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Prospective evaluation of the quality of life in a cohort of patients with early rheumatoid arthritis

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ABSTRACT

Introduction: Few studies have prospectively assessed the tools used to measure quality of life, both generic and specific, in patients with early rheumatoid arthritis (RA). **Objective:** The objective of this study was to characterize a population of patients with early RA (less than 12 months after symptom onset at the time of the diagnosis) prospectively followed for the pattern of responses to questionnaires addressing quality of life, the Health Assessment Questionnaire (HAQ) and Medical Outcomes Study SF-36 Health Survey (SF-36). **Patients and methods:** Forty patients with early RA at the time of diagnosis, treated with a standard treatment regimen, were prospectively followed for 3 years. Demographic and clinical data were recorded, and HAQ and SF-36 questionnaires were applied at baseline and after 3, 6, 12, 18, 24, and 36 months. Paired Student *t* test and Wilcoxon test were used for comparisons (significance level of 5%). **Results:** The mean age was 45 years, with a prevalence of the female gender (90%). The average score of the initial HAQ was 1.89, with a progressive decline to 0.77 in the third year ($P < 0.0001$). Most domains of the SF-36 questionnaire presented significant improvement during the three years of follow-up, except for general health and vitality. **Conclusion:** In this population of patients with early RA at the time of diagnosis, the results showed significant impact on quality of life at the time of diagnosis, as measured by HAQ and SF-36 questionnaires. The early treatment of RA seems to be associated with improved health-related quality of life reported by patients.

Keywords: early rheumatoid arthritis, cohort, HAQ, SF-36, quality of life.

INTRODUCTION

Even in its initial stages, rheumatoid arthritis (RA) can cause considerable impact on health-related quality of life (HRQoL).¹ HRQoL is a broad concept that can be simplified as the impact of health on the functional capacity and well-being of an individual perceived on the physical, mental, and social domains of life.²

Several tools have been proposed to evaluate the quality of life in AR patients, detect health changes and prognosis along time, as well as risks and benefits of a specific therapeutic

intervention,³ including both generic, such as the SF-36 (Medical Outcomes Study 36-Item Form Health Survey), and specific tools, such as the Health Assessment Questionnaire (HAQ).

Few studies have prospectively evaluated the tools used to measure quality of life, overall in patients with early RA.

The objective of the present study was to characterize a population of patients with early RA prospectively followed regarding the pattern of responses to questionnaires on quality of life.

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PATIENTS AND METHODS

A prospective study with an incident cohort was undertaken, in which consecutive patients with a diagnosis of early RA, were followed regularly for 36 months from the time of diagnosis onward, were regularly seen. Patients were evaluated in the Early Rheumatoid Arthritis Outpatient Clinic of the University Hospital of Brasília, Brazil.

Early RA was defined as articular symptoms compatible with the disease (inflammatory pain pattern edema of the joints, associated or not with morning stiffness or other manifestations suggestive of articular inflammatory disease, according to the evaluation of a single observer) lasting more than 6 months and less than 12 months, regardless of whether they met or not the classification criteria of the American College of Rheumatology (ACR).⁴ During follow-up, the diagnosis of RA was confirmed in all patients.

Investigation of rheumatoid factor (RF) was performed using the “Quanta Lite™ RF IgA ELISA”, “Quanta Lite™ RF IgG ELISA”, and “Quanta Lite™ RF IgM ELISA” assays (Inova Diagnostics, CA, USA), according to the protocols of the manufacturer. The cutoffs used to consider the test positive, *i.e.*, higher than 15 IU/mL (RF IgM and IgA) and 20 (IU/mL (RF IgG) were determined. The “Quanta Lite™ CCP IgG ELISA”, “Quanta Lite™ CCP3 IgG ELISA”, and “Quanta Lite™ CCP 3.1 IgG ELISA” (Inova Diagnostics, CA, USA) were used to determine anti-CCP, according to the protocol of the manufacturer. Results were expressed in units (U) and considered negative when < 20 U, weakly positive 20-39 U, moderately positive 40-59 U, and strongly positive ≥ 60 U for all assays.

