The prevalence of clinical remission in RA patients treated with anti-TNF: results from the Dutch Rheumatoid Arthritis Monitoring (DREAM) registry

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Abstract

Objectives. To evaluate the prevalence of clinical remission and minimal disease activity according to the ACR/European League Against Rheumatism (EULAR) remission, DAS-28 $< 2.6$ and minimal disease activity (MDA) criteria, and to compare the extent of residual disease activity with disability in RA patients after 6 months of treatment with anti-TNF.

Methods. In the Dutch Rheumatoid Arthritis Monitoring (DREAM) biologic registry the prevalence of DAS-28 $< 2.6$, MDA and ACR/EULAR remission criteria was assessed. Residual disease activity during MDA or remission was assessed as the percentage of patients with swollen and tender joints, elevated acute-phase reactants and general health on a visual analogue scale (VAS). Disability was evaluated with the HAQ score.

Results. Prevalence of DAS-28 $< 2.6$ was 27%, prevalence of MDA was 34% and ACR/EULAR remission was reached by 6% of patients. Residual disease activity was present mostly in the most lenient criteria and occurred most frequently on the level of swollen joint count and VAS score: at least one swollen joint in DAS-28 $< 2.6$, MDA and ACR/EULAR remission was present in, respectively, 51, 54 and 34% of the patients. VAS $> 1$ occurred in, respectively, 67, 69 and 0% of the patients. Modification of the cut-point of the patient-reported outcome increased the prevalence of ACR/EULAR remission, but also the level of disability.

Conclusion. MDA and DAS-28 $< 2.6$ are reachable treatment targets in RA with anti-TNF, although residual disease activity might still be present. In turn, ACR/EULAR remission criteria leave little residual disease activity, but might be too stringent for use in daily clinical practice due to the strict cut-point in the patient-reported outcome.

Key words: rheumatoid arthritis, epidemiology, biologic therapies, disability evaluation, outcome measures.
However, treatment targets for RA do shift and the following question may be raised: what currently is the appropriate treatment target in RA?

The DAS-28 \(<2.6\) remission criterion is frequently used in clinical studies. This criterion appears to be relatively lenient. Simplified Disease Activity Index (SDAI) and Clinical Disease Activity Index (CDAI) are stricter by design, whereas the preliminary ACR remission criteria are even stricter. Due to the observation that real clinical remission did not occur frequently in daily clinical practice, the concept of minimal disease activity (MDA) was introduced in 2005. MDA was defined as a state of disease activity that could be a useful target of treatment by both physician and patient [6]. In 2011, new remission criteria for RA were presented, jointly developed by ACR and European League Against Rheumatism (EULAR) [7]. These remission criteria were developed for clinical trials, and according to the authors should be easy to use, achievable in practice and stringent, in order to differentiate remission from low disease activity. In clinical trials, remission criteria are used to compare active medication with placebo or usual care at group level, whereas the goal of remission criteria in daily practice concerns the individual patient. Therefore, the ACR/EULAR remission criteria may be too strict in daily clinical practice, especially due to the low cut-point (\(<1\) cm) in the patient-reported outcome (PRO) [8, 9].

The objectives of this study were to determine reachable targets for treatment with anti-TNF in RA by studying the prevalence of remission and MDA according to three different criteria: DAS-28 \(<2.6\), MDA and ACR/EULAR remission criteria, to show the presence of residual disease activity in the different criteria and to evaluate the relation between residual disease activity and disability in RA patients after 6 months of treatment with anti-TNF.

**Patients and methods**

**Design**

The DREAM (Dutch Rheumatoid Arthritis Monitoring) biologic registry is a prospective, ongoing cohort study of RA patients treated with biologics that started in 2003. The registry contains data collected in 13 collaborating hospitals in the Netherlands. Data for RA patients who started using anti-TNF before 2003 at the Department of Rheumatology at the Radboud University Nijmegen Medical Centre were collected in the predecessor of the DREAM registry, which had the same inclusion criteria. For the current study, data from the DREAM registry and its predecessor were used for RA patients who for the first time started with anti-TNF. Prevalence of remission was studied at 6-month follow-up, since the maximal effect of anti-TNF is observed between 3 and 6 months after start of therapy, whereas the average level of disease activity stays stable after 6 months [10] (Fig. 1).

