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Original article

Performance of the American College of Rheumatology/European League Against Rheumatism 2010 criteria for the diagnosis of rheumatoid arthritis in Chinese patients

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ABSTRACT

Objectives: To evaluate the ability of American College of Rheumatology (ACR) 2010 classification criteria to diagnose rheumatoid arthritis (RA) compared to the widely used ACR 1987 criteria in Chinese patients.
Methods: Four hundred and four patients suffering from arthritis were included in the study. Two hundred and twenty-one of them were classified as RA patients and 183 had alternative diagnoses. The patients were further subdivided into three groups according to their disease duration of within one year, one to two years or more than two years. The diagnostic value of ACR/EULAR 2010 criteria for RA was evaluated by comparing the sensitivity and specificity with those of ACR 1987 criteria in these patients.
Results: The sensitivity and specificity of ACR/EULAR 2010 criteria for diagnosing RA were 95% and 92.9%, respectively. In contrast, the sensitivity and specificity of ACR 1987 criteria were 81.4% and 92.9%, respectively. The efficacy of ACR/EULAR 2010 criteria was superior to the ACR 1987 criteria by comparing their area under the curves (AUC) (0.940, 95% CI [0.912, 0.967] vs. 0.872, 95% CI [0.835, 0.909]). The recognition accuracy of ACR/EULAR 2010 criteria was higher than that of ACR 1987 criteria (94.5% vs. 86.6%, $P < 0.05$). Inter-rater analysis showed that agreement of the two criteria was substantial (Kappa = 0.744, $P < 0.001$). For patients with disease duration within one year, one to two years and over two years, the sensitivities of ACR 1987 criteria were 69.2%, 81.3% and 89.9%, while the specificities were 94.4%, 90.6% and 92%, respectively. The corresponding sensitivities of ACR/EULAR 2010 criteria in these patients were 91%, 93.8% and 98.2%, while the corresponding specificities were 94.4%, 96.6% and 89.3%, respectively. The advantage of ACR/EULAR 2010 criteria over 1987 criteria in higher sensitivity was remarkable particularly in patients with disease duration within one year ($P < 0.001$).
Conclusions: The ACR/EULAR 2010 criteria is more accurate in RA diagnosis compared to the ACR 1987 criteria by elevating the sensitivity while preserving the specificity, especially in patients with disease duration within one year. The ACR/EULAR 2010 criteria may serve as new diagnostic tools in daily clinical practice.

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1. Introduction

Over the past decades, managements of rheumatoid arthritis (RA) have been dramatically enhanced. The benefits of early aggressive therapy have been confirmed to improve clinical outcomes as well as disease-associated joint damage, disability, morbidity [1–3] and, potentially mortality Therefore, it is important to have classification criteria which could, at an early stage of the disease, determine the diagnosis of RA or predict the arthritis with chronic and erosive nature, thus allowing a rapid and early introduction of therapeutic strategies and medications. The main criteria used in RA are the American College of Rheumatology (ACR) 1987 revised criteria. However, although the ACR 1987 classification criteria were demonstrated good performance in established disease, they were not best adapted to diagnose RA at an early stage. These criteria were not developed for diagnostic purposes and some of the criteria are rarely fulfilled in the first year after the onset of RA and may therefore lack sensitivity in early RA [4–8]. Thus, to classify such individuals with short disease durations, a joint working group of ACR and the European League Against Rheumatism (EULAR) therefore developed a new approach for classification of RA in 2010. The specific aim of the new criteria was to elevate the diagnostic ability especially the sensitivity and facilitate the study of patients at earlier stages of RA before joint imaging can reveal erosions and deformations [9,10].

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The question arises as to which components of the new criteria improved performance over the prior 1987 criteria. Do the new criteria usher in a new era in the approach to the diagnosis and treatment of RA? As in the case with any dramatic improvement in diagnostic sensitivity, it is doubted that there is a potential for a corresponding loss of specificity. In the case of the new RA criteria, there is a risk that those who would never progress to persistent or destructive RA may be prematurely classified and, thus, exposed to unnecessary and potentially toxic therapies.

The new criteria had been published for identifying RA patients at early stage. However, they had not been applied widely for their sensitivity, specificity and the practical evaluation had not been elucidated clearly. The development of the 2010 ACR/EULAR criteria comprised three phases. The first was a data-driven phase using findings in 3115 patients from Europe and Canada. The second phase incorporated the expertise of 39 rheumatologists, and the third phase was a consensus phase undertaken by the same group [10–12]. However, before use in practice the discriminative abilities of such algorithms should be tested in other cohorts with similar patients as to assure the feasibility for application. In addition, it is unclear how the 2010 criteria behave compared to the 1987 criteria.