The presence of erosion on conventional X-ray on the first appointment was also recorded.

Translated and validated versions of the HAQ and SF-36 in Portuguese were used to evaluate the impact of early RA on quality of life.⁶

Demographic and clinical data, as well as the results of the questionnaires applied in the initial evaluation and at 3, 6, 12, 18, 24, and 36 months, were recorded.

During follow-up, patients received the standard treatment used by our service, including traditional disease-modifying drugs (DMARDs) and/or drugs that modify the biological response as needed.

The normalcy Kolmogorov-Smirnov test was used and the distribution was considered normal if $P > 0.05$. To detect the differences between two means, the Student *t* test or paired *t* test was used for samples with normal distribution, and the non-parametric Wilcoxon or Mann-Whitney test for those

samples in which the hypothesis of normalcy was rejected. Results were considered significant if $P < 0.05$.

Cohort size calculation was done based on a pilot sample of 10 patients, considering that a multivariate analysis of variance for repeated measurements for interaction among groups was the statistical methodology used. Considering a level of significance of 5%, a test power of 80%, and the information obtained with the pilot sample, a minimum of 40 patients was regarded as necessary.

This study was approved by the Ethics on Research Committee of the Medical School of Universidade de Brasília (Project registration: CEP-FM 028/2007).

RESULTS

Characteristics of the study population

Forty patients with a diagnosis of early RA were evaluated. The female gender predominated (36 patients, 90%), with a mean age of 45.3 (21 to 71) years. The mean duration of articular symptoms at the time of diagnosis was 27.2 weeks (4 to 48), but 13 patients (32.5%) had had the symptoms for less than 12 weeks. The majority of the patients (92%) had not received treatment for RA before the initial evaluation.

Patients were not lost for follow-up during the three years of the study.

Table 1 summarizes the demographic, clinical, serologic, and radiographic characteristics of the study population.

Therapeutic schedules

On the initial evaluation, all 40 patients were taking non-steroidal anti-inflammatory drugs (NSAIDs) and two of them (5%) were on less than 10 mg/day of prednisone (mean time of prednisone use of 14.6 ± 2.4 weeks).

After the initial evaluation, 37 patients (92.5%) were treated with methotrexate (initial dose of 7.5 mg/week) with folic acid supplementation (5 mg/week) and hydroxychloroquine (400 mg/day), and one individual (2.5%) was started on isolated methotrexate (initial dose of 7.5 mg/week) with folic acid supplementation (5 mg/week) because he refused to take hydroxychloroquine. Two patients (5%) with pulmonary manifestations received cyclophosphamide (0.8 and 1 g/m²) and monthly pulses of methylprednisolone (1 g). Two patients with cutaneous vasculitis used, in addition to DMARDs, prednisone with an initial dose of 40 mg/day.

Figure 1 summarizes the therapeutic schedules used after three years.

Table 1
Demographic, clinical, serologic, and radiographic characteristics of 40 patients with early RA in a prospective follow-up at HUB

Characteristics		n (±) ou n (%)
Age (years)		45.37 (± 12.01)
Gender	Male	4 (10%)
	Female	36 (90%)
Ethnic group	Caucasian	14 (35%)
	Caucasian/black	13 (32.5%)
	Caucasian/ Native Brazilian	11 (27.5%)
	Black	1 (2.5%)
	Black/Native Brazilian	1 (2.5%)
Duration of symptoms before the diagnosis (weeks)		27.22 (± 15.59)
Articular involvement	Acute	32 (80%)
	Insidious	8 (20%)
Persistent synovitis in the hands		32 (80%)
Duration of morning stiffness (minutes)		155.5 (± 117.97)
Number of painful joints		20.07 (± 6.74)
Number of joints with edema		14.15 (± 7.64)
Rheumatoid nodules		5 (12.5%)
Other manifestations or associated diagnosis	Fatigue	28 (70%)
	Anemia	7 (17.5%)
	Raynaud's phenomenon	4 (10%)
	Cutaneous vasculitis	2 (5%)
	Pulmonary manifestations	2 (5%)
	Eye manifestations	2 (5%)
	Cardiac manifestations	0 (0)
	Fibromyalgia	9 (22.5%)
	Depression	8 (20%)
	Sicca syndrome	7 (17.5%)
DAS28		6.86 (± 1.07)
Radiographic erosion		21 (52.5%)
RF (RF IgA, RF IgG and/or RF IgM)		21(52.5%)
Anti-CCP (CCP2, CCP3 and/or CCP3.1)		21(52.5%)

