Quality of Life of Patients With Rheumatoid Arthritis Undergoing Out-Patient Treatment With TNF Inhibitors

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Abstract

Objective: To assess the quality of life of patients with rheumatoid arthritis undergoing out-patient treatment with TNF inhibitors (etanercept and adalimumab).

Method: Observational, descriptive, and multi-centre study. A specific validated questionnaire was used (QOL-RA Scale) in its Spanish version, with complete confidentiality ensured. To measure the reliability of the results, the Cronbach alpha coefficient was used. A descriptive analysis was carried out to compare the results obtained with those obtained from studies in the USA and Colombia.

Results: A total of 82 patients were selected who mainly consisted of married housewives who had not undergone any previous studies. The average amount of years from diagnosis was 11.81 years (7.30) and the average duration of treatment with TNF inhibitors was 1.71 years (1.03). The results of the questionnaire were: physical ability 5.42 (1.67), pain 5.10 (1.83), social life 7.08 (1.96), support 7.45 (2.10), mood 6.02 (2.03), stress 5.50 (2.01), arthritis 5.15 (1.86), health 5.50 (1.77). The results obtained were similar to those from the USA, although they showed a lower score for mood and stress categories. However, the high score in the support and social-life categories was more similar to that obtained with the Colombian questionnaire. All patients considered their quality of life to have improved with the use of TNF inhibitors.

Conclusions: The quality of life in patients with rheumatoid arthritis is low, determined by pain and symptoms of depression. The patients believe that TNF inhibitors have improved their quality of life.

Key words: Quality of life. Rheumatoid arthritis. Adalimumab. Etanercept.

Calidad de vida en pacientes con artritis reumatoide en tratamiento ambulatorio con anti-TNF

Objetivo: Evaluar la calidad de vida en pacientes con artritis reumatoide en tratamiento ambulatorio con anti-TNF (etanercept y adalimumab).

Método: Estudio observacional, descriptivo y multicéntrico. Se utilizó un cuestionario específico validado (QOL-RA Scale) en su versión en español, manteniendo la confidencialidad al máximo. Para medir la fiabilidad de los resultados se utilizó el coeficiente alfa de Cronbach. Se ha realizado un análisis descriptivo para comparar los resultados obtenidos con estudios realizados en la población estadounidense y colombiana.

Resultados: Se seleccionaron 82 pacientes. Destacó el perfil de ama de casa, casada y con ningún estudio o estudios primarios. La media de años de diagnóstico fue 11,81 ± 7,30 años y la de tratamiento con anti-TNF fue de 1,71 ± 1,03 años. Los resultados para la encuesta fueron: habilidad física 5,42 ± 1,67), dolor 5,10 ± 1,83, vida social 7,08 ± 1,96, apoyo 7,45 ± 2,10), estado de ánimo 6,02 ± 2,03, tensión nerviosa 5,50 ± 2,01, artritis 5,15 ± 1,86), salud 5,50 ± 1,77. Los resultados obtenidos fueron similares a los encontrados en la población estadounidense, aunque destaca una menor puntuación en el ánimo y la tensión nerviosa. Sin embargo, la alta puntuación en lo referente al apoyo y la vida social fue más parecida a la obtenida en la población colombiana. Todos los pacientes consideraron que su calidad de vida había mejorado con la medicación anti-TNF.

Conclusiones: La calidad de vida en pacientes con artritis reumatoide es baja, determinada por el dolor y los síntomas depresivos. Los pacientes tienen la percepción de que los anti-TNF han mejorado su calidad de vida.

Palabras clave: Calidad de vida. Artritis reumatoide. Adalimumab. Etanercept.

