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CLASSIFICATION CRITERIA SETS FOR RHEUMATOID ARTHRITIS: HISTORICAL PERSPECTIVE AND CLINICAL IMPLICATIONS

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Abstract

The classification criteria for rheumatoid arthritis (RA) have undergone significant evolution since their inception, a process driven by the need to address evolving clinical requirements and shifting research priorities. To comprehensively review the historical development, comparative strengths, and limitations of major RA classification criteria sets, with emphasis on their clinical and research applications. A narrative review of the literature was conducted, examining the 1956 diagnostic criteria, 1987 American College of Rheumatology (ACR) classification criteria, 2010 ACR/European Alliance of Associations for Rheumatology (EULAR) classification criteria, and early RA classification frameworks. The 1956 criteria established the first standardized approach but presented implementation challenges. The 1987 ACR criteria demonstrated excellent specificity (87-94%) for established disease but limited sensitivity (47-58%) for early disease. The 2010 ACR/EULAR criteria resulted in a marked improvement in the early detection of disease, with higher sensitivity (62-91%) but a reduction in specificity (21-78%). Recent early RA classification frameworks have attempted to balance sensitivity (85-86%) and specificity (87-88%) specifically in early disease presentations. It is evident that each set of criteria exhibits distinct advantages, contingent on factors such as disease duration, patient population characteristics, and research objectives. Understanding the evolution and appropriate implementation of RA classification criteria is essential for both clinical research and practice. While the 2010 criteria represent significant advancement in early identification, challenges remain for seronegative patients. Incorporating imaging and novel biomarkers may further enhance classification accuracy in ambiguous presentations.

Keywords: Rheumatoid arthritis, classification criteria, American College of Rheumatology criteria, European Alliance of Associations for Rheumatology criteria, early diagnosis, seronegative arthritis

INTRODUCTION

Rheumatoid arthritis (RA) represents a chronic, inflammatory, autoimmune disease that leads to symmetrical synovitis, joint damage, and disability. RA is a heterogeneous disease with unique challenges and management for each patient. Various studies have reported its incidence between 0.1 to 0.5 per thousand and the prevalence between 10 to 18 per thousand (1). It is impossible to completely treat this disease, which can lead to disabilities and impair quality of life, under today's conditions. However, it has been demonstrated that early therapeutic interventions and new treatment agents introduced recently improve clinical outcomes and reduce joint damage and disability (2).

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Although diagnostic and classification criteria may comprise the same type of clinical, laboratory, or other markers, they have different purposes. Classification criteria aim to provide homogeneity among patients in epidemiological and clinical studies (Figure 1). These treatments must be applied to diagnosed patients and ideally have high specificity. In this way, individuals without disease will not be misclassified. Classification criteria must provide a binary answer (yes/no). On the contrary, diagnostic criteria make it easier for clinicians to establish a diagnosis in an individual patient. Ideally, diagnostic criteria must have a high positive predictive value and estimate the probability of a disease.

Since RA has a complex clinical picture, it requires a common definition that can classify patients for epidemiological and clinical studies. There are no RA diagnostic criteria that can be used. Moreover, classifying a patient who actually has a self-limiting disease as having RA can potentially lead to unnecessary long-term exposure to a toxic drug. Hence, it is recommended that classification criteria be employed more in epidemiological and clinical studies and not in diagnosis.

The objective of this review is to examine the historical evolution of RA classification criteria, to assess their strengths and limitations across various clinical scenarios, and to explore their implications for research methodology and clinical practice. A particular emphasis is placed on the challenges associated with the early identification and classification of seronegative patients, where existing frameworks exhibit significant limitations.

Revised 1956 Diagnostic Criteria for Rheumatoid Arthritis

The American Rheumatism Association [under the new name of the American College of Rheumatology (ACR)] first developed the RA diagnostic criteria set in 1956 (3). The 1956 criteria classified patients as definite, probable, and possible. The classic RA class was added to this classification criteria set revised in 1958 (4).

