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Original article

Perceived quality of life by patients with immune-mediated inflammatory diseases treated with biological therapies. SACVINFA study

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ABSTRACT

Objectives: To evaluate health-related quality of life perceived by patients with the most prevalent immune-mediated inflammatory diseases in Spain: inflammatory bowel disease (IBD), psoriasis (Ps), psoriatic arthritis (AP), rheumatoid arthritis (RA), and spondyloarthropathies (SpAs), and to determine the factors that influence patient quality of life.

Methods: The SACVINFA study (SA = satisfaction, CV = quality of life, IN = immune-mediated, FA = pharmacy) consisted of an observational study conducted in 4 hospitals in the Community of Madrid. A cross-sectional analysis was made for adult patients diagnosed with an immune-mediated inflammatory disease who attended the Pharmacy Service. Quality of life was assessed using the EQ-5D-5L questionnaire (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) and specific questionnaires: SIBDQ-9, DLQI, PsAQoL, QoL-RA, and ASQoL.

Results: A total of 578 patients were analysed (inflammatory bowel disease = 25.3%; psoriasis = 19.7%; spondyloarthropathies = 18.7%; rheumatoid arthritis = 18.5%; psoriatic arthritis = 17.8%). The mean age (standard deviation) was 49.8 (12.3) years and 50.7% were male. The average score (standard deviation) for the global EQ-5D-5L was 0.771 (0.2) and the mean (standard deviation) visual analogue scale score was 71.5 (20.0). Type of immune-mediated inflammatory diseases was associated with differences in quality of life showing psoriasis and inflammatory bowel disease higher values of EQ5D-5L than psoriatic arthritis, rheumatoid arthritis, and spondyloarthropathies, $p<.05$ in all comparisons. Patients with RA, IBD, and Ps achieved 70% of the maximum score, while patients with PsA and SpAs did not reach 50% of the maximum possible score.

Female gender, a state of moderate/severe disease severity, an older age, and a higher number of previous treatments were correlated with worse quality of life. Conversely, persistence to current treatment correlated with better quality of life.

Conclusions: Patients with immune-mediated inflammatory diseases have markedly affected quality of life, mainly in the pain/discomfort dimension, especially in those immune-mediated inflammatory diseases with a rheumatological component.

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Calidad de vida percibida por pacientes con enfermedades inflamatorias inmunomediadas tratados con terapias biológicas. Estudio SACVINFA

Palabras clave:
terapias biológicas
Enfermedades Inflamatorias Inmunes
Servicio de Farmacia
Calidad de vida
Real-World Evidence

R E S U M E N

Objetivos: Evaluar la calidad de vida de los pacientes con las enfermedades inflamatorias inmunomediadas más prevalentes en España: enfermedad inflamatoria intestinal (EII), psoriasis (Ps), artritis psoriásica (AP), artritis reumatoide (AR) y espondiloartropatías (EspA), y determinar los factores que influyen en su calidad de vida.
Métodos: El estudio SACVINFA consistió en estudio observacional realizado en 4 hospitales de Madrid. Se analizó una cohorte transversal de pacientes adultos diagnosticados de una enfermedad inflamatoria inmunomediada que acudían al Servicio de Farmacia. La calidad de vida se evaluó mediante el cuestionario EQ-5D-5L (movilidad, autocuidado, actividades habituales, dolor/malestar y ansiedad/depresión) y mediante cuestionarios específicos: SIBDQ-9, DLQI, PsAQoL, QoL-RA y ASQoL.
Resultados: Se analizaron un total de 578 pacientes (EII = 25,3%; Ps = 19,7%; EspA = 18,7%; AR = 18,5%; AP = 17,8%). La edad media (DE) fue de 49,8 (12,3) años y el 50,7% eran varones. La puntuación media (DE) para el EQ-5D-5L global fue 0,771 (0,2) y la puntuación media (DE) de la escala visual analógica fue 71,5 (20,0). El tipo de enfermedades inflamatorias inmunomediadas se asoció con diferencias en la calidad de vida mostrando psoriasis y enfermedad inflamatoria intestinal valores más altos de EQ5D-5 L que artritis psoriásica, artritis reumatoide y espondiloartropatías, $p < 0,05$ en todas las comparaciones. Los pacientes con AR, EII y Ps alcanzaron el 70% de la puntuación máxima, mientras que los pacientes con APs y EspA no llegaron al 50% de la puntuación máxima posible.