Results presented as mean (± standard deviation) or n (%).
RF = rheumatoid factor; DAS = Disease activity index.

After the three-year follow-up, eight patients (20%) remained on the same drugs prescribed initially – hydroxychloroquine (mean dose of 400 mg/day) and methotrexate (mean dose of 20.5 mg/week).

Twenty-three individuals (57.5%) were on a non-biological DMARD that was different from the one prescribed initially. One patient was on methotrexate (15 mg/week), hydroxychloroquine (400 mg/day), and leflunomide (20 mg/

day); six others were on methotrexate (mean dose 19.5 mg/week), hydroxychloroquine (400 mg/day), and sulfasalazine (mean dose 1 g/day); nine were on monotherapy with leflunomide (20 mg/day); and one patient on leflunomide (20 mg/day) and cyclosporine (100 mg/day).

Quality of life questionnaires

The difference between the final and initial HAQ scores and that of some domains of the SF-36 showed normal distribution, except for the emotional and physical aspects, mental health, and vitality domains.

Table 2 and Figures 2 and 3 show the baseline scores and those obtained after three years of follow-up at the quality of life questionnaires, HAQ and SF-36. The scores on HAQ and most of the domains for the SF-36 (except for general status and vitality domains) showed a significant improvement between the baseline evaluation and that performed after three years.

DISCUSSION

Several studies have used the HAQ⁷ and, therefore, it is possible to make comparisons among the results of the present study with those of other populations of patients with the diagnosis of early RA.

The published studies have demonstrated a wide range of variation of the mean HAQ scores in the initial assessment, but

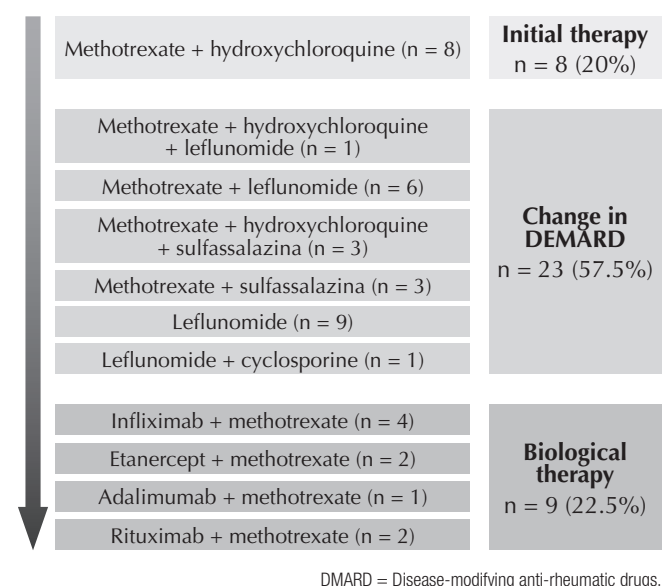


Figure 1
Treatment schedules used by 40 patients with a diagnosis of early RA, at baseline and after three years of follow-up.