**Patients**

Inclusion criteria for the DREAM biologic registry were diagnosis of RA according to the 1987 ACR criteria, starting treatment with a biologic treatment and the presence of written informed consent. According to Dutch reimbursement rules, treatment with biologic therapy is reimbursed in case of active disease (DAS-28 \(>3.2\)) after treatment failure of at least two DMARDs, including MTX. Patients were consecutively included in the cohort. Switching or stopping biologic treatment was not a reason for exclusion from the cohort. For the current analysis, patients were included if treated with anti-TNF with a minimal duration of 6 months and having follow-up data at 6 months. According to Dutch law, no approval of an ethics committee is required for this observational study.

**Remission and MDA criteria**

Criteria used in the analyses were the DAS-28 \(<2.6\) criterion, MDA and the new ACR/EULAR remission criterion. DAS-28 was calculated using the original formula with swollen joint count (SJC)-28, tender joint count (TJC)-28, ESR and general health on a visual analogue scale (VAS GH) [11, 12]. MDA was defined as the presence of SJC-28 = 0, TJC-28 = 0 and ESR \(\leq 10\) mm/h; or the presence of DAS-28 \(<2.65\) [13]. ACR/EULAR remission criteria are defined as SJC-28 \(\leq 1\), TJC-28 \(\leq 1\), CRP \(\leq 1\) mg/dl and patient global assessment (PtGA) of disease activity \(\leq 1\) on a VAS of 10 cm [7]. In the DREAM cohort, PtGA was not a standard measurement. We used VAS GH instead of PtGA in the calculations because of the large agreement between PtGA and general health measured on VASs. In a subset of patients with both assessments of VAS GH and PtGA at 6-month follow-up (\(n=147\)), the intraclass correlation coefficient (ICC) between PtGA and VAS GH was 0.79 (\(P<0.0001\)). The mean difference between PtGA and VAS GH was approaching zero (0.11 cm, \(P=0.41\)), and the limits of agreement were ±32 mm. This suggests absence of a systematic error in the presence of considerable random error, not leading to bias (supplementary Fig. S1, available as supplementary data at Rheumatology Online).
In a previous study, it has been shown that high values for the VAS assessment may occur even when SJC-28, TJC-28 and ESR are at a low or normal level [8]. Therefore, the performance of the ACR/EULAR criteria was also analysed when modifying the PRO by varying the cut-point. CDAI, SDAI and (modified) ACR remission criteria could not be calculated because physician global assessment of disease activity, morning stiffness and fatigue were not standardly assessed in all periods of the DREAM biologic registry.

Residual disease activity
Residual disease activity was defined as any detectable disease activity assessed by the number of swollen and tender joints, by acute-phase reactants ESR >20 mm/h in men and >30 mm/h in women and CRP >1 mg/dl, and by VAS GH >1 (on a scale from 0 to 10 cm).

Disability
Disability was measured by the validated Dutch version of the HAQ on a scale from 0 to 3, in which a higher score signifies more disability [14, 15].

Analysis
The prevalence of remission and MDA and the presence of residual disease activity as well as the level of disability were analysed at 6 months after start with a first anti-TNF. Missing values for ESR (9%) were imputed based on age, sex, joint counts and CRP using single imputation with a regression method including a random component [16]. Similarly, missing values for CRP (18%) were imputed based on age, sex, joint counts and ESR. Statistical testing of the prevalence and HAQ scores between different criteria was not possible due to the study design with the same patients in the different groups.