El sexo femenino, un estado de la enfermedad moderada/grave, una mayor edad y un mayor número de tratamientos previos se correlacionaron con una peor calidad de vida. Sin embargo, la persistencia al tratamiento actual se correlacionó con una mejor calidad de vida.
Conclusiones: Los pacientes con enfermedades inflamatorias inmunomediadas tienen afectada la calidad de vida, principalmente en la dimensión dolor/malestar, especialmente en aquellas enfermedades inflamatorias inmunomediadas con componente reumatológico.

Introduction

The term "immune-mediated inflammatory diseases" (IMIDs) encompasses a series of chronic, clinically heterogeneous diseases that share pathogenic mechanisms and are affected by both genetic and environmental factors.[1] The most prevalent pathologies that constitute this group are inflammatory bowel disease (IBD), psoriasis (Ps), psoriatic arthritis (PsA), rheumatoid arthritis (RA), and spondyloarthropathies (SpAs) (ankylosing spondylitis or undifferentiated). In Spain, the global prevalence of IMIDs in people aged 16 years or older is 6.4%,[2] affecting near 3 million people.[3]

The coexistence of several IMIDs in the same person is quite common, also the family aggregation of multiple IMIDs,[1] which in these cases results in a greater impact of the diseases when several members of the same family are affected.[1] In addition, people with IMID have an increased risk of developing comorbidities and complications derived from the chronic effects of inflammation, such as cardiovascular diseases, metabolic syndrome, diabetes, depression, fatty liver, or kidney diseases, complicating the management of these pathologies. Therefore, patients with IMID have high morbidity and a high degree of disability, considerably reducing their health-related quality of life (HRQoL).[1] People with IMID have an impaired ability to perform daily activities.[4] Therefore, their mood and psychological well-being can affect different social and family relationships,[5] consequently, many people are unable to work or require reduced working hours.[6] Taking into account everything said, these pathologies have a high impact on society, while individuals experience impact on their quality of life.

There are several methods to assess HRQoL. The 5-dimensional and 5-level EuroQol (EQ-5D-5L) is a generic, preference-based instrument to evaluate HRQoL of patients, that has demonstrated high validity and reliability for multiple chronic diseases.[7] In addition to the generic instruments, there are specific questionnaires that evaluate HRQoL of each IMID individually. Knowing HRQoL of chronic patients is one of the health strategies that favour the adaptation of care services to the needs of patients. Therefore, the objective of this study was to evaluate the HRQoL in patients with at least 1 of the 5 IMIDs with the highest prevalence in Spain (IBD, Ps, PsA, RA, and SpAs) and to analyse the influence of sociodemographic and clinical characteristics on the HRQoL of these patients. However, the SACVINFA study also had other objectives, such as assessing the satisfaction with the health care received by patients.[8]

Methods

Study design

The SACVINFA study (for its acronym in Spanish SA = satisfacción, CV = calidad de vida, IN = inmunomediada, FA = farmacia) was an observational, cross-sectional, and multicentre study based on real-world evidence conducted by the Pharmacy Services of 4 National Health System hospitals in the Community of Madrid.

The study was approved by the Drug Research Ethics Committee of Gregorio Marañón University Hospital and was conducted in accordance with the Declaration of Helsinki on medical research in humans.

Study population

The inclusion criteria were as follows: age at least 18 years and a diagnosis of at least one of the following pathologies: IBD (Crohn's disease and ulcerative colitis), Ps, PsA, RA, or SpAs, treatment with biological therapies, and a minimum of 3 visits to the Pharmacy Service to collect their biological therapy. The exclusion criteria were as follows: a lack of willingness or ability to comply with the procedures of the study and follow-up, current participation in a clinical trial, or an inability to understand Spanish.