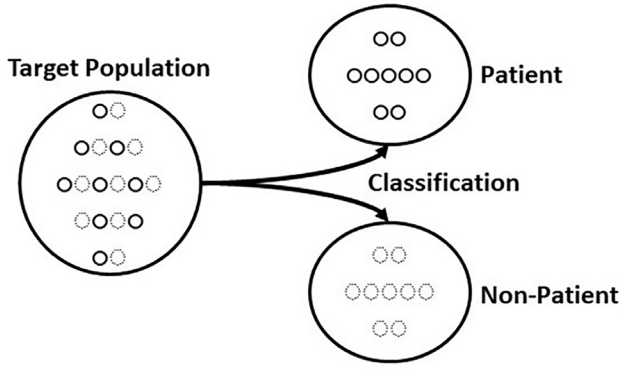

Figure 1. The primary objective of establishing classification criteria is to classify the target population into patients and non-patients

The presence of 7 of the 11 criteria, at least one of which was among the joint findings in the first five items, and the symptoms continuing uninterruptedly for at least 6 weeks were required for a classic RA diagnosis (Table 1). The presence of at least 5 criteria (at least one of which was one of the joint findings in the first five items) and the symptoms continuing uninterruptedly for a minimum of 6 weeks were required for a definite RA diagnosis. The presence of at least 3 criteria and the symptom duration of at least 6 weeks were required for a probable RA diagnosis. Separate criteria were established for a probable RA diagnosis. In the classification criteria, 20 different conditions were determined as exclusion criteria (other rheumatologic diseases, shoulder-hand syndrome, infectious arthritis, hypertrophic pulmonary osteoarthropathy, neuropathic arthropathy, paraneoplastic arthritis, and agammaglobulinemia).

The revised 1956 set of diagnostic criteria for RA was used for about 30 years. Clinical knowledge and experience in rheumatic diseases have improved considerably during this period. Many patients previously classified as having RA started to be classified as having a different disease (e.g., spondyloarthritis, polymyalgia rheumatica, and pseudorheumatoid form of pseudogout). All of these, the fact that three of the 1956 criteria were invasive procedures rarely applied, that the criteria were sensitive but not specific enough for epidemiological studies, and finally, that the exclusion criteria were impractical, necessitated the development of the 1987 classification criteria.

1987 ACR Rheumatoid Arthritis Classification Criteria Set

The ACR developed the "RA classification criteria set" in 1987 (5). Five items from the "revised 1956 diagnostic criteria set for RA" were retained in these criteria; developed from data on 263 RA and 262 control patients (patients with other rheumatic diseases). Five main changes were made to the new criteria. The definition of "probable" RA was removed in these criteria. The terms definite and classic RA concepts were replaced with the term "RA". Criteria involving invasive techniques such as synovial biopsy, joint aspiration, or a rheumatoid nodule biopsy were removed. It was reported that a patient evaluated for classification purposes could be classified as having RA if they meet at least 4 of the specified 7 criteria. It was stipulated that the first 4 criteria must be present for a minimum of 6 weeks (Table 2).

Table 1. Revised 1956 diagnostic criteria for rheumatoid arthritis* (4)
1. Morning stiffness.
2. Pain on motion or tenderness in at least one joint (determined by a physician).
3. Swelling in at least one joint (determined by a physician).
4. New joint swelling within 3 months at most (determined by a physician).
5. Symmetric joint swelling (determined by a physician) (absolute symmetry is not sought in the PIP, MCP, and MTP joints).
6. Subcutaneous nodules on bony prominences, extensor surfaces, or juxta-articular regions (determined by a physician).
7. Rheumatoid arthritis-specific X-ray changes (not just degenerative changes).
8. Positive rheumatoid factor agglutination test in two measurements.
9. Poor mucin precipitation from the synovial fluid (with fragmented and turbid solution).
10. Characteristic histological changes in the synovial membrane.
11. Characteristic histological changes in nodules.
*Seven criteria are necessary for the classic rheumatoid arthritis diagnosis, whereas 5 criteria are necessary for the definitive rheumatoid arthritis diagnosis. PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, MTP: Metatarsophalangeal

