Residual minimal disease activity in rheumatoid arthritis: a simple definition through an in-depth statistical analysis of the major outcome

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Objective. To obtain the simplest definition of minimal disease activity (MDA) and to compare it with published proposed definitions of MDA in patients with RA.

Methods. Two hundred and fourteen patients with long-standing RA (LSRA) were evaluated for clinical and laboratory parameters. Factor analysis was performed to remove redundant variables included in the core set measure for MDA definition stated by the OMERACT. Receiver operating characteristic (ROC) curves analysis allowed to obtain optimal cut-off predictors of a 28-joint disease activity score (DAS28) ≤ 2.85. These were tested in 112 LSRA and 95 early-onset RA (ERA) patients.

Results. Factor and ROC curve analysis showed that the best predictors of a DAS28 ≤ 2.85 in LSRA cohort were: (i) ESR < 20 mm/h (sensitivity: 80%, specificity: 54%); (ii) swollen joint count (out of 28) < 2 (sensitivity: 95%, specificity: 74%); (iii) patient global assessment (0–100) < 15 (sensitivity: 78%, specificity: 78%); and (iv) HAQ (0–3) < 0.5 (sensitivity: 91%, specificity: 61%). To each of these four criteria we assigned a value of 1 when it was satisfied (score ranging: 0–4). The cut-off with the highest overall accuracy for identifying RA patients with DAS28 < 2.85 was a score ≥ 3. We adopted these four parameters in order to define the residual MDA (RMDA). Comparing RMDA criteria, in distinct 112 LSRA and 95 ERA patients, with OMERACT, Simplified Disease Activity Index and Clinical Disease Activity Index definitions of MDA, we found a good agreement in the LSRA cohort and moderate agreement in the ERA cohort.

Conclusions. HAQ, PaGA, SJC28 and ESR allow identification of RA patients with an RMDA. The RMDA criteria behaves similarly to OMERACT definitions, but appears more simple and feasible.

Key words: Rheumatoid arthritis, Disease activity score, 28-Joint disease activity score, Clinical Disease Activity Index, Simplified Disease Activity Index, Residual minimal disease activity, Clinical trials.

Introduction

Clinical evaluation is of fundamental importance today to define the most appropriate therapeutic programme in RA [1]. Since we now have the evidence-based demonstration that a significant percentage of patients can really be led to remission [2], we need simple parameters that, in day-to-day clinical practice, can be used to define whether the patient has reached the major aim or not, and these should be constantly assessed and collected. The simpler they are, the higher the chance will be of having them recorded in daily practice.

Several indices are at hand to assess the minimal disease activity (MDA) and remission. Recently, in a cohort of patients with early-onset RA (ERA), Khanna et al. [3] have estimated that the agreement between different definitions of MDA was good to excellent and the agreement among the definitions of remission ranged from poor to excellent. Disease activity score (DAS), the European League Against Rheumatism (EULAR) continuous scale, is the most accepted in clinical trials [4, 5]. DAS can also be used to define MDA and as such the most acceptable, along with remission, of the possible clinical outcomes. It has also been demonstrated that the simplified disease activity index (SDAI) and the clinical disease activity index (CDAI) [6–8], more simple than DAS calculation, can be as reliable as DAS, and since they are simpler, appear to be more fit for routine employment [9].

Since remission or at least MDA is now the goal of every rheumatologist, we addressed the issue of having the simplest tool to define the major aim of any therapeutic programme in daily practice and to accurately identify the RA patients in MDA status. Hence, the tool we propose should be used to define the goal of rheumatologists in daily practice. Among the seven items suggested by the OMERACT committee [10], we investigated whether we could obtain a simpler tool by reducing the parameters but still having a valid value to define MDA.

The results define residual MDA (RMDA) that can be used to set the major goal in each patient with RA.

