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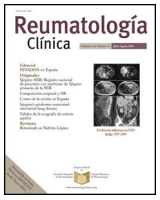

Brief report

Remote monitoring tools in rheumatoid arthritis patients: FACIT-fatigue and HAQ

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ABSTRACT

Objective: To analyze the association of clinical activity with pain, fatigue and disability in patients with RA.
Methods: Prospective observational study of 3 months of follow-up in 60 patients who initiate biological or anti-JAK therapy. We analyzed changes in the PROs reported by patients through FACIT-fatigue, HAQ questionnaires and pain VAS. Clinical activity through DAS28, DAS28-CRP, SDAI and CDAI index was measured.
Results: We observed a statistically significant association between clinical activity and the fatigue, pain and disability ($p < 0.001$). A greater fatigue was associated with a greater perception of pain and high tender joint number ($p = 0.002$). Patients who discontinued treatment presented higher fatigue ($p = 0.044$) and disability ($p = 0.0013$) than those who continued treatment, regardless of the type of treatment, the time of evolution, as well as whether or not they had received previous biological therapies.
Conclusion: PROs would be helpful in the disease control in cases where a remote monitoring is needed, since PROs showed a significant association with clinical activity in RA.

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Herramientas en el seguimiento telemático de la artritis reumatoide: FACIT-fatigue y HAQ

Palabras clave:
Artritis reumatoide
Actividad clínica
Discapacidad
Dolor
Fatiga

RESUMEN

Objetivo: Analizar la asociación de la actividad clínica con dolor, fatiga y discapacidad en pacientes con AR.
Métodos: Estudio observacional prospectivo de 3 meses de seguimiento en 60 pacientes que iniciaban tratamiento biológico o anti-JAK. Se analizaron cambios en los PROs mediante los cuestionarios FACIT-fatigue, HAQ y EVA dolor. La actividad clínica se midió mediante los índices Das28, Das28-PCR, SDAI y CDAI.
Resultados: Se observó una asociación estadísticamente significativa entre la actividad clínica y la fatiga, el dolor y la discapacidad ($p < 0{,}001$). Una mayor fatiga se asoció con una mayor percepción de dolor y un mayor número de articulaciones dolorosas ($p = 0{,}002$). Los pacientes que interrumpieron el tratamiento presentaron más fatiga ($p = 0{,}044$) y discapacidad ($p = 0{,}0013$) que los que continuaron, independientemente del tipo de terapia, del tiempo de evolución de la enfermedad o de haber recibido terapias biológicas previas.
Conclusión: Los PROs podrían ser de utilidad en el control de la enfermedad cuando se requiera una monitorización remota, dado que mostraron una asociación significativa con la actividad clínica en la AR.

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Introduction

With the communication technologies advances, and especially due to the implementation of telematics consultation in Rheumatology, there has been a decrease in the number of face-to-face consultations. However, telephone control of rheumatic diseases that require a clinical patient examination, such as rheumatoid arthritis (RA), is much more complex. Rheumatoid arthritis (RA) is a chronic autoimmune disease whose prevalence ranges from 0.5 to 1% of the population[1] and which accounts for an important part of face-to-face Rheumatology consultations. Remote control of RA patients can be hampered by the complexity of evaluating disease activity, including control and monitoring of biological therapies.

Patient-Reported Health Outcomes (PROs) are reports directly from the patient that inform about the perception of the disease and its treatment, and can be used to find out how the disease affects pain, fatigue, or functional capacity. Fatigue and disability is a common problem for RA patients, and several studies have reported prevalence of fatigue in RA ranging from 40% to 90%.[2]

The PROs use in rheumatology is increasing, not only in clinical trials and observational studies, but also in routine clinical practice to achieve better patient management,[3] and they are considered a good prognostic predictor of RA.[4] Having tools such as PROs is a possible solution for remote evaluation of the patient.

The objective of the present study was to analyze the association of clinical activity with pain, fatigue and disability in patients with RA.

Material and methods

Design

A prospective, observational analysis of 3 months of follow-up was carried out, including 60 RA patients (2010 ACR/EULAR Criteria)[5] at the beginning of the biologic or anti-JAK therapy from a Rheumatology Department of a tertiary hospital.