Results
Patients
Until June 2010 there were 2220 patients included in the DREAM registry and its predecessor who started their first anti-TNF treatment. Eleven per cent of patients had stopped anti-TNF treatment before 6 months (236/2220). Of 453 patients, there were no joint counts available at 6-month follow-up, leading to 1531 evaluable patients. The mean age of patients at start of their first anti-TNF agent was 54.4 years (s.d. 12.7), with a median disease duration of 71.0 months [interquartile range (IQR) 25.0–156.0]. Of the 1531 patients, 68.5% (1049/1531) were female and 71.7% (1066/1487) were positive for IgM RF. At baseline the mean DAS-28 was 5.00 (s.d. 1.32), and after 6 months of treatment the mean DAS-28 was decreased from 1.51 (P < 0.001) to 3.49 (s.d. 1.34). Patients included in the analysis did not differ significantly or relevantly from patients not included in the analysis (results not shown).

At baseline, 37% (562/1531) of patients started adalimumab, 42% (640/1531) etanercept and 21% (329/1531) infliximab. Fifty per cent (772/1531) of patients used one concomitant DMARD and 40% (614/1531) of patients used two or more DMARDs concomitantly. Seventy-four per cent (1139/1531) of patients used MTX and 36% (555/1531) of the patients used corticosteroids at baseline.

Remission and MDA criteria
The prevalence of clinical remission and MDA are presented in Table 1. Prevalence of DAS-28 <2.6 was

<table>
<thead>
<tr>
<th>n = 1531</th>
<th>DAS-28 &lt; 2.6</th>
<th>MDA</th>
<th>ACR/EULAR remission</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>26.9 (412)</td>
<td>33.9 (519)</td>
<td>6.1 (93)</td>
</tr>
<tr>
<td>SJC = 0</td>
<td>49.0 (202)</td>
<td>46.2 (240)</td>
<td>65.6 (61)</td>
</tr>
<tr>
<td>= 1</td>
<td>19.9 (82)</td>
<td>19.5 (101)</td>
<td>34.4 (32)</td>
</tr>
<tr>
<td>≥ 2</td>
<td>31.1 (128)</td>
<td>34.3 (178)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>SJC &gt; 0</td>
<td>51.0</td>
<td>53.8</td>
<td>34.4</td>
</tr>
<tr>
<td>TJC = 0</td>
<td>74.8 (308)</td>
<td>71.1 (369)</td>
<td>78.5 (73)</td>
</tr>
<tr>
<td>= 1</td>
<td>15.8 (65)</td>
<td>17.1 (89)</td>
<td>21.5 (20)</td>
</tr>
<tr>
<td>≥ 2</td>
<td>9.5 (39)</td>
<td>11.8 (61)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>TJC &gt; 0</td>
<td>25.2</td>
<td>28.9</td>
<td>21.5</td>
</tr>
<tr>
<td>ESR elevated</td>
<td>1.0 (4)</td>
<td>2.9 (15)</td>
<td>5.4 (5)</td>
</tr>
<tr>
<td>CRP elevated</td>
<td>8.7 (36)</td>
<td>9.8 (51)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>VAS GH &gt; 1</td>
<td>67.2 (277)</td>
<td>69.4 (360)</td>
<td>0 (0)</td>
</tr>
<tr>
<td>HAQ, median (IQR)</td>
<td>0.63 (0.25–1.09)</td>
<td>0.63 (0.25–1.13)</td>
<td>0.38 (0.13–0.63)</td>
</tr>
</tbody>
</table>

Values are represented as percentages with number within parentheses, unless otherwise mentioned. DAS-28: 28-joint DAS with cut-point 2.6; MDA: defined as DAS-28 <2.85 or SJC-28 = 0, TJC-28 = 0 and ESR ≤ 10 mm/h; ACR/EULAR remission defined as SJC-28 ≤ 1, TJC-28 ≤ 1, CRP ≤ 1 mg/dl and VAS GH ≤ 1; ESR elevated: ESR >20 mm/h (male) or >30 mm/h (female); CRP elevated: CRP >1 mg/dl, VAS GH: patient assessment of general health on a VAS from 0 to 10; HAQ score: HAQ score of patients in remission.
The prevalence of clinical remission according to the ACR/EULAR criteria was 6.1%. Agreement between DAS-28 <2.6 and MDA was 93% (κ = 0.72), between DAS-28 <2.6 and ACR/EULAR remission agreement was 78% (κ = 0.18) and between MDA and ACR/EULAR remission agreement was 72% (κ = 0.14). Modification of ACR/EULAR remission criteria by increasing the cut-point of VAS increased the prevalence of remission to 10.3% when VAS ≤ 2 and to 17.8% when VAS ≤ 4 (Table 2).