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INTRODUCTION

Rheumatoid arthritis is a chronic polyarthritis which affects more than 20 000 people in Spain. Each year, 20 000 new cases are diagnosed as shown in the EPISER study on the prevalence and impact of rheumatic illnesses carried out by the Sociedad Española de Reumatología (SER [Spanish Rheumatology Society]).[1] The illness affects the physical appearance of sufferers and, most especially, their social life, and working lives.[2] In this respect, the measurement of quality of life is a multidimensional concept which includes the physical health of individuals, their psychological condition, their level of independence and their social relationships.[3]

Measuring quality of life is particularly important in illnesses such as rheumatoid arthritis where there are difficulties involved in measuring the results of treatment.[4]

One such valid method of measuring quality of life is to use questionnaires, which help to effectively quantify health problems.[5] Several questionnaires have been used to measure quality of life in rheumatoid arthritis patients, among which are some specific questionnaires: AIMS (Arthritis Impact Measurement Scales),[6] the Rheumatoid Arthritis Quality of life (RAQoL) questionnaire,[7] the Rapid Assessment of Disease Activity of Rheumatology (RADAR),[8] and the Quality of life in Rheumatoid Arthritis (QOL-RA Scale).[9]

The objective of the study is to evaluate the quality of life of patients with rheumatoid arthritis being treated with TNF inhibitors (etanercept and adalimumab) who consult with pharmaceutical care for their medication. A special questionnaire has been used for these people, which has proven to be relevant for both the English and Spanish-speaking populations.

METHOD

Observational, descriptive, and multi-centre study. The patients selected were those diagnosed with rheumatoid arthritis receiving outpatient treatment with TNF inhibitors (etanercept or adalimumab) who agreed to take the medication to the outpatient pharmaceutical care consultant for a 1-month period, which is the usual frequency for collecting the medication. The period selected was taken as the sampling of the target population.

The Spanish version of the QOL-RA Scale was used, validated by Danao et al.[9] This questionnaire contains 8 items followed by a horizontal scale numbered from 1 (very poor quality of life) to 10 (excellent quality of life). The Cronbach alpha coefficient was used to measure the reliability of results, which rates the internal consistency of the scale, that is, the correlation of the items and to establish homogeneity.[10]

The questionnaire was explained carefully to the patients and they were asked to give their informed consent by signing.

Given that quality of life is an entirely subjective matter, the questionnaires primarily involved self evaluation, maintaining the highest level of confidentiality. When patients were unable to complete the questionnaires on their own, usually due to a low level of education, an interviewer helped to fill in the questionnaire.

A descriptive analysis of the data was carried out using the statistics program SPSS®, version 12.1. The results obtained from the surveys were compared with the studies conducted by Danao et al (United States) studies and Vinaccia et al (Colombia), which used the same survey.[9,11]

RESULTS

The survey was performed on 100% of the patients who attended the clinics diagnosed with rheumatoid arthritis who were receiving TNF inhibitor treatment. Of the 82 patients selected, 47 were women (53.3%) and 35 were men (42.7%), with an average age of 52.40 (11.82) years. The patients' socioeconomic characteristics are shown in Table 1, which shows the patients are primarily housewives, married and who have no education or only primary school education.

The average number of years the patients had been diagnosed with the illness was 11.81 (7.30) years, and the average number of years for the treatment with TNF inhibitor treatment (etanercept

Table 1. Social Demographic Characteristics of the Patients

	No.	Percentage
Education		
None	18	22
Primary	38	46.3
Secondary	16	19.5
University	10	12.2
Total	82	100
Marital status		
Married	70	85.4
Single	6	7.3
Widowed	2	2.4
Others	4	4.9
Total	82	100
Employment		
Full time	21	25.6
Part time	3	3.6
Occasional	–	–
Looking for work	–	–
Housewife	32	39
Retired	13	15.9
Disabled	13	15.9
Total	82	100
Living alone?		
Yes	3	3.7
No	79	96.3
Total	82	100

Tabla 2. Values (Average and Standard Deviation) of the Subscales of the QOL-RA Questionnaire in Patients in the Study and of the Danao et al[9] and Vinaccia et al[11] Studies Which Use the Same Survey

