Evolution of Classification Criteria for Rheumatoid Arthritis: How Do the 2010 Criteria Perform?

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KEYWORDS

• Rheumatoid arthritis • Classification criteria
• Inflammatory arthritis • Guidelines

Key Points

- The classification criteria for rheumatoid arthritis (RA) have undergone a substantial evolution since the 1950s.
- The 1987 revised criteria for rheumatoid arthritis (RA) lead to improved performance and more confidence in correct classification compared with the 1958 criteria.
- The 2010 criteria were created with a focus to facilitate study of subjects at earlier stages in the disease.
- The data show that the new 2010 American College of Rheumatology-European League Against Rheumatism criteria identify patients with RA at an earlier point in their disease course.
- The new 2010 criteria create a more heterogeneous group of patients now classified as having RA, including patients with self-limiting disease or other arthritides, and can lead to overtreatment.

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INTRODUCTION AND HISTORICAL PERSPECTIVE

In the past two decades the identification and management of rheumatoid arthritis (RA) has changed multiple times. Gone are the days of managing end-stage joints and long-term prednisone use complications. Now, early, almost subclinical, identification of RA is sought out and aggressive combination therapy is the norm. RA is a chronic systemic autoimmune disorder that leads to synovial inflammation, progressive joint erosions, and eventual disability. The American Rheumatism Association (ARA), the precursor to the American College of Rheumatology (ACR), first proposed classification criteria for RA in 1956. Eleven criteria with 19 exclusions were proposed and resulted in three categories: definite, probable, and possible RA.[1] Two years later, in an effort to increase specificity, the ARA added the category classic RA, further complicating matters. These criteria were developed from the experiences of five committee members, review of recent epidemiologic data at that time, and analysis of 332 cases provided by interested physicians from around the United States and Canada. In 1966, the New York Criteria were developed at the Third International Symposium on Populations Studies of the Rheumatic Disease. The New York Criteria were more specific; however, they were also more cumbersome and never gained wide acceptance. The 1956 classification criteria were used for almost 30 years, standardizing the vocabulary and allowing research results to be more easily compared. The criteria helped foster better communication between physicians and enabled more effective teaching. The use of the 1956 classification criteria was generally supported; however, there were some observed problems. In practice there was little difference between definite and classic RA and many patients who were labeled probable RA were ultimately found to have a different disease. The various exclusions were though to be burdensome and three of the criteria required invasive procedures, such as mucin clot, nodule biopsy, and synovial biopsy.[1]

Almost 30 years later, the clinical and biochemical knowledge of RA has expanded exponentially. The shortcomings of the 1956 diagnostic criteria became apparent and the criteria were viewed as old-fashioned. The ARA again appointed a subcommittee of the Diagnostic and Therapeutic Criteria to review and revise the criteria. Subjects with RA, as well as subjects without RA (controls), were studied and the then-current ARA classification criteria were dissected. Numerous disease discriminators were studied, such as morning stiffness, pain and swelling of various joints, nodules, and laboratory and radiographic findings, and their sensitivity and specificity were calculated. Shortly thereafter, the 1987 revised criteria were established. The revisions kept five of the original 1958 ARA criteria and provided more precise definitions for several others (**Table 1**).[1] The explicit definitions of criteria that were provided lead to improved performance and ultimately more confidence in a correct classification. These new criteria performed better than both the 1958 ARA and the New York Criteria and simplified classification because it eliminated the need for extensive radiographs and invasive procedures. The classification subcategories were dropped and definite and classic RA were relabeled as simply RA. The term probable RA was exchanged for terms such as undifferentiated polyarthritis, undifferentiated oligoarthritis, or undifferentiated monoarthritis, and the lengthy list of exclusions, previously part of the 1958 criteria, was dropped. Although it was debated that this might lead to misclassification of patients with other diseases, such as systemic lupus erythematosus, polymyalgia rheumatica, Sjögren syndrome, and HLA-B27–associated spondyloarthropathy, the advantage to eliminating this onerous list was felt to outweigh this possible risk.