Variables

Data collection were carried out between January 2020 and March 2021. The study data were collected with a data collection notebook

(DCN) and a patient diary, both in electronic format hosted by Google Forms. The researchers of each centre completed the DCN with data obtained from the clinical histories and computer records of the centre, including sociodemographic data (age and gender), clinical data (main and additional pathologies, level of severity [mild/moderate/severe] of the main pathology measured with the clinical scales used in each pathology, time since diagnosis), pharmacotherapies (current biological therapy according to the Anatomical Chemical (ATC) classification system and the route of administration), frequency of administration, duration of the current biological therapy, time since starting the first biological therapy, number of prior biological therapies, and frequency of dispensation. All these variables were collected retrospectively.

Questionnaires used

Patients completed an electronic patient diary composed of 3 questionnaires: 2 on HRQoL (the generic EuroQol-5D-5L and a specific questionnaire for each IMID of the study) and another on treatment adherence (Morisky–Green test).

The EQ-5D questionnaire, developed by the EuroQol Group (available at www.euroqol.org), is a generic and standardised instrument developed to describe and assess HRQoL.[9,10] The version used in this project was the EQ-5D-5L, which consists of 2 parts: the EQ-5D descriptive system and a visual analogue scale (VAS). The EQ-5D-5L descriptive system comprises 5 dimensions (mobility, self-care, usual activities, pain/discomfort, and anxiety/depression) with a Likert scale of 5-response levels and a score assigned from 1 to 5 (1 = no problems, 2 = mild problems, 3 = moderate problems, 4 = severe problems, and 5 = extreme or debilitating problems). The scores of the 5 dimensions are subsequently used to calculate a general utility score, which varies from 0 (worst) to 1 (best; without problems in any of the dimensions). In the VAS, patients report what they consider their health status on a scale of 0–100, with 0 being the worst health and 100 being the best.[9,11]

The specific questionnaires used for each pathology were the following: the Psoriatic Arthritis Quality of Life (PsAQoL) for PsA[12] (it consists of 20 dichotomous questions [yes = 1/no = 0]. Overall score: total sum of individual question scores, range 0–20. The greater the number of positive responses, the worse the HRQoL), the Quality of Life-Rheumatoid Arthritis (QoL-RA) for RA[13] (it is made up of 8 questions with a visual numerical scale score from 1 [very poor quality of life] to 10 [excellent]. Its total value is calculated by the average of its component values), the Ankylosing Spondylitis Quality of Life (ASQoL) for SpAs[14] (it consists of 18 dichotomous questions [yes = 1/no = 0]. The overall score is the sum of the scores of each question, range 0 [the best HRQoL] to 18 [the worst HRQoL]), the Short Inflammatory Bowel Disease Questionnaire (SIBDQ-9) for IBD[15] (it consists of 9 questions with 7 possible answers: all the time [score 1] to never [score 7]. The direct score is obtained by adding the score of each item, range 9–63. This direct score is then transformed into a scale from 0 [direct score 9 = worse quality of life] to 100 [direct score 63 = better quality of life]), and the Dermatology Life Quality Index (DLQI) for Ps[16] (it is composed of 10 questions referencing the last 7 days. Answered using a Likert scale with 4 possible answers: “not at all”, “a little”, “quite a bit”, or “a lot”. The sum of the scores provides a simple aggregate value between 0 and 30, and the result can be presented as the percentage of impact of the dermatological condition on the quality of life of the patient. The higher the score is, the greater the impact on HRQoL).

The Morisky-Green adherence test consists of 4 contrast questions with a dichotomous response (yes/no), which reflect the behaviour of the patient with respect to therapeutic compliance. In addition, it is helpful in providing information on the causes of the noncompliance, with high specificity, a high positive-predictive value, and few sociocultural requirements for its understanding.[16] A patient is considered to be adherent to the treatment when he/she answers the 4 questions with no/yes/no/no.[17,18]

All these questionnaires were given to patients during the study period and collected prospectively.