A baseline visit was made at the beginning of the biologic or anti-JAK treatment, one month and 3 months after it, and in each visit a fatigue questionnaire (FACIT-fatigue),[6] disability questionnaire (HAQ)[7] and a Visual Analogue Scale of pain (VAS) (0–10) was fulfilled in person. In addition, the patient was clinically assessed by a rheumatologist for DAS28-ESR (erythrocyte sedimentation rate) disease activity index, DAS28-CRP (C-reactive protein), simplified disease activity index (SDAI), and clinical disease activity index (CDAI).

Statistical analysis

The data obtained were described by mean and standard deviation in the case of continuous variables and by relative and absolute frequencies in the case of categorical variables. Of all the determinations made, confidence intervals were estimated at 95%. Correlations between different continuous variables were determined using the Pearson correlation index. To analyze the relationship of the response variable against different predictor variables, multivariate linear regression models were used in the case of quantitative variables, or multivariate logistic regression in the case of categorical variables. *p*-Values less than 0.05 were considered statistically significant. All analyzes were performed using R software.

Results

Sixty RA patients were included (83.33% women) with a mean age at the baseline visit of 55 ± 13 years, and the mean time of disease evolution was 13 ± 11 years.

Of the total number of patients, 39 started therapies with JAK inhibitors and 21 started treatments with TNF-α inhibitors. The 33.34% of patients were on monotherapy, and the 46.67% had received previous biological therapies. The 78.3% were also receiving corticosteroids, with a mean dose of prednisone of 4.7 mg/day. The 80% of patients continued treatment 3 months after basal visit and 20% discontinued it due to ineffectiveness (6 cases, 10%) or intolerance (6 cases, 10%). Of the 48 patients who continue treatment at three months of follow-up, 62.2% were receiving corticosteroids, with a mean dose of prednisone of 3 mg/day. At the baseline visit, 55% of the patients showed elevated CRP and 48.3% elevated ESR, and the 83.3% showed moderate or high activity (Table 1).

Using Pearson's correlation, we observed a correlation among the perception of fatigue, pain, and disability. To analyze the association of PROs with clinical activity in RA patients, linear regression models were performed, in which the patient's age at the time of the visit, smoking habit, time of evolution of the disease, the BMI, the administration of previous biological therapies and the dose of corticosteroids administered at the time of the visit, were included as corrective variables.

A statistically significant association was observed between clinical activity and the perception of fatigue ($p < 0.001$), pain ($p < 0.001$) and disability ($p < 0.001$). A greater perception of fatigue was associated with a greater perception of pain ($p < 0.001$) and higher TJCs ($p = 0.002$) (Table 2). There was no evidence of association of the PROs with the SJCs, CRP and ESR levels.

Patients who discontinued treatment before 3 months presented a higher perception of fatigue ($p = 0.044$) and disability ($p = 0.0013$) than those who continued treatment, regardless of the type of treatment (biological or synthetic therapy), the time of evolution, and previous biological therapies.

Discussion

We have observed a greater perception of fatigue and disability associated with high levels of disease activity, adjusting for variables that have been shown to influence the results of PROs such as sex, age, obesity, smoking habit, time of evolution of the disease, the administration of previous biological therapies and the dose of corticosteroids administered at the time of the visit.[8–10]

The use of PROs can offer the rheumatologist a fairly close approximation of the clinical activity of the RA patient. This is of special interest in patients who are being treated with targeted biological or synthetic therapies. As observed in the study, both the HAQ and the FACIT-fatigue questionnaire offer an approximation to the clinical activity of the patient, as they are associated with clinical activity factors as DAS28, DAS28-CRP, SDAI and CDAI index. In fact, the perception of pain is also evident with these PROs, as shown by the statistically significant associations with the VAS-pain scale and the tender joints count in RA patients.

Even in cases where clinical activity persists and the ineffectiveness of treatment in controlling RA activity is evident, PROs showed significant differences with respect to those cases where clinical activity is controlled throughout the three months of follow-up. Previous studies have already shown the correlation of the PROs with the clinical response to treatments and even to the presence of residual inflammation evaluated by ultrasound in RA with low clinical activity.[11,12]

Table 1
Evolution of clinical activity parameters, perception of fatigue, pain, and disability throughout the follow-up.