Patients and methods

Patients

Four hundred and twenty-one consecutive patients with RA attending two Italian tertiary rheumatology departments’ outpatient clinics of the Catholic University of the Sacred Heart, Rome, and Polytechnic University of Marche Medical School, Ancona, between January 2005 and December 2007, were included in the study [79% were females; mean (S.D.) age: 56.3 (13.5) years; mean disease duration: 7.3 (5.1) years]. All patients fulfilled the ACR criteria for RA and were grouped into three groups (A, B and C). Group A consisted of 214 patients with long-standing RA (LSRA) (duration of illness at last follow-up was >3 years) examined at Division of Rheumatology in Rome. These patients (derivation sample) were recruited to define the possible cut-off points for MDA. The other two populations (B and C) consisted of two completely independent cohorts of 112 RA patients with a long disease duration (Group B) examined at the Rheumatology Clinic of the Polytechnic University of Marche, Ancona, and Group C consisted of 95 RA patients with ERA (disease duration at the time of diagnosis was <1 year and duration of illness at the most recent clinical evaluation was <3 years), examined at the Division of Rheumatology in Rome. The two last independent cohorts (validation samples) were used for validation of the obtained

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MDA criteria. All these patients were on DMARDs (≥1) or on a combination of MTX plus an anti-TNF agent treatment. If the patients were seen more than once during the study period, the most recent encounter was analysed.

**Assessment visit (data collection)**

For every patient, we reported the ‘core’ sets of variables to be used to define the RA disease activity according to the EULAR and the World Health Organization/International League Against Rheumatism (WHO/ILAR) recommendation, and to evaluate the functional impairment [11, 12]. A detailed assessment by the physicians included all the core set outcome measures required to calculate the DAS [13], including a full tender joint count (TJC) and swollen joint count (SJC), the acute-phase reactants measures (ESR and CRP), as well as the 0–10-cm visual analogue scale (VAS) for physician and patient global assessments (PhGA and PaGA, respectively) and patient pain assessment plus the HAQ for patient outcome assessment. A 28-Joint DAS (DAS28) was calculated according to the published algorithm using the TJC and SJC assessed on 28 joints, the ESR in mm/h and the value of PaGA [14].

**Definitions of MDA**

The OMERACT group has proposed preliminary definitions for achieving MDA [10]. Patients with no tender joints and no swollen joints and an ESR <10 mm/h are considered to be in MDA. If patients do not meet this criterion, they are still considered to be in MDA if either their DAS28 score is ≤2.85 or they meet at least five of the seven WHO/ILAR core set measure thresholds: patient pain assessment ≤2 (0–10), SJC ≤1 (out of 28), TJC ≤1 (out of 28), HAQ ≤0.5 (0–3), PhGA ≤1.5 (0–10), PaGA ≤2 (0–10) and ESR ≤20 mm/h. A low disease activity (LDA) status, based on the CDAI and SDAI [7], was considered when the CDAI scores were ≤10 and the SDAI scores were ≤11.

**Study design and statistical analysis**

The data recorded at every visit were entered into a database (Microsoft Office Excel 2007; Microsoft, Redmond, WA, USA). Analysis were conducted in SPSS for Windows version 11.0 (SPSS, Chicago, IL, USA) and in MedCalc® version 9.5.1.0. (MedCalc Software, Mariakerke, Belgium).

We tried to remove redundant (highly correlated) variables from those that are included in the profile used in the survey on MDA stated by OMERACT (ESR, TJC, SJC, HAQ, PhG, PaGA and VAS-pain), with a factor analysis (varimax rotation method with Kaiser normalization) [15]. Factor analysis consists of: extraction of initial components by use of principal-component analysis; rotation of factors; and finally, interpretation of each factor based on the estimated values for the factor loadings. Principal-component analysis identifies the number of components that are rotated into interpretable factors. Interpretation is based on correlations between the factors and the original variables. The final number of factors was limited to 4.

We then evaluated the ability of these remaining variables, used to replace the original variables, to discriminate the subjects with LDA, using receiver operating characteristic (ROC) curve analysis [16].

ROC curves were also used to obtain, among the variables, the best cut-off points emerging as good predictors of DAS28 ≤2.85 (according to the OMERACT definition of MDA). For every parameter we obtained an area under the curve (AUC) with s.e. and 95% CI, sensitivity, specificity, positive and negative likelihood ratio (LR+ and LR−). Criterion value corresponding to the highest accuracy (minimal false negative and false positive results) was selected as like cut-off points.