Statistical analysis

The sample included all patients who met the selection criteria during the study period. To determine possible confounding variables, a subanalysis was performed for each pathology and how the sociodemographic and clinical characteristics influenced the quality of life results were analysed. Missing data were not considered for the analysis.

For the descriptive analyses, the means and standard deviation were calculated for the quantitative variables and frequencies and percentages for the qualitative variables. The minimum and maximum values were included for the specific HRQoL questionnaires for each pathology. Bivariate comparisons of the results of the EQ-5D-5L questionnaire between genders and adherence for each pathology were performed using Student's *t* test. For comparison of the EQ-5D-5L score for each pathology with different quantitative variables, the Pearson correlation coefficient was used. Comparisons of the EQ-5D-5L score between the different pathologies were assessed with ANOVA and the post hoc Games-Howell test if homoscedasticity was violated or the Scheffé test if it was not. In all comparisons, it was assumed that the criterion of normality was met due to the high sample size, and a p value equal to or less than 0.05 was applied to reject the null hypothesis. The calculations were performed with R version 4.0.5 software.

Results

A total of 596 patients were recruited from the 4 participating centres, 18 of whom were excluded (7 for not meeting the inclusion criteria, and 11 for unwillingness to complete the patient diary), for a total of 578 patients included in the final analysis (PsA = 17.8%, RA = 18.5%, SpAs = 18.7%, IBD = 25.3%, Ps = 19.7%).

The sociodemographic and clinical characteristics of the patients included in the study and the adherence reported by the patients are shown in Supplementary table 1. The mean age and standard deviation (SD) of all patients was 49.8 (12.3) years. A total of 50.7% of the participants were men. The pathology with the greatest difference between the genders was RA, in which 81.3% were women. The mean (SD) on the current biological therapy was 4.2 (3.5) years. A total of 92.0% of patients were administered their treatment subcutaneously. Tumour necrosis factor-α (TNF-α) inhibitors were administered to 60.9% of patients. A total of 42.9% of all patients had their main pathology in remission, 33.4% had mild disease, and 23.7% had moderate/severe disease. In addition, 8.3% of patients also had a second pathology, and 0.3% had 2 additional pathologies. Patients with PsA were most likely to have moderate/severe disease (34.0%) and to present with an additional pathology. In contrast, Ps patients were least likely to present with moderate/severe disease (1.8%). According to the data reported, more than 70% of all patients properly adhered to their therapy, being PsA patients the most adherent group (76.8%), and RA patients (63.1%) the least adherent group.

Fig. 1 shows the general scores of the EQ-5D-5L questionnaire. The average (SD) overall score for all patients was 0.77 (0.22). Significant differences were observed between the pathologies with the highest (mean (SD): Ps, 0.87 (0.17) and IBD, 0.81 (0.20)) and the lowest scores (mean (SD): SpAs, 0.71 (0.21), RA, 0.72 (0.25), and PsA, 0.73 (0.24)). Regarding the VAS, patients with Ps had the highest mean (SD) score, at 76.9 (17.6), and patients with RA had the lowest mean (SD) score, at 67.5 (22.5). The difference between these groups was statistically significant ($p = .024$).

In assessing the relationship of the baseline sociodemographic and clinical characteristics with the average general utility scores of the EQ-5D-5L of all patients, it was observed that gender, disease severity,

