft	11.28	-2.63; 25.19	0.11
Others / retirees	11.26	-2.35; 24.86	0.10
VITALITY[4]			
Fatigue	-0.19	-0.26; -0.12	< 0.01
Fibromyalgia	-5.27	-10.43; -0.10	0.046
Depression			
Mild	-10.71	-16.42; -5.01	< 0.01
Moderate	-18.03	-25.29; -10.77	< 0.01
Moderately severe	-20.92	-29.44; -12.41	< 0.01
Severe	-24.15	-34.95; -13.35	< 0.01
Anxiety	-5.48	-10.83; -0.13	0.045
Mild	-6.32	-13.19; 0.55	0.07
Moderate	-6.50	-14.43; 1.43	0.11
Severe			
Physical Activity	0.0001	8.3407; 0.0001	0.047
Occupation			
Professional	3.32	-6.68; 13.32	0.51
Student	24.58	6.53; 42.63	< 0.01
Teacher	2.07	-8.91; 13.06	0.71
Merchant	1.14	-10.54; 12.81	0.85

SF-36 SCALES	β coefficient	95%CI	*p value*
Administrative employee	11.40	1.14; 21.65	0.03
Housewife	10.70	1.73; 19.67	0.02
Craft	8.32	-2.32; 18.96	0.12
Others / retirees	5.80	-4.45; 16.05	0.27
Table 4B: SF-36 domains 5–8			
SF-36 SCALES	β coefficient	95%CI	p value
SOCIAL FUNCTION [5]			
Xerostomia	-0,09	-0,17; -0,01	0,02
Fibromyalgia	-7,56	-13,78; -1,33	0,02
Anxiety	-10,29	-16,98; -3,60	< 0,01
Mild	-8,56	-17,15; 0,02	0,051
Moderate	-19,20	-29,17; -9,22	< 0,01
Severe			
Depression			
Mild	-3,31	-10,44; 3,82	0,36
Moderate	-21,01	-29,24; -12,79	< 0,01
Moderately severe	-33,05	-43,44; -22,67	< 0,01
Severe	-39,75	-52,32; -27,18	< 0,01
Age	-0,24	-0,40; -0,09	< 0,01
MENTAL HEALTH[6]			
Anxiety			
Mild	-9.16	-14.58; -3.74	< 0.01
Moderate	-14.34	-21.49; -7.18	< 0.01
Severe	-21.72	-30.15; -13.28	< 0.01
Depression			
Mild	-7.59	-13.18; -1.99	< 0.01
Moderate	-16.20	-22.78; -9.63	< 0.01
Moderately severe	-18.71	-27.21; -10.21	< 0.01

SF-36 SCALES	β coefficient	95%CI	*p value*
Severe	-27.65	-37.49; -17.82	< 0.01
Arthralgia	-4.36	-8.42; -0.31	0.04
PHYSICAL FUNCTION [7]			
Fatigue	-0.13	-0.23; -0.03	0.01
Anxiety			
Mild	-6.48	-13.69; 0.73	0.08
Moderate	7.21	-2.76; 17.17	0.16
Severe	12.02	1.12; 22.91	0.03
Depression			
Mild	-6.89	-14.59; 0.80	0.08
Moderate	-21.38	-32.61; -10.15	< 0.01
Moderately severe	-28.64	-41.22; -16.06	< 0.01
Severe	-33.69	-51.30; -16.08	< 0.01
Fibromyalgia	-9.53	-18.64; -0.43	0.04
Osteoarthritis	-9.00	-15.19; -2.81	< 0.01
Occupation			
Professional	19.10	6.20; 32.01	< 0.01
Student	41.74	27.72; 55.76	< 0.01
Teacher	20.13	5.33 ; 34.92	< 0.01
Merchant	23.66	7.13; 40.18	< 0.01
Administrative employee	16.54	1.70; 31.37	0.03
Housewife	18.15	5.41; 30.89	<0.01
Craft	11.21	-6.10; 28.53	0.20
Others / retirees	5.29	-10.13; 20.71	0.50
EMOTIONAL ROLE [8]			
Fatigue	-0.005	-0.01; -0.00048	0.03
Depression			
Mild	-0.95	-1.31; -0.58	< 0.01
Moderate	-1.23	-1.63; -0.82	< 0.01

SF-36 SCALES	β coefficient	95%CI	*p value*
Moderately severe	-1.70	-2.15; -1.25	< 0.01
Severe	-2.21	-2.79; -1.62	< 0.01

Table 5
HRQOL according with site of care and educational level as surrogates of socioeconomic condition.