Table 2. 1987 ACR rheumatoid arthritis classification criteria*	
1. Morning stiffness	Morning stiffness in and around joints that lasts for a minimum of 1 hour.
2. Arthritis of 3 or more joint areas	Observed simultaneously by a physician in at least 3 joint areas (not bony enlargement alone). Right or left PIP, MCP, wrist, elbow, knee, ankle, and MTP joints are among the 14 possible areas.
3. Arthritis of hand joints	Swelling in at least 1 area of the wrist, MCP, or PIP joints.
4. Symmetric arthritis	Simultaneous involvement of the same joint areas on both body sides (absolute symmetry is not sought in the bilateral involvement of PIP, MCP, or MTP joints).
5. Rheumatoid nodules	Subcutaneous nodules over bony prominences or extensor surfaces or in joint areas observed by a physician.
6. Serum rheumatoid factor	Demonstration of abnormal amounts of serum rheumatoid factor by any method.
7. Radiographic changes	RA-specific typical radiographic changes on posteroanterior hand and wrist radiographs (osteoarthritic changes alone are inadequate).
*The patient is classified as having RA when meeting at least 4 of the 7 criteria. ACR: American College of Rheumatology, PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, MTP: Metatarsophalangeal	

2010 Classification Criteria for Rheumatoid Arthritis

The 1987 criteria performed very well in distinguishing individuals with long-standing and active RA from individuals with other arthritis (with 95% sensitivity and 87% specificity). Nevertheless, they were inadequate in diagnosing the disease in its early stages. Numerous research have revealed that early aggressive treatment can stop or slow the progression of bone erosions, reduce disability due to the disease, and increase the remission rate (2,6,7). Hence, the ACR and European League Against Rheumatism (EULAR) joint working group was created to develop a new approach for earlier detection of RA in the clinic. A 3-phase study established the "2010 RA classification criteria" (8). In phase 1, possible criteria were identified, and the diagnostic significance of variables was computed (Table 3). In phase 2, clinician-based data on the relative contribution of clinical and laboratory factors to the development of RA were obtained. In phase 3, the scoring system was developed using the data obtained from phases 1 and 2.

The 2010 ACR/EULAR RA classification criteria set was established by considering joint (number and type), serology, level of acute phase reactants, and symptom duration (Table 4). A score between 0-10 is obtained as a result of applying the aforesaid criteria, and a score of 6 and above indicates the definite presence of RA. A patient who scores below 6 cannot be classified as having definite RA, but may be re-evaluated since they might meet the criteria in the future. The differential diagnosis varies from patient to patient. Psoriatic arthritis, systemic lupus erythematosus, crystal arthritis, and infectious arthritis should be considered and tested in order to rule out these diseases if necessary.

The 2010 ACR/EULAR RA classification criteria set is for individuals with newly diagnosed disease. This classification criterion set does not consider radiographic findings, which are the most important diagnostic value of the disease and provides important clues about the disease course. However, it should be remembered that even though RA is typical erosive arthritis, but does not completely meet the 2010 criteria, it can still be considered RA (Figure 2). Patients who have had the disease for a long period but whose disease is inactive (whether or not they receive treatment), and who have typical erosions detected in the current records, whether or not they meet the 2010 criteria, can also be considered to have RA.

This criterion set can ensure that RA is diagnosed earlier. Its sensitivity is higher than that of the previous criterion, but its specificity is lower. It is challenging for seronegative patients to meet the criteria (9,10). In a patient with a four-month history who has swelling in eight small joints, and morning stiffness in arthritic joints, C-reactive protein (CRP) is high, but rheumatoid factor (RF) and anti-citrullinated protein antibody (ACPA) are negative. This patient scores 5 according to the 2010 set (not considered as having RA) but meets four criteria from the 1987 set (considered as having RA). In a patient with swelling in a proximal interphalangeal joint (PIP) joint for 6 days, CRP is high, and ACPA is positive at high titer; this patient scores 6 according to the 2010 set (considered as having RA) and meets 3 criteria from the 1987 set (not considered as having RA).