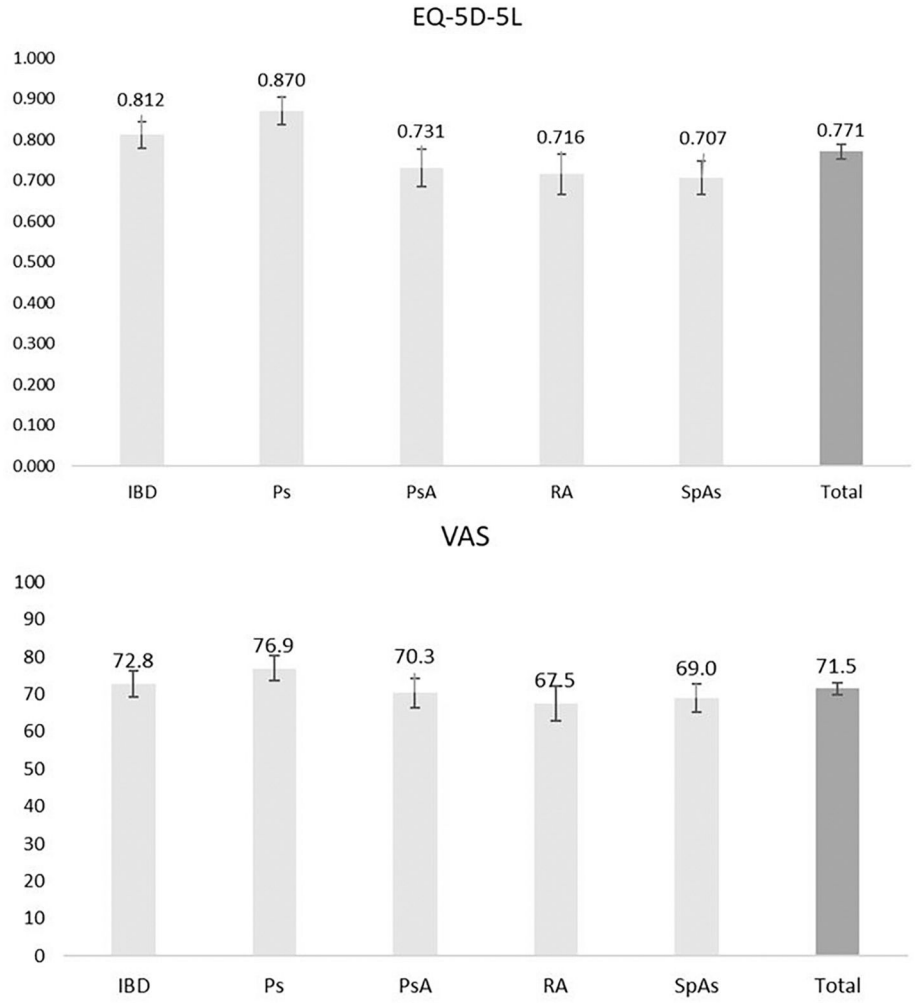

Fig. 1. Mean EQ-5D-5L and VAS scores. IBD: inflammatory bowel disease; Ps: psoriasis; PsA: psoriatic arthritis; RA: rheumatoid arthritis SpAs: ankylosing spondylitis; VAS: visual analogue scale. EQ-5D-5L: Statistically significant differences were observed in the patient scores for the following pairwise comparisons: IBD vs. PsA ($p = .040$); IBD vs. RA ($p = .011$); IBD vs. SpAs ($p = .001$); Ps vs. PsA ($p < .001$); Ps vs. RA ($p < .001$); Ps vs. SpAs ($p < .001$). VAS: Significant differences were observed in the scores of patients with Ps vs. RA ($p = .024$).

patient age, number of previous treatments, and duration of the current biological therapy were associated with statistically significant differences in the HRQoL of the patients (Supplementary table 2). Female patients reported a lower score on the EQ-5D-5L than the male participants, and the difference was statistically significant for all pathologies (women: 0.74; men 0.80; $p = .002$) and for SpAs (women: 0.63; men 0.75; $p = .007$). In relation to disease severity, among all patients, those with moderate/severe disease reported a worse HRQoL than those in remission or with mild disease ($p < .001$ for both) (Supplementary table 2).

Regarding the relationship between HRQoL and patient age, age was significantly inversely related to HRQoL in the total sample ($p < .001$) and in patients with RA ($p = .004$). Likewise, for all patients, the greater the number of treatments prior to the current therapy, the worse HRQoL was reported ($p < .001$). This was also observed in all IMIDs except Ps. In contrast, in all patients, a positive correlation was observed between the duration of the current biological therapy and HRQoL: the persistence was, the higher HRQoL ($p = .005$). This correlation was also observed for patients with IBD and Ps ($p = .012$ and $p = .049$, respectively) (Supplementary table 2).