Item	Patients in the Study	Danao et al[9]		Vinaccia et al[11]
		Anglosaxons	Latins	
Physical ability	5.42 (1.67)	5.76 (1.98)	5.29 (1.89)	7.74 (1.92)
Pain	5.10 (1.83)	5.46 (2.31)	4.76 (2.39)	6.72 (2.35)
Social life	7.08 (1.96)	7.21 (2.32)	6.49 (2.21)	8.16 (1.89)
Support	7.45 (2.10)	6.95 (2.19)	6.49 (2.21)	8 (2.21)
Mood	6.02 (2.03)	6.22 (2.19)	6.08 (2.14)	7.41 (2.19)
Stress	5.50 (2.01)	5.74 (2.22)	5.65 (2.03)	6.82 (2.63)
Arthritis	5.15 (1.86)	5.28 (2.28)	4.99 (2.04)	6.83 (2.42)
Health	5.50 (1.77)	5.6 (2.17)	5.84 (2.269)	7.06 (2.22)
Total, average	5.90	5.54	5.28	7.32

or adalimumab) was 1.71 (1.03).The patients took an average of 2.52 (2.05) medications per day.

Table 2 shows the subscales scores of the QOL-RA study compared to those obtained in US (Danao et al)[9] and Colombian (Vinaccia et al)[10] patients. The total average of the 8 items was 5.90 (2.07) with a Cronbach alpha coefficient of 0.90.

All patients considered that their quality of life had improved since receiving TNF inhibitor medication.

DISCUSSION

The measurement of quality of life in rheumatoid arthritis patients is very important to be able to evaluate the impact of the illness and the patients' treatment.[12] The questionnaire used in the study (QOL-RA Scale) is the only one specifically for rheumatoid arthritis which is adapted simultaneously to English and Spanish (language validation) and was easy for the patients to understand and use. Most of the questionnaires were self-administered by the patient; however, the drawbacks of this method were not detected, such as a high incidence of missing data or incomplete questionnaires.[13]

As for the reliability of the results, a similar Chronbach alpha coefficient to the original English version of the QOL-RA was obtained, which was superior to the Spanish version, which is evidence of good homogeneity and internal consistency of the results.[9,11]

With regards to the size of the sample, the study is representative of all patients in the hospitals included, which was around 100, with a confidence level of 95% and a confidence interval of 5. Although the results are not representative of the entire Spanish population, they are a useful reference for patients in the health area evaluated.

With respect to the sociodemographic characteristics of the selected population, the married housewife profile is significant. Limitations worthy of consideration are the influences of occupational incapacity and lack of independence in the workplace, which affect quality of life, and the subjective factor of better health in those who are married as opposed to those who are not married.[2,14] Other data can also influence the quality of life results, such as the period of treatment or the amount of drugs taken, which are not high results in this study. A stratified analysis of the results would be needed to confirm the definitive influence of these variables.

Globally, the results obtained in the study for the different items are similar in the scale to those obtained in the United States' population with whom the original questionnaire validation was undertaken, although a lower score was obtained for mood and stress. A high score was also evident in reference to support and social life, with results more similar to those values found in the Colombian population.[10] It must be considered that patients with rheumatoid arthritis who feel highly satisfied with the social support they receive show a better level of adaptation to the illness.[15]

There are different studies which show that pain perception and depressive symptoms (mood, stress) are more important predictive factors of quality of life.[16,17] In this regard our results corroborate these data: pain is the most limiting factor for quality of life and it is necessary to determine the results using specific pain questionnaires.[18]

It is also relevant that in the study all the patients considered that the treatment has improved their illness and quality of life, similar data to those of the Romero Crespo et al study carried out in patients with rheumatoid and psoriatic arthritis in treatment with etanercept, with the figure of 92%.[19] It must be considered that only TNF inhibitors (etanercept or adalimumab) outpatient treatment has been taken into account and this has not reflected to patients being treated with infliximab in day hospital, where factors such as transitory hospital stay or intravenous administration of the medication may vary the results obtained.

In conclusion, quality of life in patients with rheumatoid arthritis is low, fundamentally limited by pain and depressive symptoms these patients experienced because of their illness. It is necessary to consider these factors from a multidisciplinary point of view. In fact, the Núñez et al study shows that patients who receive therapeutic education as well as treatment show better progress than those who only receive treatment.[20]

On the other hand, all patients perceived that the TNF inhibitor treatment had improved their quality of life; therefore, a greater

effectiveness of these treatments is shown in the perception of the patients' quality of life.

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