



Radiographic outcome in Hispanic early rheumatoid arthritis patients treated with conventional disease modifying anti-rheumatic drugs

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ABSTRACT

Objectives: To determine rates of incident erosive disease in early rheumatoid arthritis patients, to identify baseline predictors and to evaluate erosion's impact on patient-reported outcomes.

Methods: 82 patients with ≤ 12 months of disease duration, ≥ 3 years of follow-up and conventional treatment were included. Consecutive evaluations assessed swollen and tender joint counts, treatment and comorbidity, acute reactant-phase determinations and patient-reported outcomes. Digitized radiographs of the hands and feet were obtained at baseline and yearly thereafter. RA was defined as erosive when at least one unequivocal cortical bone defect was detected. Descriptive statistics and Cox regression analysis were performed.

Results: At baseline, 71 of the patients were ♀, population median (range) age was of 38.7 (16–78.2) years, 58 patients had antibodies and all the patients had active disease and substantial disability. Follow-up cohort was of 299.3 person-years. At last follow-up (49 ± 13.8 months), 28 patients developed erosions. Erosion's location was the feet, in 12 patients. Incident rates of erosive disease at one, two, three and four years were of 8.1, 12.8, 13.8 and 5.6 per 100 person-years, respectively. Higher C-reactive protein (HR: 1.20, 95%CI: 1.04–1.4, $p=0.01$) and positive antibodies (HR: 5.09, 95%CI: 1.08–23.86, $p=0.04$) were baseline predictors of incident erosive disease. Erosions had minor impact on patient-reported outcomes. **Conclusion:** Rheumatoid arthritis patients with antibodies and higher C reactive protein at baseline are at risk for incident erosions which appear most frequently at the feet. Up to 1/3 patients conventionally treated develop incident erosions, which minimally impact function.

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1. Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory entity in which the joints of both hands and feet are frequently affected. Joint destruction is the hallmark of the disease and in the majority of the patients it becomes visible after 1–2 years of disease duration [1].

In 2007, the American College of Rheumatology (ACR) proposed a starter set of quality indicators for several rheumatic diseases, among them for RA [2]. Two measures pertinent to treatment were included. One of them states that treatment should be modified when evidence of increased disease activity or of progression of RA bony damage over a 6 months period is identified. Accordingly,

radiological outcomes should be routinely investigated although there is no consensus about how, how often and when. Different imaging methods have been used to assess radiographic damage. Conventional radiography, even with its limitations among which are the lack of visualization of the synovial membrane and the lack of sensitivity in detecting early erosive changes remains the reference standard [3].

A relevant point of routinely detecting patients who develop erosions is that predictors may be identified meanwhile a better understanding of variables that favor better/worse outcomes helps to select patients suitable to particular therapeutic strategies and follow-ups. Several risks factors have been linked to joint destruction [4,5] and it is additionally recognized that joint damage increases with increasing disease activity [6]. Nonetheless, there is a paucity of data obtained from scenario that reflect conditions of daily medical practice where unselected patients, patients with substantial comorbidity and traditional treatment are included as well as from non-Caucasians patients.

The main purpose of the present study was to evaluate radiographic outcomes in Hispanic (self-defined and corroborated by

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their rheumatologist) early RA patients treated with conventional DMARDs in whom standard clinical and radiographic follow-up was performed in an Early Arthritis Clinic. As we were interested in detecting incident erosive disease during the early stages, at least 3 years of continuous clinical and radiographic follow-up at the Clinic were required.

Specific objectives of the study were

1. To determine rates of incident erosive disease in early RA patients with at least 3 years of follow-up.
2. To identify baseline predictors of radiographic damage.
3. To investigate the impact of incident erosive disease on patient-reported outcomes (PROs).

2. Patients and methods

2.1. Study population

The Early arthritis Clinic of the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán, a referral Centre for Rheumatic Diseases in México City was established in February 2004. Patients had rheumatoid arthritis of less than a year of disease duration. Standard follow-up includes 2-monthly-apart clinical evaluations within the first two years and thereafter every 2, 4 or 6 months depending on patients and disease's characteristics. Hand and feet radiographies are scheduled at baseline and thereafter yearly. Up to May 2010, 133 consecutive patients had been evaluated at the Clinic, 9 of them were diagnosed as having a different autoimmune disease than RA, 30 had less than 3 years of scheduled follow-up at the Clinic and 7 were lost to follow-up although their baseline characteristics were similar to the population who completed the study follow-up. Data from patients with either incomplete or insufficient follow-up were excluded from the analysis. Of the remaining 87 early RA patients, 5 patients (6%) had erosive disease when entering the Clinic and their data were also excluded. Finally, information from 82 patients with early RA, at least 3 years of follow-up and non-erosive disease at baseline evaluation was analyzed.