Disability
HAQ score in ACR/EULAR remission is 0.38 and is lower than the mean HAQ of 0.63 in patients in DAS-28 <2.6 and MDA (Fig. 2). When modifying the cut-point of VAS GH, HAQ score did not change when increasing the cut-point from 1 to 2. When the VAS cut-point was increased to 3 or 4, the median HAQ increased from 0.38 to 0.50.

Discussion
The prevalence of remission and MDA after 6 months of treatment with anti-TNF in RA patients differed largely between criteria, according to the results of this study. MDA and DAS-28 <2.6 were quite lenient, with 26–33% of patients being in remission at 6 months and ACR/EULAR remission criteria were quite strict, with 6% of patients being in remission at 6 months. Obviously, residual disease activity occurred more frequently in the more lenient criteria. For DAS-28 <2.6 and MDA criteria, most residual disease activity was present in the VAS GH > 1 cm, up to 69% of patients in MDA. In the ACR/EULAR remission criteria residual disease activity is part of the criteria. The majority of patients with no swollen or tender joints and a CRP ≤ 1 mg/dl, who may be considered to be in clinical remission to an important extent, were not classified as being in remission according to the ACR/EULAR remission criteria because of their VAS GH > 1 cm. Another striking result is that patients who score 1 on every item of the ACR/EULAR remission criteria have a DAS-28 of 2.8, which is higher than the cut-point of DAS-28 remission. Due to these results, and in addition to the VAS GH being the variable with the most residual disease activity in DAS-28 <2.6 and MDA, it appears that the low cut-point (≤ 1 cm) in the PRO of the ACR/EULAR remission criteria is too strict to be applied in daily clinical practice. When the criteria were modified by varying the cut-point of VAS GH stepwise to 4, the prevalence of remission increased to ~18%.

Our last objective, to evaluate the relation between residual disease activity and disability, showed that more

### Table 2: Prevalence of remission and residual disease activity in modification of the ACR/EULAR remission criteria

<table>
<thead>
<tr>
<th>n = 1531</th>
<th>VAS ≤ 1</th>
<th>VAS ≤ 2</th>
<th>VAS ≤ 3</th>
<th>VAS ≤ 4</th>
<th>No VAS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Prevalence</td>
<td>6.1 (93)</td>
<td>10.3 (157)</td>
<td>14.4 (221)</td>
<td>17.8 (272)</td>
<td>22.5 (345)</td>
</tr>
<tr>
<td>SJC = 0</td>
<td>65.6 (81)</td>
<td>63.7 (100)</td>
<td>65.6 (145)</td>
<td>65.1 (177)</td>
<td>66.1 (228)</td>
</tr>
<tr>
<td>= 1</td>
<td>34.4 (32)</td>
<td>36.3 (57)</td>
<td>34.4 (76)</td>
<td>34.9 (95)</td>
<td>33.9 (117)</td>
</tr>
<tr>
<td>TJC = 0</td>
<td>78.5 (73)</td>
<td>76.4 (120)</td>
<td>73.8 (163)</td>
<td>71.7 (195)</td>
<td>71.3 (246)</td>
</tr>
<tr>
<td>= 1</td>
<td>21.5 (20)</td>
<td>23.6 (37)</td>
<td>26.2 (58)</td>
<td>28.3 (77)</td>
<td>28.7 (99)</td>
</tr>
<tr>
<td>ESR elevated</td>
<td>5.4 (5)</td>
<td>7.0 (11)</td>
<td>8.6 (19)</td>
<td>11 (30)</td>
<td>11 (38)</td>
</tr>
<tr>
<td>HAQ, median (IQR)</td>
<td>0.37 (0.13–0.63)</td>
<td>0.38 (0.13–0.63)</td>
<td>0.50 (0.13–0.88)</td>
<td>0.50 (0.25–1.00)</td>
<td>0.63 (0.25–1.13)</td>
</tr>
</tbody>
</table>

