

New Criteria Support Earlier Diagnosis of RA

BY MITCHEL L. ZOLER

New criteria for diagnosing rheumatoid arthritis—introduced last October and expected in print later this year—should lead to earlier diagnoses, easier insurance coverage for treatment, and improved patient outcomes, agreed many rheumatologists. The new criteria are also likely to be adopted fairly quickly by most U.S. rheumatologists, experts added.

“It’s a paradigm shift: Prevent disease or significantly abrogate it if rheumatoid arthritis is caught early. If you wait for the 1987 criteria to be fulfilled, patients will have established disease. Our goal is to identify and treat patients as early as possible,” said Dr. Clifton O. Bingham III, associate director of the Johns Hopkins Arthritis Center in Baltimore and a member of the panel that came up with the new RA criteria.

A panel of 22 rheumatologists formed by the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR) worked for 3 years to devise new RA diagnostic criteria to replace the existing RA classification criteria that were released by the ACR in 1987 (Arthritis Rheum. 1988;31:315-24). An initial public report on the new diagnostic criteria occurred last October at the annual meeting of the ACR in Philadelphia. (See box.) A peer-reviewed, written version of the criteria, as well as reports on the multistage process that led to their creation, should be published later this year, said Dr. Gillian A. Hawker, chief of medicine at Women’s College Hospital in Toronto and a project leader.

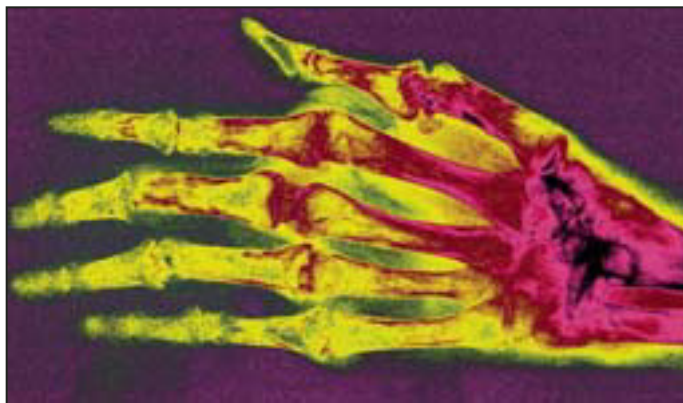
Although the U.S. rheumatologists who were interviewed for this article weren’t completely uniform in their expectations of how the new criteria will likely affect practice, most agreed on several broad consequences, starting with the way by which the new criteria will change the timing of RA diagnosis and treatment.

“This will lead to earlier, definitive assessment and treatment of patients with RA. A major weakness of the previous classification criteria is that they included a bad outcome [and] erosions, and required more extensive disease. We want to treat patients before erosions occur,” said Dr. Eric L. Matteson, professor and chairman of rheumatology at the Mayo Clinic in Rochester, Minn.

“These criteria should help clinicians diagnose patients at an earlier stage, and possibly lead to earlier treatment as well, thereby improving outcomes. They may help qualify patients for therapy at an earlier stage of their disease,” said Dr. Arthur F. Kavanaugh, professor of medicine at the University of California, San Diego.

A major way in which the new criteria enable earlier diagnosis is by setting

a lower threshold for the number of involved joints, noted Dr. Michael E. Weinblatt, professor of medicine at Harvard Medical School and associate director of the center for arthritis and joint diseases at Brigham and Women’s Hospital, both in Boston. “A lot of times patients don’t seek care or don’t get referred because only a couple of joints are involved.” The



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new criteria make it clear that “a couple of joints could be RA.”

These criteria “will allow for earlier diagnosis, but there is a great deal of clinical judgment [involved], and I’ve certainly diagnosed RA in many patients who did not fulfill the [1987] ACR criteria,” said Dr. Daniel Furst, professor of medicine at the University of California, Los Angeles. “What this does is codify and validate the fact that we make diagnoses earlier” than the old classification criteria allowed. Now rheumatologists and even primary care physicians “will feel comfortable making an earlier diagnosis,” he said.

Earlier diagnosis was a major goal of the panel that came up with the new diagnostic criteria, based on an “increasing concern that we were missing patients with aggressive, erosive disease,” said Dr. Philip J. Mease, a member of the panel and a rheumatologist at Swedish Hospital Medical Center in Seattle. “I’m not sure that the criteria will identify more patients, but they will more precisely identify patients who will have an aggressive course. The hope is that if you start treatment [of these patients] sooner, you may prevent disease progression.”

Experts were split on how confident they were that earlier diagnosis and treatment would lead to better outcomes, although that’s what they generally expect. “We hope it leads to better outcomes. That’s the underlying assumption,” Dr. Furst said.