To each of the selected parameters we assigned a value of 1, if the criterion is met, thus having, by the summation, a score ranging from 0 to 4. To identify the value obtained from the combination of these four measures arising as a good predictor of MDA status, as defined by DAS28 ≤2.85, we tested the new data with an ROC curve analysis.

To evaluate the agreement between the various classifications of MDA we used the Cohen’s linear weighted κ-statistic and the κ-value was interpreted as proposed by Altman [17]: ≤0.20 strength of agreement—very poor; 0.21–0.40 strength of agreement—fair; 0.41–0.60 strength of agreement—moderate; 0.61–0.80 strength of agreement—good; 0.81–1.00 strength of agreement—very good. Categorical and quantitative variables were, respectively, described as numbers (n), percentage (%) and mean (s.d.). A value of P < 0.05 was considered statistically significant.

**Results**

**Demographic, clinical and biological data**

In Table 1, we describe the characteristics of the cohort of patients from which we obtained the cut-off (Group A) and of the subjects of the two cohorts (Groups B and C) that were used to validate the criteria obtained. The derivation sample is made of 214 patients, the mean age was 54.9 (12.9) years and the mean disease duration was 11.1 (7.0) years.

Fifty-nine RA subjects (28%) reached the DAS28 value to define MDA status (DAS28 ≤2.85). On the other hand, according to the fulfillment of five of the seven WHO/ILAR core set criteria definition, 32% of the patients (68 subjects) achieved MDA. The proportion of patients achieving LDA, as defined by a SDAI score ≤11 or a CDAI score ≤10, were similar: 48% (102 subjects) and 47% (100 subjects), respectively (Table 2).

The validation samples were made, respectively, of 112 LSRA and of 95 ERA patients. The mean disease duration at the most recent follow-up visit was 4.5 (1.8) years for Group B (long disease duration) and 2.1 (0.8) years for ERA patients (Group C); instead, the mean disease duration at diagnosis for ERA was 0.5 (0.3) years (Table 1). The percentage of the patients included into the validation samples in MDA status, i.e. LDA, according to the various definitions is summarized in Table 2.

**RMDA definition**

Factor analysis was used for WHO/ILAR core set variables reduction. A cumulative percentage of variance of 89.13% could be explained by four components, with only one factor that had eigenvalues ≥1 (data not shown). Analysing the rotated

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<tr>
<th>TABLE 1. Characteristics of the three cohorts of patients with RA</th>
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<tr>
<td>Female, n (%)</td>
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<tr>
<td>Age, (yrs)</td>
</tr>
<tr>
<td>Mean disease, years*</td>
</tr>
<tr>
<td>Tender joints (0–28)</td>
</tr>
<tr>
<td>Swollen joints (0–28)</td>
</tr>
<tr>
<td>ESR, mm/h</td>
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<tr>
<td>CRP, mg/dl</td>
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<tr>
<td>HAQ (0–3)</td>
</tr>
<tr>
<td>PaGA (0–10)</td>
</tr>
<tr>
<td>PaPhGA (0–10)</td>
</tr>
<tr>
<td>Pain score assessment</td>
</tr>
<tr>
<td>DAS28</td>
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<tr>
<td>CDAI (0–76)</td>
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<tr>
<td>SDAI (0–86)</td>
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</table>

*Values are mean (S.D) if not stated otherwise. **The values reported indicate the mean of disease duration at the last follow-up visit. In Group C (ERA), the disease duration at diagnosis was 0.5 ± 0.3 years. ESR: Westergren ESR (mm/h).
component matrix (varimax with Kaiser normalization), we have determined which of the variables present in the core set of WHO/ILAR were most highly correlated with the four components and were better representative (Table 3). The analysis suggested that we could focus on PaGA, SJC (out of 28), HAQ and ESR.

We then evaluated and compared the ability of these variables (ESR, SJC on 28, HAQ and PaGA) to discriminate in the derivation sample the subjects that achieved an LDA status, as defined by a DAS28 score ≤ 2.85, using ROC curve analysis. Based on the ROC curve analysis (see supplementary figure 1 available as supplementary data at Rheumatology Online), we have chosen, for the selected variables, the cut-off points that provided the highest diagnostic accuracy (minimal false negative and false positive results) (Table 4).