Table 2

HAQ and SF-36 scores of 40 patients with a diagnosis of early RA in prospective follow-up at HUB – baseline assessment and after three years

Questionnaires	Mean Evaluation (standard deviation)		T	P
	Baseline	Three years		
HAQ	1.89(0.78)	0.77(0.64)	7.49	< 0.0001
SF-36 (Domains)				
Social aspects	41.87(34.27)	77.24(26.42)	-5.77	< 0.0001
Pain	23.00(19.77)	57.51(23.14)	-7.08	< 0.0001
General status	57.35(25.86)	66.33(23.72)	-1.77	0.08
Functional capacity	23.50(25.32)	56.28(29.22)	-5.32	< 0.0001
Questionnaires	Evaluation Median (interquartile amplitude)		Wilcoxon test	P
	Baseline	Three years		
SF-36 (Domains)				
Mental health	52.00(20.00)	56.00(12.00)	133.00	0.03
Emotional aspects	0(0)	66.67(100.00)	139.50	< 0.0001
Vitality	50.00(15.50)	50.00(20.00)	14.00	0.08
Physical aspects	0(0)	25.00(100.00)	146.50	< 0.0001

HUB = Hospital Universitário de Brasília; RA = rheumatoid arthritis; HAQ = Health Assessment Questionnaire; SF-36 = Medical Outcomes Study 36-Item Form Health Survey.

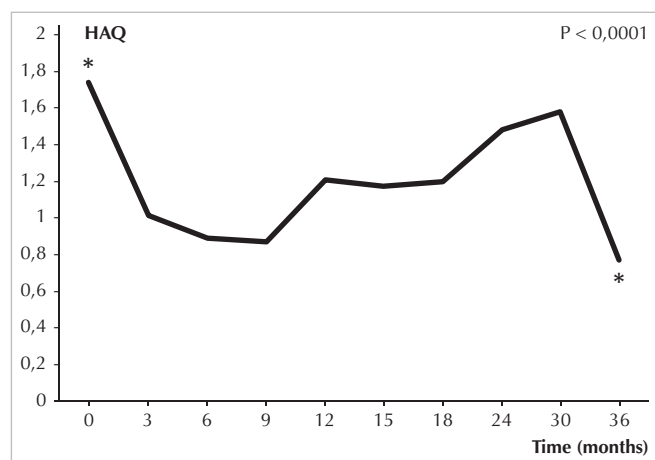


Figure 2
Mean HAQ scores of 40 patients with a diagnosis of early RA in prospective follow-up at HUB for three years.

HUB = Hospital Universitário de Brasília; RA = rheumatoid arthritis; HAQ = Health Assessment Questionnaire.

the mean score in the majority of them is around 1 (0.8 to 1.3),⁸⁻¹¹ which was lower than the one observed in our population, whose mean HAQ scores at the initial evaluation was 1.9, decreasing to 0.8 after three years of follow-up.

Although most studies have shown an improvement in HAQ scores throughout the first few years after the diagnosis

of RA, a wide variation can be observed regarding the rate of change in HAQ. After two years of follow-up, 10% of 147 patients in the study by van der Heijde *et al.*,¹² and 29%, in the study by Wiles *et al.*,⁹ still had a HAQ score greater than 1. Combe *et al.*¹¹ reported that 27% of 191 patients had HAQ scores > 1 after three years of follow-up, and 22% still maintained this mean score after five years of treatment. The study by Young *et al.*⁸ showed 34% and 38% for the same periods of time (three and five years). Possible explanations for variations in the evolution of HAQ scores include different study designs and the influence of other parameters, such as the effects of treatment and socioeconomic status.¹³

Six large studies in patients with early RA in the United Kingdom – NOAR¹⁴ and ERAS¹⁵ – Sweden, France, and Holland,¹⁶⁻¹⁹ showed that the behavior of the HAQ presents a “J curve” pattern, demonstrated by an initial fall in HAQ scores followed by a gradual increase along the years. In those studies, the mean initial HAQ score was 0.92 (ranging from 0.63 to 1.3). After three years, the mean score decreased to 0.74, but a subsequent increase of up to 0.83 occurred in the fifth year.