A NEW AGE

Another 20 years passed and, again, rheumatologists found themselves dealing with out-of-date classification criteria. Although the 1987 criteria were not meant to be

Table 1
Comparison of 1987 and 1958 classification criteria for RA

1987	1958
Morning stiffness in and around joints for at least 1 h	Morning stiffness
Soft tissue joint swelling observed by physician in at least 3/14 joint groups (Right or left: MCP, PIP, wrist, elbow, knee, ankle, MTP)	Swelling of a joint
Symmetric swelling of one joint area	Swelling of another joint
Rheumatoid nodule	Pain on movement or tenderness in a joint
Rheumatoid factor by method positive in <5% normal population	Symmetric swelling
Radiographic changes in wrist or hands: erosions or juxtaarticular osteoporosis	Rheumatoid nodule
—	Rheumatoid factor
—	Radiographic changes
—	Mucin clot
—	Synovial biopsy
—	Nodule biopsy
RA: 4/7	Classical RA: 7/11 Definite RA: 5/11 Probable RA: 3/11

Abbreviations: MCP, metacarpalphalangeal; MTP, metatarsalphlangeal; PIP, proximal interphalangeal.

Data from Silman AJ. The 1987 revised American rheumatism association criteria for rheumatoid arthritis. Br J Rheumatol 1988;27(5):341–3.

used for diagnosis, in the rheumatology community these criteria were largely deemed the gold standard for the diagnosis of RA. In the past two decades, rheumatologists again had an exponential growth in their knowledge of RA. Studies emerged, highlighting the effectiveness of early, aggressive, combination therapy. For the first time, remission of disease was a realistic therapeutic goal and the need to uniformly identify patients in the earliest stage became imperative. Korpela and colleagues[2] with the FIN-RACo (Finnish Rheumatoid Arthritis Combination Therapy) Trial Group found that aggressive initial treatment with methotrexate, sulfasalazine, hydroxychloroquine, and prednisolone resulted in more rates of remission and less peripheral joint radiographic damage when compared with disease-modifying antirheumatic drug (DMARD) monotherapy. This group found that aggressive treatment early in a subject's course was key. Verstappen and colleagues[3] confirmed this idea with the CAMERA (Computer Assisted Management in Early Rheumatoid Arthritis) trial. This group demonstrated intensive treatment in early RA (<1 year) resulted in higher rates of remission when compared with more conventional treatment. Verstappen and colleagues[3] used frequent visits and standardized criteria to aggressively titrate medications early in the disease course and found this resulted in lower inflammatory markers and decreased morning stiffness and tender and swollen joints. The BeST (Behandel-Strategieën) Study challenged previous paradigms of treatment algorithms by evaluating the effectiveness of four different treatment strategies: sequential DMARD monotherapy, step-up combination therapy, initial combination therapy with tapered high-dose prednisone, and initial combination therapy with the tumor

necrosis factor antagonist infliximab. Goekoop-Ruiterman and colleagues[4] found that initial combination therapy, with either prednisolone or infliximab, was superior to monotherapy and the step-up combination treatment strategy in function and Health Assessment Questionnaire scores. These studies, and others, emphasized the idea of a window of opportunity to drastically alter the course of the disease for a patient with aggressive, early therapy.

As in 1983, at the beginning of the new millennium the pitfalls of the 1987 ARA classification criteria were becoming apparent. One pitfall was that early disease was often not appropriately identified.[5] From France, Saraux and colleagues[6] evaluated at the ability of the 1987 criteria to correctly predict the diagnosis of RA in a cohort of subjects with arthritis followed for 2 years. Using the opinion of a panel of five rheumatologists as the gold standard of an RA diagnosis, they evaluated the specificity and sensitivity of the 1987 criteria at a subject's initial visit as well as 2 years later. They found that the 1987 criteria were not as effective at predicting a diagnosis of RA 2 years later, thus making these criteria limited in identifying early disease.[6] They further evaluated each criterion and how well it performed (**Table 2**). Not surprisingly, criteria such as rheumatoid nodules and radiographic changes had a low sensitivity but high specificity for the diagnosis of RA at the initial visit. This was not unexpected because many patients do not exhibit these findings early in their disease course.

NEW CRITERIA EMERGE

As new therapies were introduced and aggressive approaches were becoming more common, there was a growing need for clinical trials focusing on early RA. However, this was hampered by the lack of validated and accepted uniform criteria that reliably identify RA in the early stages. A joint working group of the ACR and the European League Against Rheumatism (EULAR) was formed to develop new criteria specifically for this reason. The focus was not to develop diagnostic criteria but to formulate new classification criteria to facilitate the study of subjects at earlier stages in the disease. This working group set out to develop a set of rules that would identify the subset of subjects at high risk for chronicity and erosive damage, be used as a basis for initiating DMARDs, and would not exclude those later in the disease course.[7] Through a three-phase approach, the joint working group studied and evaluated data on thousands of subjects, identifying variables and their contribution to a diagnosis of RA. A set of new classification criteria based on a scoring system was produced. The criteria can be used at any point in the patient's disease course. Although there are no exclusion criteria, it is noted that these criteria are meant to be used in the proper clinical setting (ie, when there is objective evidence of joint swelling).