The value of the AUC-ROC curve for the variables that indicate the state of inflammation (ESR) was 0.758 (s.e. 0.03). For ESR the cut-off point was ≤20 mm/h (79.7% of sensibility and 54.2% of specificity).

For the variables that evaluate joint examination (SJC of 28), a value of the AUC-ROC curve was: 0.899 (s.e. 0.02). For the SJC, the cut-off point was ≤2 (94.2% of sensibility and 72.9% of specificity). The value of the AUC-ROC for PaGA was 0.818 (s.e. 0.03). For PaGA, the cut-off point was ≤1.5 (78.1% of sensibility and 80.6% of specificity). The AUC-ROC for the HAQ had a value of 0.833 (s.e. 0.027). For HAQ, the cut-off point value was ≤0.5 (91.5% of sensibility and 60.6% of specificity).

To each of these four criteria we assigned a value of 1, thus having a score ranging from 0 to 4. To identify the value obtained from the combination of these four measures arising as a good predictor of OMERACT-MDA status, as defined by DAS28 ≤ 2.85, we tested the new data with another ROC curve analysis. The cut-off point with the highest overall accuracy for identifying RA patients with DAS28 ≤ 2.85 was a score of ≥3 [84.7% of sensitivity (95% CI 73.0, 92.8) and 88.4% of specificity (95% CI 82.3, 93.0), with LR+ 7.30]. The AUC for the total score increased up to 0.913 (s.e. 0.026; 95% CI 0.866, 0.947) (data not shown). From now on, we consider a patient as having an RMDA if he meets more than or equal to three of the four criteria: (i) ESR ≤20 mm/h; (ii) SJC (on 28 joints) ≤2; (iii) PaGA (0–10) ≤1.5; and (iv) HAQ (0–3): ≤0.5.

**Validation of RMDA definition**

We then estimated the effective capacity of such parameters to define an MDA status in an independent validation samples constituted by 112 subjects with LSRA and 95 patients with ERA, and we compared the new definition with the other published proposed definitions (OMERACT, CDAI and SDAI). In Table 1, we summarize the main characteristics of two cohorts of subject examined.

We analysed the data searching the subjects with an LDA status that fulfilled the RMDA definition [at least three of the four criteria: ESR ≤20 mm/h; PaGA ≤1.5 (0–10), SJC ≤2 (out of 28 joints) and HAQ ≤0.5 (range 0–3)].

In Group B, the patients with LDA status, according to RMDA definition, were 14 (12% of the total subjects with LSRA). Seven subjects out of 21 (33%) with DAS28 ≤ 2.85 did not fulfil the RMDA definition. However, 11 patients out of 21 (52%) with DAS28 ≤ 2.85 did not reach an MDA according to WHO/ILAR core set criteria.

Among subjects with ERA (Group C), the number of patients who fulfilled the RMDA definition for LDA status were 67 (71% of the total subjects evaluated). Out of 52 subjects, 4 (8%) who had DAS28 ≤ 2.85 did not reach the MDA according to RMDA criteria. Out of 52 subjects, 5 (10%) who had DAS28 ≤ 2.85 did not fulfil the WHO/ILAR core set criteria for LDA. We also assessed the agreement, in these two distinct populations, among the different definitions of MDA compared with RMDA criteria.

In the LSRA patients, the agreement between RMDA criteria and DAS28 ≤ 2.85, SDAI and CDAI definitions was good (range of κ: 0.642–0.765); a good agreement (κ: 0.721), moreover, arose between RMDA definition and the fulfilment of five of seven WHO/ILAR core set criteria.

In ERA patients, the agreement among three of four RMDA criteria for MDA and five of the seven WHO/ILAR core set criteria was good (κ: 0.750); a moderate agreement, instead, was found between RMDA and DAS28 ≤ 2.85 (κ: 0.496), SDAI (κ: 0.497) and CDAI definition (κ: 0.467) (Table 5).