	MEAN	MEAN DIFFERENCE	95% CI OF DIFFERENCE OF MEANS	*p value*
HRQOL: SITE OF CARE				
PHYSICAL ROLE				
PUBLIC	34.93	-19.49	-30.24; -8.73	< 0.01
PRIVATE	54.41			
BODILY PAIN				
PUBLIC	48.96	-9.77	-16.36; -3.19	< 0.01
PRIVATE	58.73			
EMOTIONAL ROLE	46.81			
PUBLIC	59.48	-12.63	-23.75; -1.58	0.03
PRIVATE				
HRQOL : EDUCATIONAL LEVEL.				
PHYSICAL ROLE				
Incomplete secondary or lower.	36,65	-10,94	-21,86; -0,026	0,0495
Complete secondary or higher.	47,29			
BODILY PAIN				
Incomplete secondary or lower.	47,71	-8,74	-15,33; -2,15	< 0,01
Complete secondary or higher.	56,45			

Table 6
HRQOL and socioeconomic conditions, and its relationship with clinical manifestations and comorbidities

SF-36 and socioeconomic condition	β coefficient	95% CI
Physical Rol-Public centers (n: 121)		
Fatigue	-0.37	-0.59; -0.14*
Depression (PHQ9 categories)	Mild: -35.88	-54.14; -17.61*
	Moderate: -37.98	-56.84; -19.12*
	Moderately severe:	-52.33; -12.33*
	-32.33	-73.77; -23.54*
	Severe: -48.66	
Occupations	Student: 74.65	28.49; 120.82*
	Teaching profession: 47.81	5.70; 89.92*
Physical role- private centers (n: 100)		
Depression (PHQ9 categories)	Mild: -18.49	-34.19; -2.78*
	Moderate: -30.03	-48.31 to -11.75*
	Moderately severe:	-73.25; -25.96*
	-49.60	-73.67; -3.03*
	Severe: -38.35	
Fibromyalgia	-33.25	-50.43; -16.06*
Xeroderma	-0.26	-0.49; -0.02*
Cutaneous vasculitis	-56.95	-101.45; -12.45*
Physical role-educational level less than complete secondary school (n: 96)		
Depression (PHQ9 categories)	Moderate:	-60.59; -13.8*
	-37.24	-62.75; -22.15*
	Moderately severe:	-78.82; -45.98*
	-42.45	
	Severe: -62.40	
Physical role-educational level greater than or equal to complete secondary school (n: 123)		
Fatigue	-0.26	-0.46; -0.05*

SF-36 and socioeconomic condition	β coefficient	95% CI
Depression (PHQ9 categories)	Mild: -20.94	-36.31; -5.55*
	moderate: -28.89	-46.11; -11.66*
	moderately severe: -59.15	-81.69; -36.62*
	severe: -47.24	-77.55;-16.92*
Fibromyalgia	-25, 11	-40.37; -9.85*
Cutaneous vasculitis	-54.55	-99.93; -9.18*

*All p values were ≤ 0,05

Figures

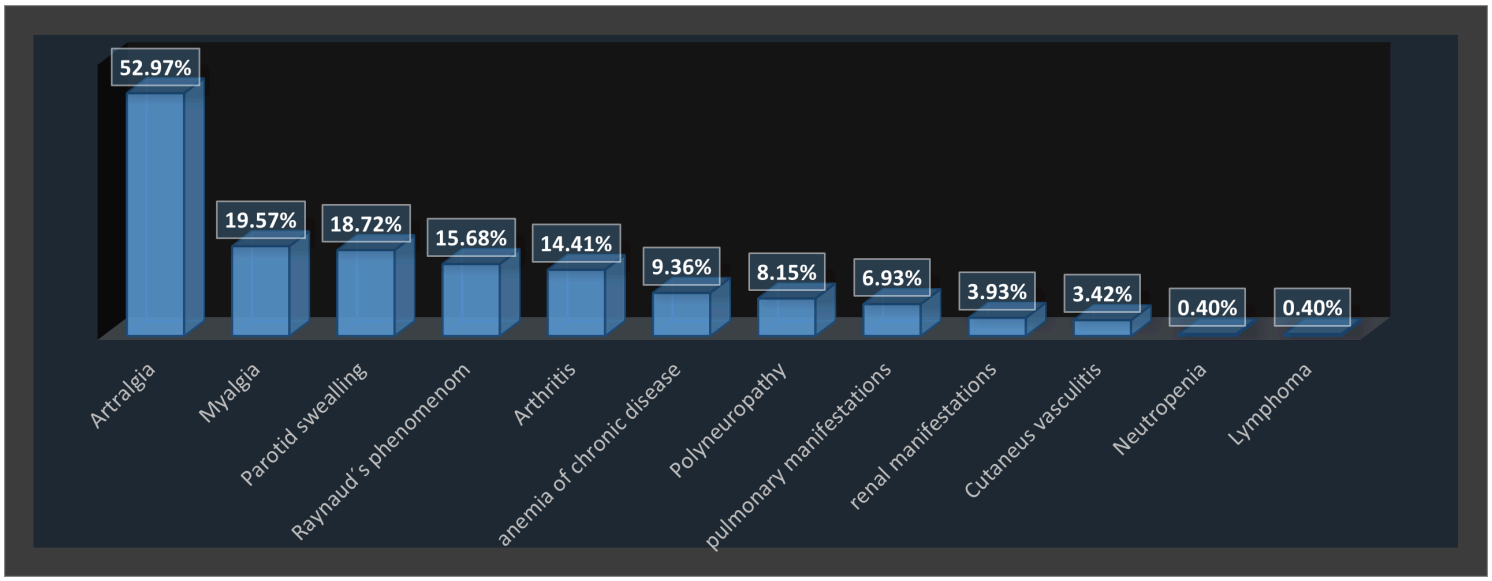


Figure 1

Frequency (%) of clinical manifestations within the previous 4 weeks.

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