PUTTING THE NEW CRITERIA TO THE TEST

Armed with new criteria, the rheumatology world has set forth to evaluate their performance and compare them to the previous model (**Table 3**). In Amsterdam, Britsemmer and colleagues[8] used the 2010 criteria on a cohort of subjects from the early arthritis cohort at the Jan van Breeman Institute. This cohort was made of up individuals older than 18 years of age with at least two swollen joints for less than 2 years who were DMARD naïve. Patients with osteoarthritis, crystal arthropathy, spondyloarthritis, systemic lupus erythematosus, Sjögren syndrome, and infectious arthritis were not a part of the cohort. The subjects were classified using the 2010 criteria as well as the 1987 criteria and the initiation of methotrexate was considered the gold standard for a diagnosis of RA. The investigators found that the 2010 ACR-EULAR criteria had a high sensitivity when compared with the 1987 ACR criteria, 0.85 versus 0.76,

Table 2
The 2010 ACR-EULAR classification criteria for RA

	Score
Target population (who should be tested?)	—
1. Patients who have at least 1 joint with definite clinical synovitis (swelling)[a]	—
2. Patients with the synovitis not better explained by another disease[b]	
Classification criteria for RA (score-based algorithm: add score of categories A-D; a score of ≥6/10 is needed for classification of a patient as having definite RA)[c]	—
A. Joint involvement[d]	
1 large joint[e]	0
2–10 large joints	1
1–3 small joints (with or without involvement of large joints)[f]	2
4–10 small joints (with or without involvement of large joints)	3
>10 joints (at least 1 small joint)[g]	5
B. Serology (at least 1 test result is needed for classification)[h]	
Negative RF and negative ACPA	0
Low-positive RF *or* low-positive ACPA	2
High-positive RF *or* high-positive ACPA	3
C. Acute-phase reactants (at least 1 test result is needed for classification)[i]	
Normal CRP *and* normal ESR 0	0
Abnormal CRP *or* normal ESR 1	1
D. Duration of symptoms[j]	
<6 wk	0
≥6 wk	1

Abbreviations: ACPA, anticitrullinated protein antibody; CRP, C-reactive protein; ESR, erythrocyte sedimentation rate.

[a] The criteria are aimed at classification of newly presenting patients. In addition, patients with erosive disease typical of RA with a history compatible with prior fulfillment of the 2010 criteria should be classified as having RA. Patients with long-standing disease, including those whose disease is inactive (with or without treatment) who, based on retrospectively available data, have previously fulfilled the 2010 criteria should be classified as having RA.

[b] Differential diagnoses differ in patients with different presentations, but may include conditions such as systemic lupus erythematosus, psoriatic arthritis, and gout. If it is unclear about the relevant differential diagnoses to consider, an expert rheumatologist should be consulted.

[c] Although patients with a score of less than 6 out of 10 are not classifiable as having RA, their status can be reassessed and the criteria might be fulfilled cumulatively over time.

[d] Any swollen or tender joint on examination, which may be confirmed by imaging evidence of synovitis. Distal interphalangeal joints, first carpometacarpal joints and first metatarsophalangeal joints are excluded from assessment. Categories of joint distribution are classified according to the location and number of involved joints, with placement into the highest category possible based on the pattern of joint involvement.

[e] Shoulders, elbows, hips, knees and ankles.

[f] The metacarpophalangeal joints, proximal interphalangeal joints, second to fifth metatarsophalangeal joints, thumb interphalangeal joints and wrists.

[g] At least one of the involved joints must be a small joint; the other joints can include any combination of large and additional small joints, as well as other joints not specifically listed elsewhere (eg, temporomandibular, acromioclavicular, sternoclavicular).

[h] International unit (IU) values that are less than or equal to the upper limit of normal (ULN) for the laboratory and assay. Low-positive are IU values that are higher than the ULN but three or less times the ULN for the laboratory and assay. High positive are IU values that are more than three times the ULN for the laboratory and assay. When rheumatoid factor (RF) information is only available as positive or negative, a positive result should be scored as low-positive for RF.

[i] Normal or abnormal is determined by local laboratory standards.

[j] Patient self-report of the duration of signs or symptoms of synovitis (eg, pain, swelling, tenderness) of joints that are clinically involved at the time of assessment, regardless of treatment status.

Data from Aletaha D, Neogi T, Silman AJ, et al. 2010 Rheumatoid arthritis classification criteria: an American College of Rheumatology/European league against rheumatism collaborative initiative. Ann Rheumatic Dis 2010;69:1580–8.