Fig. 2 shows the values of each dimension of the EQ-5D-5L. For the total sample, pain/discomfort (2.177) had the greatest impact, followed by daily activities (1.727) and anxiety/depression (1.724). Patients with Ps reported the best state in each of the dimensions evaluated.

The results reported by the patients for the specific questionnaires for each pathology are shown in Table 1. Patients with RA, IBD, and Ps achieved 70% of the maximum score, while patients with PsA and SpAs did not reach 50% of the maximum possible score.

Discussion

The SACVINFA study analysed HRQoL of a large multicentric cohort of patients with IMIDs treated in the Pharmacy Services of various hospitals. A set of factors were identified as associated with a better HRQoL: male gender, low disease activity, and persistence to current treatment. In contrast, patient age was negatively associated with HRQoL; the older the patients were, the worse the HRQoL. To the best of our knowledge, few studies have evaluated HRQoL of patients with IMID. Most of the published studies evaluated HRQoL for a single IMID pathology, but the SACVINFA study is the first to evaluate HRQoL of the 5 IMIDs with the highest prevalence in Spain.

The results of the SACVINFA study are in line with published findings on HRQoL both in the general Spanish population and in patients with rheumatological diseases. In a study carried out on non-institutionalised adults from a Spanish population ($n = 20\,587$), female gender, age, and a greater number of chronic diseases were negatively associated with HRQoL.[19] These results are in concordance with the results observed in studies with patients with RA, SpAs, and