	VISIT 0 (basal visit) $n=60$	VISIT 1 (month 1) $n=57$	VISIT 3 (month 3) $n=48$
VAS pain	6 ± 2	4 ± 3	5 ± 3
HAQ	1.33 ± 0.61	1.06 ± 0.64	1.06 ± 0.69
FACIT-fatigue	25.52 ± 12.19	31.03 ± 12.9	32.76 ± 12.46
TJC	7 ± 5	3 ± 3	3 ± 3
SJC	3 ± 3	2 ± 2	1 ± 2
DAS28-ESR	4.78 ± 1.2	3.6 ± 1.33	3.54 ± 1.44
DAS28-CRP	4.31 ± 1.06	3.19 ± 1.14	3.05 ± 1.28
SDAI	22.72 ± 9.88	13.58 ± 8.58	12.97 ± 9.32
CDAI	21.75 ± 9.62	12.88 ± 7.96	12.36 ± 9.11
High/moderate clinical activity	15 (83.33%)	5 (57.89%)	4 (46.67%)
Elevated CRP, *n* (%)	33 (55%)	19 (33.33%)	18 (47.5%)
Elevated ESR, *n* (%)	29 (48.33%)	18 (31.58%)	13 (27.08%)

TJC: tender joints count; SJC: swollen joints count; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

Table 2
Multivariate analysis of clinical activity factors associated with perception of fatigue and disability in RA patients ($n=48$) comparing 3th month of follow-up with basal visit.

	HAQ	EE coeff.	CI (95%)	*p*-Value
FACIT-fatigue				
DAS28-ESR	−4.006	0.441	−4.872, −3.155	<0.001
DAS28-CRP	−4.301	0.455	−5.222, −3.44	<0.001
SDAI	−0.552	0.053	−0.659, −0.451	<0.001
CDAI	−0.565	0.054	−0.674, −0.462	<0.001
TJC	−0.614	0.197	−0.987, −0.231	0.002
VAS pain	−1.169	0.27	−1.803, −0.672	<0.001
HAQ				
DAS28-ESR	0.252	0.025	0.204, 0.301	<0.001
DAS28-CRP	0.273	0.025	0.224, 0.322	<0.001
SDAI	0.033	0.003	0.027, 0.04	<0.001
CDAI	0.034	0.003	0.028, 0.04	<0.001
TJC	0.03	0.011	0.009, 0.051	0.008
VAS pain	0.09	0.015	0.063, 0.122	<0.001

TJC: tender joints count; SJC: swollen joints count; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein.

The COVID-19 pandemic and protocols to prevent the spread of the virus have forced a rethinking of healthcare and have prompted a transformation of outpatient care in patient care. One of the most relevant changes has been the implementation of the telephone consultation,[13] facilitating patient access to the healthcare system in circumstances related to COVID-19, where face-to-face consultations were not allowed. However, COVID-19 led in some cases to exclusively telematics follow-up in patients who require physical examination, as is the case of RA, which may affect the evaluation of disease activity and the management of biological therapies or directed synthetics. In situations in which physical presence in health centers is not possible, the PROs would provide valuable information to the specialist and would be a great help in controlling the disease.

Thus, due to the association of the PROs with clinical activity in RA patients and the ease with which they can be completed and evaluated by the healthcare professional, these tools can be of great value for remote monitoring of the disease. Its application in the telephone follow-up of the patient, as has occurred as a result of the COVID-19 pandemic, would mean an improvement in its clinical evaluation, since the necessary information for its clinical follow-up would be reported and face-to-face consultation would be avoided in situations that require it.

Conclusion

In conclusion, our findings highlight that PROs such as the HAQ and FACIT-fatigue questionnaires are closely associated with disease activity indices in RA and can therefore serve as reliable tools for assessing clinical status. Their correlation with established clinical measures underscores their potential utility not only in routine monitoring but also in contexts where in-person evaluations are limited, such as during telemedicine consultations.

Significance and innovation:

- This is one of the first reports on qualitative evaluation of the HAQ and FACIT-fatigue supports for assessing follow-up of pain and fatigue on daily living of patients with RA, in Spain.
- HAQ and FACIT-fatigue questionnaire offer a fairly close approximation to the clinical activity of the patient with RA.
- The association of the PROs with clinical activity can be of great value for remote monitoring of the disease.

Ethical considerations

The present study was carried out in accordance with the Declaration of Helsinki on ethical principles for medical research in humans, and approved by the Ethics and Clinical Research Committee of HUP La Fe. In all cases, the individuals participating in the study they were duly informed of the objectives and methodology of the study and previously signed the consent prepared for this purpose.

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Conflict of interests

The authors declare no conflicts of interest.

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