In ERA patients, the agreement among three of four RMDA criteria for MDA and five of the seven WHO/ILAR core set criteria was good (κ: 0.750); a moderate agreement, instead, was found between RMDA and DAS28 ≤ 2.85 (κ: 0.496), SDAI (κ: 0.497) and CDAI definition (κ: 0.467) (Table 5).

**Analysing the number of subjects who fulfilled the EULAR criteria for remission (DAS28 ≤ 2.6), we observed that in the LSRA population 12 (75.0%) of the 16 subjects in remission achieved the LDA as defined by RMDA criteria compared with 8 (50.0%) subjects in MDA according to WHO/ILAR core set criteria and 14 (87.5%) subjects in MDA as defined by the SDAI score ≤11; every patient in remission status according to EULAR criteria had a CDAI score ≤10.

**Table 4. Value of ROC curve analysis for selected parameter**

<table>
<thead>
<tr>
<th>Variable</th>
<th>Cut-off</th>
<th>AUC (95% CI)</th>
<th>Sens. (95% CI)</th>
<th>Spec. (95% CI)</th>
<th>LR+</th>
<th>LR−</th>
</tr>
</thead>
<tbody>
<tr>
<td>ESR, mm/h</td>
<td>≤ 20</td>
<td>0.758 (0.695, 0.814)</td>
<td>79.66 (67.2, 89.0)</td>
<td>54.19 (46.0, 62.2)</td>
<td>1.74</td>
<td>0.38</td>
</tr>
<tr>
<td>SJC (28)</td>
<td>≤ 2</td>
<td>0.899 (0.851, 0.936)</td>
<td>94.92 (85.8, 98.9)</td>
<td>72.90 (65.2, 79.7)</td>
<td>3.50</td>
<td>0.07</td>
</tr>
<tr>
<td>PaGA (0–10)</td>
<td>≤ 1.5</td>
<td>0.818 (0.760, 0.867)</td>
<td>77.97 (65.3, 87.7)</td>
<td>78.06 (70.7, 84.3)</td>
<td>3.94</td>
<td>0.26</td>
</tr>
<tr>
<td>HAQ (0–3)</td>
<td>≤ 0.50</td>
<td>0.833 (0.776, 0.880)</td>
<td>91.53 (81.3, 97.2)</td>
<td>60.65 (52.5, 68.4)</td>
<td>2.33</td>
<td>0.14</td>
</tr>
</tbody>
</table>

Among the ERA population, 45 subjects (47% of total population) reached a DAS28 score <2.6, 43 (95.6%) of these patients obtained a status of MDA according to RMDA definition; 42 (93.3%) subjects were not in MDA according WHO/ILAR core set criteria. Everyone in this subset also achieved the LDA status as defined by CDAI and SDAI criteria.

**Discussion**

DAS28 is a widely used and well-accepted scoring system in trials. Vander Cruyssen et al. [18], comparing validity for the various disease activity indices, suggested that the DAS28 is the best determinant of physician opinion, based on each physician’s decision to modify the dose of infliximab in patients with RA. Other indices are available to measure RA activity on a continuous scale; in particular, the CDAI and SDAI scores are simple to calculate and easy to use. CDAI and SDAI, which were not developed to oppose the DAS (or DAS28) but only to provide rheumatologists with a simple tool [19], exhibit similar validity to DAS, with the potential exception of the LDA ranges [18, 20, 21]. However, quantitative measures and indices are often not assessed in standard rheumatology care. As reported by Pincus and Segurado [22] and Wolfe et al. [23], most patient visits in standard care do not include formal joint counts or patient questionnaires. For these reasons, there is a need to adopt a valid, feasible, simple and easy measure for daily clinical practice when the aim is clinical remission.

The parameters that have been selected to obtain the core set criteria for this new definition of RMDA are the most common and informative clinical and laboratory assessments that a physician usually performs in daily practice at the outpatient clinics.