A study evaluated 313 patients who presented for the first time, 76 of whom were diagnosed with RA. In the study in question,

Table 3. Significance levels of the parameters determined in phase-1

Variables	Comparisons	Weights
Swollen MCP joint	Yes vs. no	1.5
Swollen PIP joint	Yes vs. no	1.5
Swollen wrist	Yes vs. no	1.6
Hand sensitivity	Yes vs. no	1.8
AFR level	Slightly high vs. normal	1.2
AFR level	High vs. normal	1.7
Serology	Low titer vs. negative	2.2
Serology	High titer vs. negative	3.9

PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, AFR: Albumin-to-fibrinogen ratio

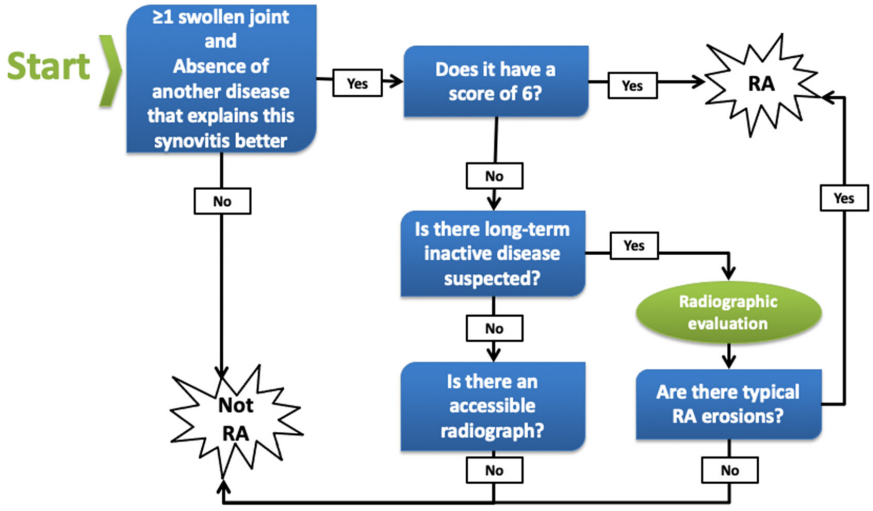

Figure 2. Patients who do not meet the 2010 ACR/EULAR rheumatoid arthritis classification criteria but have typical radiographic findings
ACR/EULAR: American College of Rheumatology/European Alliance of Associations for Rheumatology, RA: Rheumatoid arthritis

Table 4. 2010 rheumatoid arthritis classification criteria

Patients meeting the 2 criteria below constitute the target population: 1. Presence of definite clinical synovitis (swelling) in at least one joint (a) 2. Absence of another disease that explains this synovitis better (b)	A score of ≥6/10 is required to classify the patient as having definite RA (c)
A. Joint involvement (d)	**Score**
1 large joint (e)	0
2-10 large joints	1
1-3 small joints (with or without concomitant large joint involvement) (f)	2
4-10 small joints (with or without concomitant large joint involvement)	3
>10 joints (a minimum of one small joint) (g)	5
B. Serologic results (at least 1 test result required for classification) (h)	**Score**
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 required for classification) (i)	**Score**
Normal CRP or normal ESR	0
Abnormal CRP or abnormal ESR	1
D. Symptom duration (j)	**Score**
<6 weeks	0
≥6 weeks	1