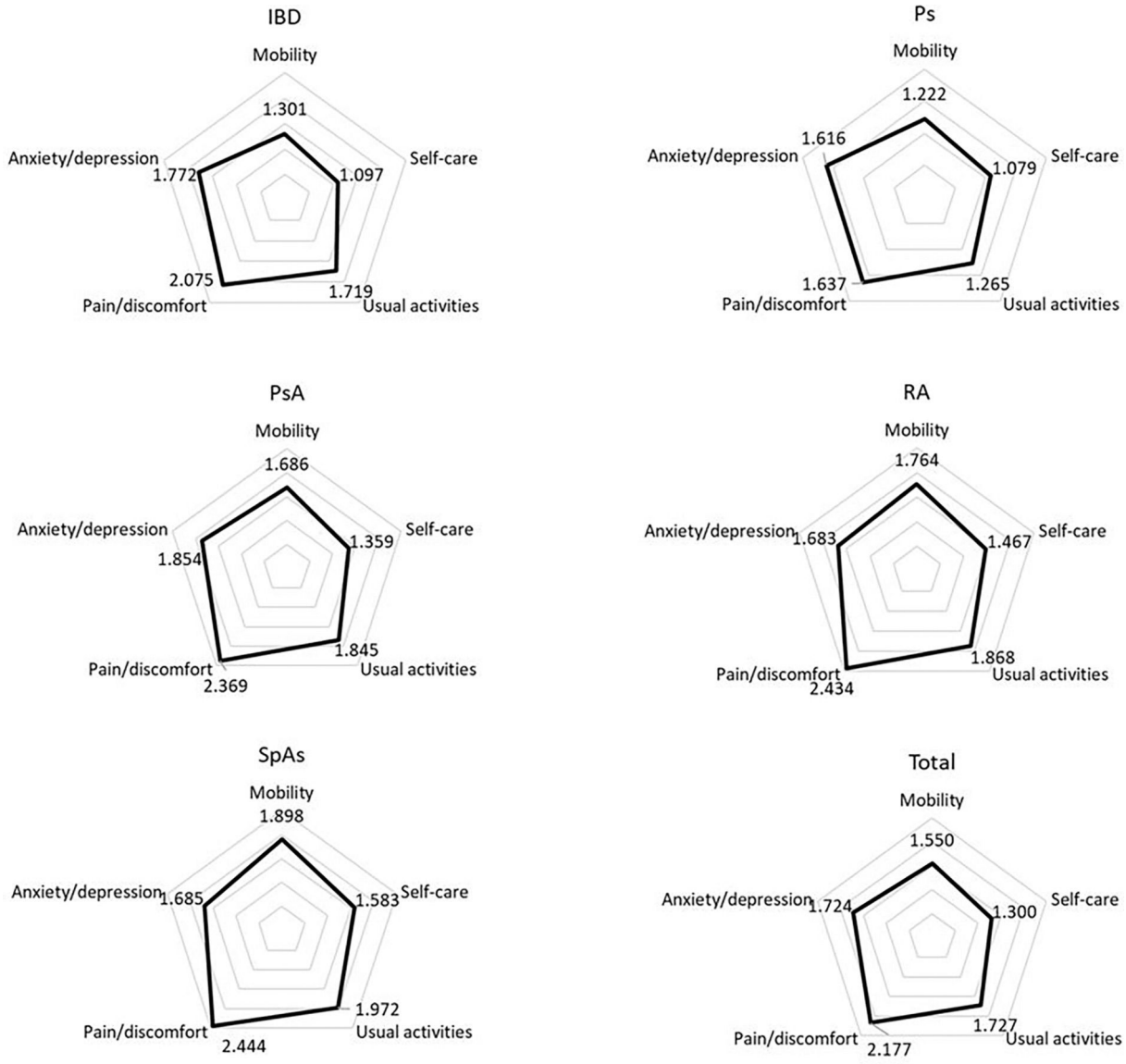

Fig. 2. Dimensions of the EQ-5D-5L. IBD: inflammatory bowel disease; Ps: psoriasis; PsA: psoriatic arthritis; RA: rheumatoid arthritis SpAs: ankylosing spondylitis.

rheumatological diseases, in which the scores of EQ-5D-5L questionnaire were significantly lower in female than male patients.[20–22] Advanced age and longer disease duration were also significantly associated with a lower HRQoL score.[21,22] Disease severity was also associated with a worse HRQoL in patients with RA[21] and Ps.[23] In the SACVINFA study, a worse HRQoL was observed among patients with moderate/severe disease than those with mild disease ($p<.001$) or in remission ($p<.001$) for all IMIDs except IBD.

In relation to the dimensions evaluated in the EQ-5D-5L questionnaire, what affected in the most negative HRQoL was pain/discomfort, followed by the ability to perform daily activities and anxiety/depression. These results are in line with the literature, since IMIDs share some common symptomatic characteristics that may be responsible for functional deterioration, including fatigue and pain, which negatively influence the ability to perform daily activities[24] and trigger anxiety or depression disorders,[25] which are very common among patients with IMID.[26] Comparing the pathologies, it should be noted that patients who presented inflammatory rheumatic diseases (PsA, RA, and SpAs) reported a worse general health status in the EQ-5D questionnaire (with scores of 0.73, 0.72, and 0.71, respectively) than patients diagnosed with IBD or Ps (with scores of 0.81 and 0.87, respectively). The dimensions most affected among patients with a rheumatological component pathologies were pain/discomfort, the ability to perform daily activities and mobility, which could be explained by the joint inflammation that occurs in these pathologies. Similar results were observed in other studies of patients with IMIDs, in which patients with diseases with a rheumatic component had worse self-reported health status than those without an inflammatory component in all. This was especially evident in domains related to mobility, and in relation to limitations in performance and usual activities due to physical function and bodily pain.[22]

The anxiety/depression achieved similar scores for patients of all IMIDs. It was the third most affected dimension in total population,

Table 1
Specific HRQoL questionnaires.

	Questionnaire	*N*	Minimum	Maximum	Average	Standard deviation
IBD	SIBDQ-9	145	40.6	93.1	64.1	9.8
Ps	DLQI	114	0.0	24.0	3.1	4.9
PsA	PsAQoL	102	0.0	20.00	6.6	5.7
RA	QoL-RA	106	1.4	9.9	6.9	1.8
SpAs	ASQoL	106	0.0	17.0	6.0	5.2

IBD: inflammatory bowel disease; Ps: psoriasis; PsA: psoriatic arthritis; RA: rheumatoid arthritis; SpAs: spondyloarthropathies.

which is in concordance with published literature, since patients with IMIDs tend to have a high prevalence of anxiety and/or depression compared to the general population.[27] In addition, recent studies have demonstrated interaction between inflammation and mood disorders, especially for patients with high levels of inflammatory mediators such as interleukin-6 (IL-6) and TNF-α.[3,28] Likewise, both the duration of the disease and the number of treatments that are usually administered over time could result in negative feedback for the mood of the patient.