This new definition of LDA was tested to achieve through the four simplest parameters (HAQ, PaGA, SJC assessed on 28 joints and ESR) a valid index to identify RA patients with an RMDA, obtaining results comparable with the criteria available at present. The RMDA definition is intended to be used as the end-point of any therapeutic programme for each RA patient in clinical practice. It could also be used to define classes of different disease activity, either in ERA or in LSRA. In fact:

(a) the RMDA criteria seems to behave similarly to WHO/ILAR core set as stated by OMERACT, but appears to be more simple and feasible;

(b) the definition appears to be the simplest aid to discriminate the status of subjects in a specific phase of the disease, and to define the major outcome of RA cohorts under treatment;

(c) it performs quite well in LSRA, since the correlation with DAS28 and CDAI or SDAI is even better than the DAS28 definition; of interest, DAS28 definition correlates only fairly with SDAI and CDAI in ERA.

The OMERACT variables were selected based on putative patient charts, not on real patients and the selection of cut-off values based on the agreement between the experts involved in the definition. The cut-off values we derived from our study are based on real patients and have been validated in independent cohorts, thus leading us to conclude that the values and the score we present are strong enough to define the MDA in the real world.

As expected, at least three of four RMDA criteria, like other definitions of MDA, also identified the majority of patients in DAS28 remission. Therefore, a score of at least 3 for RMDA identifies MDA as well as remission. This is clinically very important since trials with TNF-α blockers have clearly shown that the arrest of structural damage progression can be obtained in patients reaching a status of LDA and or remission. Along this line, when we tried to separate patients in DAS28 remission in our data set using a different RMDA cut-off values we were not able to better separate the two possible subsets.

**Rheumatology key messages**

- Evidence-based MDA criteria are needed for RA in clinical practice.
- The RMDA parameters are the most common clinical and laboratory assessments that a rheumatologist performs.
- There was substantial agreement between WHO/ILAR core set and RMDA criteria.

**Disclosure statement:** The authors have declared no conflicts of interest.

**Supplementary data**

Supplementary data are available at *Rheumatology* Online.

**References**


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TABLE 5. Agreement between the different definitions of LDA in LSRA and ERA patients (validation samples) a

<table>
<thead>
<tr>
<th></th>
<th>Three of four RMDA criteria</th>
<th>Five of seven WHO/ILAR core sets</th>
<th>DAS28 ≤2.85</th>
<th>SDAI ≤11</th>
<th>CDAI ≤10</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>LSRA (Group B)</strong></td>
<td></td>
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<tr>
<td>Three of four RMDA criteria</td>
<td>1</td>
<td>0.721 (good)</td>
<td>0.765 (good)</td>
<td>0.672 (good)</td>
<td>0.642 (good)</td>
</tr>
<tr>
<td>Five of seven WHO/ILAR core sets</td>
<td>1</td>
<td>0.596 (moderate)</td>
<td>0.573 (moderate)</td>
<td>0.490 (moderate)</td>
<td>0.490 (moderate)</td>
</tr>
<tr>
<td>DAS28 ≤2.85</td>
<td>1</td>
<td>0.856 (excellent)</td>
<td>0.866 (excellent)</td>
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<tr>
<td>SDAI ≤11</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.494 (excellent)</td>
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<tr>
<td>CDAI ≤10</td>
<td>1</td>
<td></td>
<td>1</td>
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<td><strong>ERA (Group C)</strong></td>
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<tr>
<td>Three of four RMDA criteria</td>
<td>1</td>
<td>0.750 (good)</td>
<td>0.496 (moderate)</td>
<td>0.497 (moderate)</td>
<td>0.467 (moderate)</td>
</tr>
<tr>
<td>Five of seven WHO/ILAR core sets</td>
<td>1</td>
<td>0.700 (good)</td>
<td>0.431 (moderate)</td>
<td>0.398 (fair)</td>
<td></td>
</tr>
<tr>
<td>DAS28 ≤2.85</td>
<td>1</td>
<td>0.359 (fair)</td>
<td>0.346 (fair)</td>
<td></td>
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<tr>
<td>SDAI ≤11</td>
<td>1</td>
<td></td>
<td>1</td>
<td>0.956 (excellent)</td>
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<tr>
<td>CDAI ≤10</td>
<td>1</td>
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aDegree of agreement indicated by x-values: <0.2 = poor agreement; 0.21–0.40 = fair agreement; 0.41–0.60 = moderate agreement; 0.61–0.80 = good agreement; 0.81–1.0 = excellent agreement.


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