a) These criteria aim to classify newly emerging patients. Additionally, if RA is typical erosive arthritis and patients have previously met the 2010 criteria, they are still considered to have RA. Patients who have had the disease for a long period but whose disease is inactive (whether or not they receive treatment) but who are determined to have met the 2010 criteria in the current records should also be considered to have RA.
b) Differential diagnosis varies according to patients' different clinical presentations. Furthermore, SLE, PsA, and gout should also be considered. If the diseases to be considered in the differential diagnosis are unclear, it is necessary to consult an expert rheumatologist.
c) Although patients scoring <6/10 cannot be classified as having RA, their conditions should be re-evaluated. Patients may meet the criteria in the future.
d) The condition expressed by joint involvement is the presence of swelling or tenderness in any joint during examination. This condition can also be provided by evidence of synovitis with imaging techniques. DIP, 1st carpometacarpal, and 1st MTP joints are excluded from the evaluation. Joint distribution is categorized in accordance with the location and number of the affected joints. The joint involvement pattern should be addressed in the highest possible category.
e) Large joints: Shoulder, elbow, hip, knee, and ankle.
f) Small joints: MCP, PIP, 2nd, 3rd, 4th, and 5th metatarsophalangeal, thumb interphalangeal, and wrist.
g) At least one of the affected joints in this category should be a small joint. There may be any association of large or small joints with other joints, including joints not specifically listed anywhere such as temporomandibular, acromioclavicular, and sternoclavicular.
h) A negative result refers to a value below the upper limit of the specified range. A low positive result indicates a value above the upper limit of normal but three times and less than the upper limit. A high positive result is a value greater than three times the upper limit of normal. If the laboratory cannot quantify RF and only reports it as (+) or (-), it must be evaluated as a low positive result.
i) Normal or abnormal values are determined based on the reference values of the laboratory.
j) Symptom duration: It is the duration of synovitis symptoms such as pain, swelling, and tenderness in the joints determined to be impacted during the examination, as reported by the patient.

RA: Rheumatoid arthritis, RF: Rheumatoid factor, ACPA: Anti-citrullinated protein antibody, CRP; C-reactive protein, ESR: Erythrocyte sedimentation rate. PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, MTP: Metatarsophalangeal, SLE: Systemic lupus erythematosus, PsA: Psoriatic arthritis, DIP: Distal interphalangeal

when the 2010 criteria were applied, the sensitivity and specificity were found to be 73.5% and 71.4%; when the 1987 criteria were applied, the sensitivity and specificity were determined to be 47.1% and 92.9%, respectively (11). Many studies have reported different specificity and sensitivity rates (sensitivity between 62-91% and specificity between 21-78%) (12). Another study found that when the criteria were applied simultaneously, about 10% of RA patients meeting the 1987 criteria could not be classified as having RA in line with the 2010 criteria (Table 5) (13).

In a study evaluating patients with very early arthritis (14), 303 patients with symptom duration ≤16 weeks who had not previously received disease-modifying anti-rheumatic drug (DMARD) treatment were followed up for 52 weeks. It was reported that 75% of patients diagnosed with RA scored ≥6 following the 2010 criteria in the initial evaluation, and 75% of patients diagnosed with undifferentiated arthritis scored <6 at the beginning after follow-up. These data support the effectiveness of the 2010 set in distinguishing RA from undifferentiated (poly or oligo) arthritis. When the clinical stages and pre-stages of RA are considered, the classification criteria should be prepared appropriately for the group they will be applied to (Figure 3).

Classification Criteria Set for Early Rheumatoid Arthritis

The 1987 ACR criteria set is suitable for established RA patients but is difficult to apply in the diagnosis of early RA patients. The sensitivity of the 2010 ACR/EULAR set, developed to this end, is higher than that of the 1987 ACR set, but its specificity is considerably lower. Low specificity means misdiagnosis, and incorrect and unnecessary treatments. Despite these two sets being available, it is obvious that new sets are still needed, particularly for early RA (15).