Table 3
The sensitivity and specificity of the 2010 ACR-EULAR classification criteria for RA

Study	Number of Patients	Gold Standard for RA Diagnosis, Outcomes Used[a]	Sensitivity	Specificity
Van der Linden et al[12,b]	2258	1. Initiation of methotrexate within 1st y 2. Initiation of DMARD within the 1st y 3. Persistence of arthritis in those followed for 5 y	1. 0.84 2. 0.74 3. 0.71	1. 0.60 2. 0.74 3. 0.65
Cader et al[9]	265	1. DMARD use 2. Methotrexate use	1. 0.62 2. 0.68	1. 0.78 2. 0.72
Britsemmer et al[8]	455	1. Methotrexate treatment within first y 2. Expert opinion 3. Erosive disease at 3 y	1. 0.85 2. 0.90 3. 0.91	1. 0.5 2. 0.48 3. 0.21
Varache et al[14]	270	Combination of opinion of office-based rheumatologist and treatment with DMARD or glucocorticoid at 2 y	0.51	0.90
de Hair et al[11]	301	Meeting 1987 criteria after 2 y of follow-up	0.88	0.76

[a] Direct comparison of studies is difficult as there is no true gold standard for the diagnosis of RA and each study used a different method to confirm diagnosis.
[b] Used in the development of the ACR-EULAR 2010 Classification Criteria for Rheumatoid Arthritis.

respectively. The new criteria do carry with it a higher risk of false positives, which could lead to unnecessary exposure to toxic DMARDs.[8]

A second group, from The University of Birmingham, also sought to investigate the criteria. Selecting subjects from the early inflammatory arthritis clinic at Sandwell and West Birmingham Hospitals National Health Service Trust, Cader and colleagues[9] studied subjects with less than 3 months of synovial swelling. The investigators found the 2010 criteria identified more subjects at baseline as RA when compared with the 1987 criteria. The new criteria identified more subjects that would go on to use DMARD therapy, especially methotrexate, with a sensitivity of 0.68 (2010 criteria) versus 0.42 (1987 criteria).[9] Interestingly, this group also showed 26% of those who met only the 2010 criteria at baseline went on to have disease resolution without DMARD therapy over an 18-month follow-up period. This supports the notion that early aggressive treatment in some individuals will lead to over treatment in others.

In Amsterdam, these findings were replicated in a cohort of subjects with early arthritis who were DMARD naïve.[10] The 1987 and the 2010 classification criteria were used with this cohort, using fulfillment of the 1987 criteria at 2 years as the gold standard for an RA diagnosis. Of those subjects that would have been classified as having undifferentiated arthritis using the 1987 criteria, 85% fit the 2010 criteria for RA at baseline. The investigators also found high level subjects who were false positive among those who initially fit the 2010 criteria. These subjects were characterized as having high rates of monoarthritis, negative IgM-rheumatoid factor (RF) and anticitrullinated protein antibody (ACPA), and they had self-limiting disease at 2-year follow-up.[10]

Although many of the subjects in the Leiden Early Arthritis Clinic cohort were used in the development of the 2010 criteria, a larger number from this cohort were studied to determine if the new 2010 criteria could identify subjects in an earlier stage when

compared with the 1987 criteria.[11] Over 2000 subjects were studied and outcome measures included use of methotrexate within the first year, use of any DMARD within the first year, and persistence of arthritis at 5 years. Within this cohort, 68% of subjects who did not meet the 1987 criteria at baseline but did 1 year later meet the 2010 criteria at baseline. However, similar to the other studies, using only the 2010 criteria would have misclassified 9.4% of the subjects as having RA.[11] Although this does not validate the use of the 2010 criteria because many of the subjects were the same as those used in the development of the criteria, it does support what other cohort studies have demonstrated. The new criteria do detect disease at an earlier stage with the sacrifice of misclassifying patients with some with milder, self-limiting disease. From South Korea, Jung and colleagues[12] found that when subjects did not fulfill the 2010 criteria it was mostly because of a lack of RF and/or cyclic citrullinated peptide, or too few affected joints.