2.2. Clinical evaluations

At baseline, a complete medical history and socio-demographic data were recorded. Rheumatoid factor (RF) and antibodies to cyclic citrullinated peptides (a-CCP) were performed by nephelometry and second generation ELISA, respectively. Standard baseline and consecutive follow-up evaluations consisted of 68 tender and 66 joint counts, patient-reported outcomes (PROs) which included Hispanic versions of the rheumatoid disease activity index (RADAI) [7], the Medical Outcomes Study Short Form 36 (SF-36) [8], the health assessment questionnaire (HAQ) [9] and both pain- and overall disease activity-visual analogue scale (VAS), C reactive protein (CRP) serum levels by nephelometry, erythrocyte sedimentation rate (ESR) determination by the Westergren method and the 28 joints Disease Activity Scoring (DAS28) [10].

2.3. Treatment and comorbidity

At baseline and follow-ups, treatment was recorded on standardized formats and included the use of corticosteroids (yes/no), the use of DMARDs (yes/no) and the number of DMARDs/patient. Comorbidity was established by record review.

Radiographic evaluation: (Digitized, CR900 Direct view, Serie number: 3172897, 120 V, 10 A, Kodak).

Digitized images of radiographs of the hands and feet (posteroanterior and oblique views) were scheduled at baseline and

yearly. Radiographs were read in chronological order by a radiologist and a rheumatologist. RA was classified as erosive (at least one unequivocal cortical bone defect or break) or as non-erosive disease by both physicians after a careful review of radiographs. Disagreement in classification was immediately resolved by consensus.

2.4. Excellent outcomes

They were arbitrarily defined when present and maintained for the last six months of follow-up: RADAI ≤ 1 , SF-36 global, mental and physical scores ≥ 80 , HAQ ≤ 0.20 , visual analogue scales (0–10) ≤ 1 , DAS28 < 2.4 , ESR < 30 mm/h or < 20 mm/h for a female or male, respectively, and CRP ≤ 1.57 mg/dL (according to manufacturer recommendations, Beckman Coulter, Inc.).

2.5. Statistics

Student's *t* test and χ^2 were used for normally distributed variables and Mann–Whitney *U* for non-normally distributed variables.

In order to summarize serial measurements mean of consecutive values from corresponding evaluations was calculated for each patient.

To test the probability of being erosive-free at the end of the follow-up Kaplan–Meier curves were used.

Multivariate Cox proportional hazard models were constructed. The dependent variable was erosive disease at last follow-up: 82 patients completed 3 years of follow-up of whom 56 and 24 patients, respectively, completed the 4 and 5 years follow-up radiographic evaluations, respectively. Their data up to last observation were included in the model. At first, variables that were significant at $p \leq 0.10$ in the bivariate analysis were entered into the multivariate model. Correction was additionally performed for potential confounders. Correlation between variables was examined. All statistical tests were 2-sided and evaluated at the 0.05 significance level. Statistical analysis was performed using the SPSS/PC program (v.12.0; Chicago, IL).

2.6. Ethics

Patients agreed to participate in the EAC and approved clinical and radiological assessments. Treatment was prescribed by the rheumatologist in charge of the Clinic according to the characteristics of the patients and/or the disease. The appropriated ethical approval was granted from the Institutional Review board of the Instituto Nacional de Ciencias Médicas y Nutrición Salvador Zubirán. Written informed consent was signed by all the patients. The study was conducted according to the guidelines of the Declaration of Helsinki.

3. Results

3.1. Characteristics of the study population (Table 1)

At baseline, most of the patients were female ($N = 71$, 86.6%), had positive RF ($N = 62$, 75.6%), positive a-CCP ($N = 58$, 71.6%) and were never smokers (58, 70.7%). Their median (range) age was of 38.7 (16–78.2) years, disease duration of 4.9 (0.5–12.5) months and number of RA ACR 1987 criteria of 5 (1–7). The population had active disease as median (range) DAS28 was of 6.4 (3.1–8.6), ESR of 24 (2–105) mm/h and CRP of 1.2 (0–14.7) mg/dL. Table 1 shows that at study entry, the disease had a substantial burden on patient-reported-outcomes although median comorbidity/patient was low: 0 (0–4). When referred to the Clinic, 25 patients (30.5%) were receiving corticosteroids and 32 (39%) DMARDs and proportions were similar between erosive and non-erosive patients.

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