A prospective multicenter study was performed in a large cohort of patients with early inflammatory arthritis with the objective of developing criteria that could be readily utilized in clinical practice for early RA diagnosis (16). The research included 803 patients with a symptom duration of less than 1 year. Patients were followed up for one year at 3-month intervals. Five hundred fourteen patients were diagnosed with RA, other rheumatic diseases, and undifferentiated arthritis. Variables with high sensitivity for the diagnosis of RA in comparison with the initial variables included symmetric arthritis, and arthritis of the hand joints (wrist, metacarpophalangeal joint, or PIP swelling), followed by arthritis of 3 or more joint areas, positive RF, and positive anti-cyclic citrullinated peptide. Four different sets of criteria were acquired from the obtained data, and the most sensitive criteria set in identifying patients diagnosed with RA was selected at the end of one year (Table 6). The presence of 3 out of 5 criteria is adequate for early RA classification.

The sensitivity of the early RA classification criteria set defined here was computed as 85% (58% for the 1987 set and 83% for the 2010 set), and specificity was computed as 87% (94% for the 1987 set and 55% for the 2010 set).

The importance levels of the criteria used in early RA classification and the corresponding score were identified (Table 7). In the score-based classification set prepared according to these data, if patients who reached ≥5 points were accepted as having RA, the sensitivity was computed to be 86% and the specificity was 88%.

Table 5. Differences between 1987 and 2010 criteria

	1987 criteria	2010 criteria
Target population	Established RA	Early RA
CCP	No	Yes
Morning stiffness	Yes	No
Radiographic findings	Yes	No
Subcutaneous nodule	Yes	No
Sensitivity	47.1	73.5
Specificity	92.9	71.4

CCP: Cyclic citrullinated peptide, RA: Rheumatoid arthritis

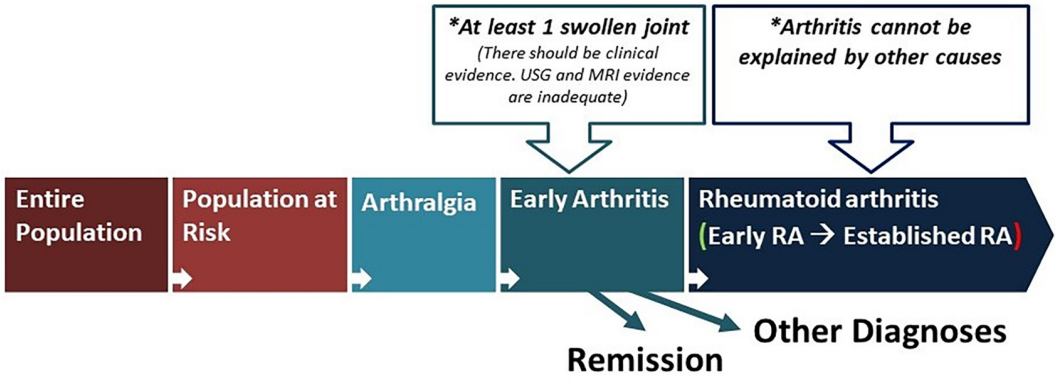

Figure 3. When considering rheumatoid arthritis disease and its pre-stages, classification criteria should be established according to the target population to be screened
USG: Ultrasonography, MRI: Magnetic resonance imaging, RA: Rheumatoid arthritis

Table 6. Early rheumatoid arthritis classification criteria set*

Criteria	Definitions
1. Morning stiffness	Morning stiffness in and around joints that lasts longer than 30 minutes.
2. Polyarthritis	Swelling in at least 3 of 14 joint areas consisting of right and left PIP, MCP, wrist, elbow, knee, ankle, and MTP joints.
3. Arthritis in hand joints	Swelling in at least one of the wrists, MCP, or PIP joint areas.
4. RF positivity	Above normal range is considered positive.
5. ACPA positivity	Above normal range is considered positive.