From Brittany, France, Varache and colleagues[13] sought to evaluate not only the effectiveness of the ACR-EULAR 2010 criteria and compare it to the ACR 1987 criteria, but also attempted to establish whether a scoring system using a combination of factors would improve specificity and sensitivity for an RA diagnosis. This group used a cohort of 270 subjects with greater than one joint synovitis for less than 1 year and followed these subjects for 2 years. As a gold standard for the diagnosis of RA, these investigators used a combination of an office-based rheumatologist's opinion and treatment with a DMARD and/or glucocorticoid after 2-year follow-up. From the original cohort of 270 subjects, there was a large proportion (111) that had an alternate diagnosis at baseline, leaving 143 subjects to be scrutinized. Using the 2010 ACR-EULAR criteria, 42.2% of those who did not meet the new criteria (scores $\leq$6) went on to have RA at the end of 2 years, whereas 75.6% of those with scores greater than 6 had confirmed RA after 2 years. Although the 2010 criteria did perform slightly better when compared with the 1987 criteria, there was no statistically significant difference in diagnostic accuracy between the two criteria sets. This was true when applied to their overall cohort as well as when applied to a subgroup of subjects having synovitis, no radiographic evidence of RA, and no other likely diagnosis. Varache and colleagues[13] then went on to evaluate each criterion and found that the addition of symmetric joint involvement increased accuracy. It was also found that the most significant difference adding to any improvement seen with the 2010 criteria when compared with the 1987 criteria was the exclusion of subjects with an alternate diagnosis.

A NEW FACE

With the earlier identification of RA it does beg the question, what will undifferentiated arthritis look like? From the Netherlands, Krabben and colleagues[14] studied subjects identified as having undifferentiated arthritis from their Leiden Early Arthritis Clinic and applied the 2010 criteria to them. The 2010 criteria were applied to 1696 subjects with either undifferentiated arthritis or RA and 776 subjects with 2010 undifferentiated arthritis. When compared with the previously labeled subjects with undifferentiated arthritis or the 1987 undifferentiated arthritis patients, the 2010 subjects with undifferentiated arthritis were found to have overall milder disease with fewer swollen and tender joints and less frequent positive autoantibodies (RF and ACPA).[14] After 1 year of follow-up, a DMARD was initiated more often in the 1987 undifferentiated arthritis group and DMARD-free remission was achieved more often in the 2010 undifferentiated arthritis group. This implies that previously labeled undifferentiated arthritis are now being classified as RA using the 2010 criteria. Zeidler[15] reviews the results from six recent studies, evaluates the performance of the 2012 ACR-EULAR RA

criteria, and likewise concludes that there is a significant risk for misclassification in early and very early RA.

BEYOND RA

The data show that the 2010 ACR-EULAR criteria identify patients as RA at an earlier point in their disease course. Many of these patients go on to require DMARD or biologic therapy. On the other hand, the new criteria create a more heterogeneous group of patients now classified as RA, including patients with self-limiting disease or other arthritides. Classifying a patient as having RA, who in actuality has a self-limiting disease, can potentially lead the patient to undergo unnecessary exposure to a toxic medication. There exists the possibility of misclassifying a patient as having RA who, in fact, should have a different diagnosis such as systemic lupus erythematosus, spondyloarthropathy, Sjögren syndrome, or a crystal-induced arthropathy. As previously discussed, many studies have been performed to evaluate the performance of the 2010 criteria using early arthritis cohorts that tend to exclude subjects with other inflammatory arthritides. One of the daily dilemmas for a practicing rheumatologist is to identify, then classify the type of inflammatory arthritis occurring in an afflicted patient. Although the 2010 criteria may allow a rheumatologist to identify a patient with RA earlier in the disease course, it is unclear whether these criteria can aid in distinguishing between the various other inflammatory arthritides. It is possible that imaging modalities, such as MRI and musculoskeletal ultrasound, can be used to increase sensitivity and specificity of the criteria.[16] These modalities are already being put to use in clinical practice and are likely to grow in popularity. In Iran, Salehi and colleagues[17] have designed the Iran Criteria for Rheumatoid Arthritis. These criteria include erosions found with MRI as one of its criteria and have found it to be successful. The investigators purport that their criteria is more sensitive in detecting RA patients in the early stages of the disease.

RA is a chronic, inflammatory, autoimmune arthritis that leads to symmetric articular synovitis, articular damage, and physical disability. Not all patients with RA are alike. Patients with RA are a heterogeneous group of people, each with their unique challenges. Classification criteria are created in an attempt to produce a homogenous group of patients that can then be used as subjects for clinical and basic science research. With the development of the new 2010 ACR-EULAR Classification Criteria for Rheumatoid Arthritis, a different population of subjects than those has previously investigated will be studied. Rheumatologists in clinical practice are not limited only to classification criteria for diagnosis of RA. Their clinical acumen and sophisticated imaging modalities guide their judgment. Because the utility of the 2010 criteria will undoubtedly continue to be assessed, the longevity of the 2010 criteria remains to be determined.

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