A possible explanation for this “J curve” pattern is that RA patients experience considerable difficulty before starting the treatment. Initially, the use of NSAIDs and DMARDs improve the synovitis and the incapacity associated with it. However, functional limitation increases slowly and gradually with the progression of the articular damage and other disease

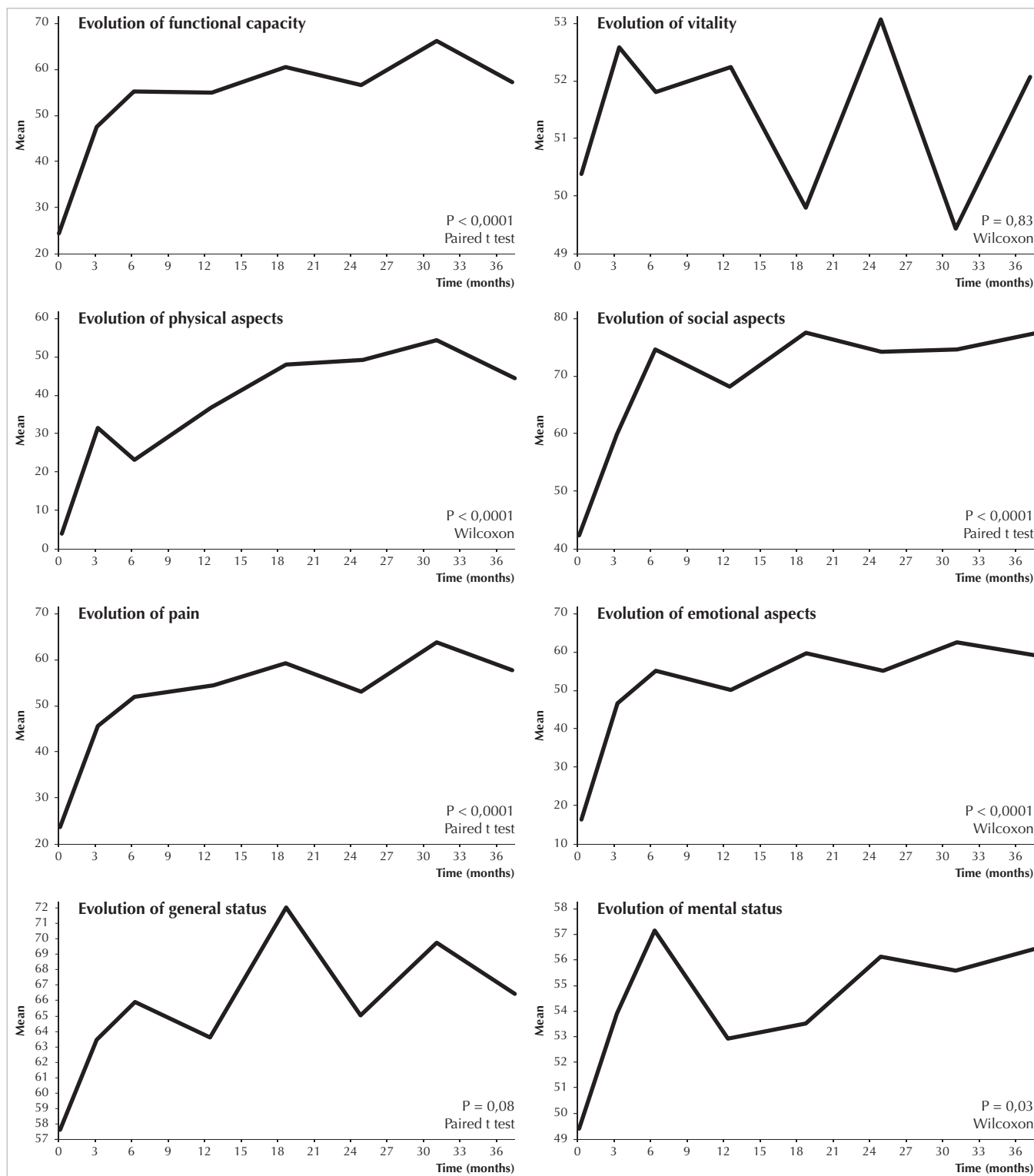


Figure 3 Scores (means-paired t test, and medians-Wilcoxon) of the domains of the SF-36 of 40 patients with a diagnosis of early RA in the prospective follow-up at HUB for three years.