*Patients who meet ≥3 of the 5 criteria specified above are classified as having rheumatoid arthritis. RF: Rheumatoid factor, ACPA: Anti-citrullinated protein antibody, PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, MTP: Metatarsophalangeal

Table 7. The importance levels of the criteria determined to be used in early RA classification and the score-based classification

Variables	Correlation coefficient	Score‡
ACPA positivity	4.2	4
*Swelling in ≥3 out of 14 joint areas	1.6	2
Morning stiffness lasting ≥30 minutes	1.4	1
Symmetric arthritis	1.3	1
Arthritis in hand joints: swelling in at least one of the wrists, MCP, or PIP joint areas	0.9	1
RF positivity	0.7	1

*14 joint areas consist of right and left PIP, MCP, wrist, elbow, knee, ankle, and MTP joints. ‡Patients who reach ≥5 points in the score-based classification set are accepted to have RA. RF: Rheumatoid factor, RA: Rheumatoid arthritis, ACPA: Anti-citrullinated protein antibody, PIP: Proximal interphalangeal, MCP: Metacarpophalangeal, MTP: Metatarsophalangeal

DISCUSSION

Diagnostic criteria are typically expansive, designed to encompass the diverse manifestations of a disease to accurately detect as many affected individuals as possible. In contrast, classification criteria are standardized frameworks aimed at forming consistent, relatively uniform groups for clinical research purposes. These criteria focus on including most patients who exhibit core common traits of the condition, rather than all potential cases. As such, classification criteria are not applied for diagnosing patients in clinical settings but are utilized to ensure uniform patient inclusion in research studies (17).

Classification criteria may have different sensitivity and specificity depending on age, gender, race, and geographic region (17). Therefore, the validity of classification criteria may vary from population to population. Therefore, there has always been a need for more sensitive and precise classification criteria that can be applied to all societies. From time to time, there has been a need to change the classification criteria.

Each set of RA classification criteria exhibits distinct advantages, contingent on the clinical context and research objectives. The 1987 criteria demonstrate proficiency in the classification of established disease with high specificity but exhibit inadequate sensitivity in the identification of early presentations. Conversely, the 2010 criteria have been shown to enhance early detection by increasing their sensitivity, though this has come at the expense of specificity, particularly in the classification of seronegative patients (9,18). This trade-off has been demonstrated in several comparative studies. In a study of 313 patients presenting with newly diagnosed arthritis, the 2010 criteria exhibited 73.5% sensitivity and 71.4% specificity, while the 1987 criteria demonstrated 47.1% sensitivity and 92.9% specificity (19). When applied concurrently, approximately 10% of patients meeting the 1987 criteria fail to be classified under the 2010 framework (20). For very early arthritis (symptom duration ≤16 weeks), the 2010 criteria have demonstrated encouraging utility. A study of 303 DMARD-naïve patients followed for 52 weeks found that 75% of those ultimately diagnosed with RA scored ≥6 on the 2010 criteria at initial assessment (21). However, the reduced specificity raises concerns about potential misdiagnosis and inappropriate treatment initiation, particularly in seronegative presentations.

The incorporation of advanced imaging techniques such as ultrasonography and magnetic resonance imaging has the potential to further enhance early detection capabilities, especially in cases where traditional classification criteria yield ambiguous results (22,23). Several studies have demonstrated

that the integration of imaging parameters can improve diagnostic accuracy in early disease, particularly when clinical manifestations remain equivocal (24).

CONCLUSION

The evolution of RA classification criteria is indicative of significant advancements in our understanding of disease pathogenesis, clinical presentation, and the critical importance of early intervention. To ensure optimal clinical application, rheumatologists must understand the comparative performance of these criteria sets while recognizing that classification criteria are primarily intended for research standardization rather than individual diagnosis.

Clinical judgment remains paramount, particularly in seronegative presentations or atypical manifestations where existing criteria may have limitations. As our understanding of RA pathophysiology continues to evolve, future classification frameworks will likely incorporate biomarkers of pre-clinical disease states, genetic risk factors, and novel imaging parameters to enable intervention at increasingly earlier stages of disease development.

Footnotes

Authorship Contributions

Surgical and Medical Practices: İ.G., A.K., Concept: İ.G., Design: A.K., Data Collection or Processing: İ.G., Analysis or Interpretation: A.K., Literature Search: İ.G., A.K., Writing: İ.G., A.K.

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