“Earlier treatment of RA means better outcomes, including less irreversible damage,” Dr. Matteson said.

Dr. Mease said that some evidence already exists for improved outcomes from early treatment. He cited results from studies such as TICORA (Tight Control for Rheumatoid Arthritis) (Lancet 2004;364:263-9), BeSt (Behandel-Strategieën) (Arthritis Rheum. 2005;52:3381-90), and CAMERA (Computer-Assisted Management of Early Rheumatoid Arthritis) (Ann. Rheum. Dis. 2007;

66:1443-9). Results from all three studies showed that aggressive treatment early in RA led to better outcomes, with lower joint counts, better function, and more significant inhibition of radiologic damage, Dr. Mease said in an interview.

The new criteria should also ease insurance-coverage problems, some experts said. Currently, some insurers ask whether the patient fulfills the 1987 criteria for RA, “and if you answer truthfully, some patients [with early RA] may not fulfill the criteria.” The 2009 criteria “may allow earlier access to medications. This will make it easier to document RA,” Dr. Bingham said.

The number of involved joints has been a diagnostic feature that has held up insurance coverage for some patients, with insurers insisting that patients meet the 1987 standard of at least six involved joints, Dr. Weinblatt

said. Dr. Furst and Dr. Matteson also cited experiences with denied insurance coverage, something they anticipate will become a thing of the past, more or less, with the new criteria.

“The first thing insurers ask in prior authorization forms is whether a patient meets the criteria for RA,” Dr. Weinblatt noted in commenting on the new criteria last October. This slowed the use of disease-modifying antirheumatic drugs in some patients. The new criteria will eliminate this barrier in many cases, he said.

Although all the experts who were interviewed agreed that the new criteria accurately reflected current thinking on what constitutes RA, a few envisioned certain situations that could cause problems. One concern involved mixing apples and oranges: Could results from RA patients in prior treatment studies always be appropriately applied to patients

whose disease is defined by the new criteria? Dr. Furst asked. Similarly, he wondered whether drug toxicity profiles that were worked out in prior cohorts of RA patients would match the toxicities faced by newly defined RA patients.

Dr. Mease said he worried about a group of patients who are sick but fall short of the diagnostic criteria. These are the patients who present with fewer than 10 involved medium or large joints, low titers of rheumatoid factor and anti-citrullinated protein antibody, and a very high level of C-reactive protein, a constellation showing that the patient “clearly has an inflammatory process,” yet one that would tally a diagnostic score of 4-5 points (depending on symptom duration), which is less than the 6 points needed for a definitive RA diagnosis. Despite such concerns, Dr. Furst noted that the 2009 criteria have higher specificity and sensitivity than did the 1987 criteria. Also, new serologic and genomic tests that will likely emerge in the next several years will further refine diagnoses and will be incorporated into the scoring formula, Dr. Mease said.

“Most rheumatologists accept the concept of a need for early intervention, which these criteria speak to,” Dr. Matteson said. They will be accepted and used by most U.S. rheumatologists, he predicted.

“I think it will improve the outcome of our patients, and so it’s a very good thing,” Dr. Furst said. ■

Disclosures: Dr. Bingham and Dr. Mease both participated on the panel that developed the new diagnostic criteria; this work was sponsored by the ACR and EULAR. The other rheumatologists cited had no role in developing the criteria. The rheumatologists who were interviewed said that because the new criteria do not deal directly with treatment, they did not have financial disclosures relevant to the topic.

The New Diagnostic Criteria in Brief

Patients are definitively diagnosed with RA if they score 6 or more points according to the following criteria:

Joint involvement

- ▶ 1 medium-large joint (0 points)
- ▶ 2-10 medium-large joints (1 point)
- ▶ 1-3 small joints (2 points)
- ▶ 4-10 small joints (3 points)
- ▶ More than 10 small joints (5 points)

Serology

- ▶ Not positive for either rheumatoid factor or anti-citrullinated protein antibody (0 points)
- ▶ At least one of these two tests are positive at low titer, defined as more than the upper limit of normal but not higher than three times the upper limit of normal (2 points)
- ▶ At least one test is positive at high

titer, defined as more than three times the upper limit of normal (3 points)

Duration of synovitis

- ▶ Lasting fewer than 6 weeks (0 points)
- ▶ Lasting 6 weeks or longer (1 point)

Acute phase reactants

- ▶ Neither C-reactive protein nor erythrocyte sedimentation rate is abnormal (0 points)
- ▶ Abnormal CRP or abnormal ESR (1 point)

Note: Patients receive the highest point level they fulfill within each domain. For example, a patient with five small joints involved and four large joints involved scores 3 points.

Note: Based on a presentation by Dr. Hawker at the annual meeting of the American College of Rheumatology, October 2009.