ACR/EULAR Criteria Define RA Remission

BY MIRIAM E. TUCKER

FROM ANNALS OF THE RHEUMATIC DISEASES

The American College of Rheumatology and the European League Against Rheumatism have issued two new provisional definitions for remission in rheumatoid arthritis for clinical trials.

The need for two definitions was based on considerations of both face and predictive validity, the need for stringency, and the determination by a 27-member committee that patient-reported outcomes should be among the criteria, reported lead author Dr. David T. Felson, professor of medicine and epidemiology at Boston University, and his coauthors (Ann. Rheum. Dis. 2011;70:404-13).

One definition requires the patient to satisfy all of the following at any time point: no more than one tender or swollen joint, C-reactive protein of less than or equal to 1 mg/dL, and a patient global assessment of 1 or less on a 0- to 10-point scale. For the tender and swollen joint counts, it is preferable to include feet and ankles in addition to the standard 28-joint count.

The second definition is based on a composite index of RA activity, the Simplified Disease Activity Index (SDAI) score, which is the sum of the tender and swollen joint count (using 28 joints), patient global assessment (0-10 scale), physician global assessment (0-10 scale), and C-reactive protein level (mg/dL). At any time point, the patient must have an SDAI score of 3.3 or less to be considered to be in remission.

The authors recommend that one of the two definitions be selected as a trial outcome measure but that the results of both be reported.

The criteria have been approved provisionally by both ACR and EULAR, meaning that they have been quantitatively validated using patient data but have not undergone validation based on an external data set. As such, they are expected to undergo intermittent updates.

The previous ACR definition of remission in RA was developed in 1981, prior to the introduction of the RA core set measures and before the advent of biologics for treatment, when true remission was rare.

In an accompanying editorial, Dr. Lennart T.H. Jacobsson and Dr. Merete Lund Hetland said the new criteria represent a step forward (Ann. Rheum. Dis. 2011;70:401-3) .

"The old remission criteria were like silent films – with disease potentially progressing silently under a cover of remission that allowed substantial disease activity to be present. The new criteria are more like a 3-D movie, requiring no or minimal activity based on three dimensions: clinician's (swollen and tender joint counts) and patient's (global health score) judgments together with laboratory data (CRP)."

The ACR/EULAR authors noted that because the definitions have not yet been validated in observational data sets – that's the next step – their uses in clinical practice settings are limited.

The document provides additional definitions including joint counts and physican/observer/patient global assessments that do not require an acute-phase reactant (such as C-reactive protein) and therefore may be more useful in clinical settings.

"Nevertheless, our preliminary suggestions for defining remission in clinical practice are still incomplete, as we did not test them in a clinic-based setting." Inclusion of acute-phase reactants is important because they predict later radiographic damage, they noted.

However, the editorialists Dr. Jacobsson and Dr. Hetland noted that the criteria are feasible to use in routine care, and they can assist in the monitoring of treated patients.

Moreover, the generalizability of the criteria is likely to be improved by the use of contemporary data from clinical trials published during the last decade in which modern biological therapy has been represented in one or more treatment arms.

The new definitions also "represent another successful ACR-EULAR collaboration," said Dr. Jacobsson, professor of clinical sciences (rheumatology) at Lund University, Malmo, Sweden, and Dr. Hetland, of Copenhagen University Hospital, Glostrup, Denmark.

And, they added, "With 'treat to target' as the modern treatment principle, permanent remission is the ultimate goal – although not a realistic one in all patients. Nevertheless, aiming at remission will also improve outcome in those patients who do not achieve remission."

They noted that subsequent additions of additional response criteria such as imaging techniques will probably render the definitions more complex and less suitable for use in clinical practice.

"The new preliminary ACR/EULAR criteria are therefore likely to be used for a long time."

The project was funded by the ACR, EULAR, and a grant from the National Institutes of Health. Dr. Felson, Dr. Jacobsson, and Dr. Hetland all stated that they had no disclosures. ■

Demographics Determine Access to DMARDs in RA

BY MARY ANN MOON

FROM JAMA

Whether patients with rheumatoid arthritis receive appropriate antirheumatic medications varies widely and depends on their age, sex, race, income, the neighborhood and area of the country where they reside, and their health care plan, judging from recent study findings.

"Although RA was once an inevitably deforming and disabling condition, the development of new DMARDs [disease-modifying antirheumatic drugs] and support for their early use has dramatically improved clinical outcomes for many patients.

"This study suggests that one mechanism for the sociodemographic disparities in RA outcomes in the United States may relate to differences in DMARD receipt," according to Dr. Gabriela Schmajuk of Stanford (Calif.) University and her associates.

Recent population-based studies have shown consistently low rates of DMARD use, even though evidence-based guidelines recommend early and aggressive treatment.

Dr. Schmajuk and her colleagues assessed medication use in a cohort of 93,143 RA patients enrolled in Medicare managed care plans during a recent 4-year period.

The cohort comprises a nationally representative sample of the managed care population aged 65 years and older.

Overall, 37% of patients were not receiving DMARDs.

These include abatacept, adalimumab, anakinra, azathioprine, cyclophosphamide, cyclosporine, etanercept, gold, hydroxychloroquine, infliximab, leflunomide, methotrexate, minocycline, penicillamine, rituximab, staphylococcal protein A, and sulfasalazine.

In some cases, patients may have declined DMARD treatment, may have had quiescent disease that didn't require treatment, or may have had contraindications to all 17 of these drugs.

The greatest variation in the rate of DMARD use occurred by patient ag.

Only 42% of patients aged 85 years or older received DMARDs, compared with 72% of those aged 65-69 years.

It is possible that older patients had more comorbidities limiting their ability to use these drugs.

It also is possible that age bias played a role in this result, according to the investigators.

Men had slightly lower rates of use than women, and patients self-identified as black or "other" had lower rates of use (57% and 58%, respectively) than white patients (64%).

The rate of DMARD use was 55% among patients with a low personal income, compared with 64% among those with higher incomes.

Similarly, patients who lived in neighborhoods of low socioeconomic status were less likely to be taking DMARDs than patients living in neighborhoods with higher socioeconomic status.

It is possible that some of these patients don't get DMARDs because they are unable to afford copayments or other forms of cost sharing, the investigators said.

Patients living in the South Atlantic and Middle Atlantic regions of the country had rates of use that were 10% lower than those living in other regions.

The use of DMARDs was 6% lower among patients who were enrolled in for-profit health plans than among those who were enrolled in not-for-profit plans, a difference that was small but statistically significant.

However, variability by health plan was much greater than that statistic alone would convey.

Rates of use of DMARDs varied from a low of 16% in one health plan to a high of 87% in another. This findings held true even after the data had been adjusted to account for differences in case mix.

This finding is "concerning," Dr. Schmajuk and her associates said (JAMA 2011;305:480-6).

It is unknown whether this 70-point difference in DMARD use is due to differences in the availability or accessibility of specialty care within some health plans or differences in allowances on prescription drug benefits between health plans.

It may even reflect in part inaccurate reporting on the forms used to collect the data, they added.

Whatever the explanations, the large variations in DMARD use are "unacceptable," the researchers said.

"Targeting educational and quality improvement interventions to patients who are underusing DMARDs and their clinicians will be important to eliminate these disparities," they said. ■

VITALS

Major Finding: The use of disease-modifying antirheumatic drugs varies widely according to patient age, sex, and race; income; location; and health plan.

Data Source: An analysis of Healthcare Effectiveness Data and Information Set data on medication use in a nationally representative sample of 93,134 RA patients enrolled in Medicare managed care plans.

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