Several recent studies had evaluated the performance of the 2010 criteria and confirmed the higher sensitivity (73%–91%) and lower specificity (48%–71%) compared to the 1987-criteria [13–17]. Although the sensitivity is reasonable to classify early RA, the specificity is questionable, because 26–40% of patients with early arthritis may be misclassified as having RA [18]. These data came from the Dutch, the English and the Japanese. However, there is no data from Chinese patients up to present. The aim of this study is to evaluate the ability of ACR/EULAR 2010 classification criteria to diagnose RA compared to the widely used ACR 1987 criteria in a cohort of Chinese patients.

2. Methods

2.1. Patients and data

Patients who had arthritic complaints and visited the Department of Rheumatology and Clinical Immunology, Peking University First Hospital between January of 2009 and December of 2009 were screened. When the patients had at least one joint with definite clinical synovitis (swelling) at physical examination the medical documents were collected by the rheumatologist. At the first visit, clinical characteristics of the patients were reviewed, including gender, age, joints involvement, duration of arthritis symptom, morning stiffness, rheumatoid nodules, smoking status, etc. The 2010 ACR/EULAR criteria and ACR 1987 criteria were performed at inclusion. All the patients were followed up for at least one year. At inclusion, if the diagnosis was confirmed, therapies were performed. DMRADs were prescribed for patients diagnosed as RA. For patients whose diagnoses were not identified, only NSAIDs were prescribed to relieve the symptoms.

Physical examination, radiographs as well as laboratory tests were performed. C reactive protein (CRP), erythrocyte sedimentation rate (ESR), IgM-rheumatoid factor (RF) and ACPA (anticitrullinated protein/peptide antibodies) [anti-CCP2 (cyclic citrullinated peptide)] were tested. RF was detected by immunonephelometry method with the cut-off value of 30 IU/mL. Anti-CCP antibodies were tested by using the second generation ELISA kit (Euroimmun, Germany) and the cut-off value was 5 RU/mL. The radiographs of both hands were performed and interpreted by the Radiologists from Peking University First Hospital. As a classifier for correct diagnosis two outcomes were evaluated at one year: the use of methotrexate and persistent disease, defined as synovitis present at physical examination after one year, or the use of disease-modifying antirheumatic drugs (DMARD) including biological agents. Patients with a definite alternative diagnosis such as gout were not classified as persistent disease.

2.2. Analysis

The 2010 ACR/EULAR criteria were applied as described by Aletaha et al. [9,10]. We used the 66-swollen joint count and 68-tender joint count. According to the guideline, the distal phalangeal joints, 1st carpo-metacarpal joint and 1st metatarso-phalangeal joints were excluded from assessment. Involvement of interphalangeal joints of the feet was considered as small joint involvement. The cut-off value for RF in our cohort is 30 IU/mL, therefore a level $\geq$ 90 IU/mL was considered as high-positive. Similarly, the cut-off value for anti-CCP-2 is 5 RU/mL in our cohort and a level of $\geq$ 15 RU/mL was considered as high-positive. According to the reference values, an abnormal CRP was defined as $\geq$ 8 mg/L, and an abnormal ESR was $\geq$ 20 mm/hr for females and $\geq$ 15 mm/hr for males. The patients were further subdivided into three groups according to their disease duration. Patients with disease duration within one year were defined as group A, one to two years as group B and over two years as group C. In addition, they were also subdivided into two groups according to having morning stiffness or not.

Then the following analysis was performed. The baseline clinical, laboratory and radiographic data of all patients with arthritis were studied and the proportions of patients that were classified as RA according to the 2010 criteria and the 1987 ACR-criteria were calculated, respectively. It was assessed whether patients diagnosed as RA by using the 1987 ACR criteria fulfilled the 2010 criteria as well. The sensitivity and specificity of the 1987 criteria and 2010 criteria were determined and their differences were compared. The area under the receiver operator characteristic curve (AUC) of the two criteria was calculated and compared. The accuracy rate of the two criteria was compared. Consistency test was performed to evaluate the diagnostic efficacy of the two criteria. The sensitivity and specificity of the two criteria applied in each subgroup were also evaluated and compared, respectively.

The study protocol was approved by the Medical Ethics Committee of Peking University First Hospital.

2.3. Statistics

Data analysis was performed using SPSS for Windows software, version 10.0. c2 analysis was performed to compare the accuracy. *Z* test was performed to compare the area under the curves (AUC) of the two criteria. The inter-rater reliability statistics were used to test the agreement of the two criteria. *P* value less than 0.05 was considered significant.

3. Results

3.1. Patients

Four hundred and four patients who visited our clinic and suffered from arthritis were included in the study. By the baseline data analysis, after follow up for one year, 221 were diagnosed as RA and 183 had alternative diagnoses. The demographic and clinical features of patients of each group were shown in Table 1. Two hundred and sixty-nine of them were females (66.6%) and 135 were males (33.4%). The gender constitution was comparable between RA and non-RA patients (female/male = 163/58 in RA patients vs. 106/77 in non-RA patients, $P > 0.05$). There was no significant difference in terms of age between RA patients and non-RA patients (47.4 vs. 51.7, $P > 0.05$). The median disease duration was 24 (0.1–600)

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