The specific questionnaires for each IMID are not comparable to each other, but in relation to the best possible score, patients with pathologies with a rheumatological component reported the worst HRQoL results, except for patients with RA, who achieved a score of approximately 7/10 in their specific questionnaire.

Finally, it is worth mentioning that in the SACVINFA study, pharmacological adherence did not significantly influence in HRQoL. This result has also been observed in other studies conducted on patients with IMID (RA and IBD), in which no significant differences were observed among psychological factors or HRQoL and pharmacological adherence.[29] However, other studies on patients with IMID (PsA and Ps) did report a positive relationship between adherence and HRQoL; those patients who did adhere to and persisted with the medication showed significant improvements in clinical parameters, functionality, and in their quality of life.[30] Likewise, in another study in which RA, PsA, and SpAs patients were evaluated, patients with greater adherence to treatment had a higher score on the VAS.[31]

One strength of the present study was the involvement of a large patient cohort, the context of real-world evidence, the multicentre setting, and a reasonable balance of involved pathologies. Regarding the limitations, it is worth mentioning that the patients were not randomly selected, which would have provided more solid evidence. The consecutive inclusion of patients was chosen to favour the collection of data due to the different periods of medication collection. On the other hand, other comorbidities with impact on the quality of life were not considered in addition to immune-mediated inflammatory diseases. The patient care model was also not analysed, e.g. the existence of multidisciplinary units.

Conclusion

The results of the SACVINFA study showed that patients with IMIDs have impaired HRQoL, especially those IMIDs with a rheumatological component. Older age, female gender, greater disease severity, and a shorter treatment duration were related to a worse HRQoL in these patients. However, treatment adherence did not affect HRQoL. All these findings are relevant and can help in clinical decision-making and the establishment of priorities for the management of people with these diseases with the goal of improving their HRQoL.

Contribution to scientific literature

The SACVINFA study evaluated the quality of life related to health by patients with the most prevalent Immune-mediated inflammatory diseases in Spain. The results of the study could help to generate knowledge to establish strategies that help to optimise adherence, achieve therapeutic goals, and prevent complications.

Sources of funding

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Ethics approval statement

Ethical approval was granted by the Clinical Research Ethics Committee of the Hospital General Universitario Gregorio Marañón (code: ESC-INM-2019-01).

Statement of patient consent

All subjects personally gave consent and signed and dated the written informed consent form.

CRediT authorship contribution statement

Esther Chamorro-de-Vega: Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Alberto Calvo:** Writing – review & editing, Validation, Investigation, Data curation. **María Fernández-Pacheco:** Writing – review & editing, Methodology, Investigation, Conceptualization. **Belén Hernández-Muniesa:** Writing – review & editing, Validation, Methodology, Investigation. **Rosa Romero-Jiménez:** Writing – review & editing, Validation, Methodology, Investigation, Formal analysis, Data curation. **Araceli Casado-Gómez:** Visualization, Formal analysis, Data curation. **Esther Ramírez:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Alberto Morell:** Writing – review & editing, Validation, Investigation, Data curation. **Nuria Herrero:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Bárbara Úbeda:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Arantza Ais-Larisgoitia:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Elena Lobato-Matilla:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Álvaro Muñoz:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Miguel Ángel Casado:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation. **Vicente Escudero-Vilaplana:** Writing – review & editing, Writing – original draft, Validation, Investigation, Data curation.

Data availability statement

Data are available from the corresponding author upon reasonable request.

Declaration of competing interest

The authors have no conflicts of interest.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.farma.2024.04.006.

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