HUB = Hospital Universitário de Brasília; RA = reumatoid arthritis; SF-36 = Medical Outcomes Study 36-Item Form Health Survey.

manifestations.²⁰ In the present study, the improvement in HAQ scores was fast (large decrease in the score in the first six months of treatment), but progressive worsening (increase in HAQ scores) between the sixth and 30th month of treatment occurred. From the 30th month until the end of the 36th month a progressive improvement was observed once again, reaching a mean level that was significantly lower than the initial level.

As for the SF-36 questionnaire, the reduced levels of the scores of the domains in the initial evaluation demonstrated a great impact on the health-related quality of life in our population of patients with early RA. The domains “physical limitation” and “emotional limitation” showed very low scores, demonstrating that, in our study population, those were the most affected aspects of quality of life at the initial evaluation. The “mental health” and “vitality” domains were the least affected at the time of the diagnosis.

West and Jonsson reported the SF-36 score in a group of 40 patients with initial RA followed for two years. At the initial evaluation, patients had lower scores (worse) for all eight domains of the SF-36 when compared to the control group. After two years, patients reported improvement in several domains, including pain and physical function.²¹

Comparison with other cohorts is less feasible when the SF-36 questionnaire is used, when compare to HAQ, since very few prospective studies on patients with early RA using the SF-36 can be found in the literature. Moreover, as the SF-36 is a generic tool, not specific for RA, therefore influenced by other conditions, such as age, gender, socioeconomic status, presence of comorbidities, as well as symptoms of depression and fibromyalgia,²² it becomes difficult to compare scores among different populations.

Uhlig *et al.*²³ and Talamo *et al.*²⁴ published the results of the analysis of the HRQoL in 1,052 patients of the Oslo RA Registry and 137 English patients, respectively. Both reported better performance than our population in six domains of the SF-36, except for “general status” and “vitality”, which had higher scores in the population of the present study. However, neither the Norwegian nor the English studies evaluated patients with initial RA, but rather individuals with established RA (13.8 and 11 years of mean disease evolution, respectively) treated with DMARDs and biological drugs, which makes it difficult to compare them with the initial data of our cohort.

In the present study, all evaluated domains, except for general health status and vitality, showed significant improvement throughout three years of follow-up. The final scores obtained in our cohort were similar to that of the study by Wiles *et al.*²⁵ regarding the fifth year of follow-up of 303 patients with a diagnosis of initial RA of the NOAR cohort.

A study similar to the present one, which evaluated the profile of the evolution of SF-36 domains along time, cannot be found in the literature. In the present study, the different pattern of the domains along the 36 months of follow-up could reflect several impacts of the disease and its treatment on the characteristics evaluated or be attributed to the subjectivity of the responses to the questionnaire, which can be influenced by other aspects.

The population followed in our study showed a greater impact of RA on quality of life, according to the evaluation obtained by the HAQ and SF-36, at the time of the diagnosis, when compared to other studies. On the other hand, a considerable improvement in disability was observed during the first months of treatment, which persisted until the end of the third year. The early treatment of RA, in our cohort, seemed to be associated with improvement in health-related quality of life reported by the patients.

CONCLUSIONS

The population evaluated in the present study presented a great impact of RA on their quality of life, according to the HAQ and SF-36, at the time of the diagnosis, which was greater than that presented by other studies.

In patients with early RA receiving standard treatment for the disease, a significant improvement in quality of life, evaluated by the HAQ and in the majority of the physical health components of the SF-36, except for general health status and vitality, was observed. The early treatment of RA seems to be associated with improvement in health-related quality of life reported by the patients.

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