Values are represented as percentages with numbers within parentheses, unless otherwise mentioned. ACR/EULAR remission criteria: SJC = 0, TJC = 0, CRP > 1 mg/dl. The prevalence of MDA (DAS-28 <2.6) was 33.9%. The prevalence of clinical remission according to the ACR/EULAR criteria was 6.1%. Agreement between DAS-28 <2.6 and MDA was 93% (κ = 0.72), between DAS-28 <2.6 and ACR/EULAR remission agreement was 78% (κ = 0.18) and between MDA and ACR/EULAR remission agreement was 72% (κ = 0.14). Modification of ACR/EULAR remission criteria by increasing the cut-point of VAS increased the prevalence to 10.3% when VAS ≤ 2 and to 17.8% when VAS ≤ 4 (Table 2).
residual disease activity also led to increased disability scores. This was shown when comparing ACR/EULAR remission with the more lenient criteria, but also in the increasing HAQ when modifying the cut-point of VAS in the ACR/EULAR remission criteria.

As RA patients may have a different prognosis for joint damage progression, based on the presence of e.g. shared epitope, anti-CCP positivity or RF positivity, this implies that ACR/EULAR remission must not be the most appropriate treatment target for all RA patients. In the presence of less favourable prognostic factors such as anti-CCP and residual presence of swollen joints, pharmacological treatment may be intensified if not leading to unacceptable toxicity.

The prevalence of remission and MDA differs between health care systems and countries [2–4]. The prevalence of 25% in DAS-28 <2.6 as found in our study falls well within the range of prevalences found in other daily practice studies of anti-TNF that varied from 16 to 32% [17–20]. The differences in prevalence may depend on follow-up time, disease duration and baseline disease activity. MDA is less frequently reported than DAS-28 <2.6 in clinical studies. Three trials with adalimumab and abatacept showed a prevalence of MDA of 15–31% [21, 22]. In two cohorts of RA patients using non-biologic DMARDs, a prevalence of MDA was found of 20–23% [23, 24]. Prevalence of ACR/EULAR remission in cross-sectional analysis in cohorts of daily practice was 7.5–8.8% [25, 26].

Residual disease activity, especially of swollen joints, is a known feature in DAS-28 <2.6. This is explained by the fact that low scores in one variable can compensate for high scores in others and the relatively low weight for swollen joints in the DAS-28 formula. In our cohort 51% of patients had one or more swollen joint, which is higher than the range 9–30% found in the literature. Twenty-five per cent of patients with tender joints when DAS-28 was <2.6 is in agreement with 8–40% of patients with DAS-28 <2.6 in other studies [27–29]. Residual disease activity in MDA or ACR/EULAR remission criteria was not previously published.

In the literature, the HAQ score accepted as remission is 0.5, representing hardly any difficulties in daily activities. HAQ of 1.0 represents mild disability with some difficulties in all activities [30]. The median HAQ score of patients in ACR/EULAR remission is below the cut-point of 0.5. After modification of the VAS cut-point to 3 or 4, the median HAQ did not exceed 0.5. The IQR of the HAQ became larger, but does not exceed the cut-point for mild disability.

Treatment targets for RA are shifting. True clinical remission, which can be defined as the complete absence of clinical signs and symptoms, is still difficult to reach. MDA or DAS-28 <2.6 might be a more reachable treatment target in practice. MDA and DAS-28 <2.6 appear to perform quite similarly, with regard to prevalence as well as the occurrence of residual disease activity. Given the amount of residual disease activity allowed for in DAS-28 <2.6, it is proposedly rather describes a state of near remission or minimal disease activity just like MDA does.

ACR/EULAR remission criteria were developed to define a strict, though achievable target that distinguishes remission from low disease activity. By its construction, the ACR/EULAR remission criteria effectively decrease the presence of residual disease activity as measured by tender, swollen joints and acute-phase reaction, but they seem hard to achieve.

Fig. 2 Prevalence of MDA and remission and mean HAQ score.

(A) Prevalence of MDA, DAS-28 <2.6 and ACR/EULAR remission. MDA defined as DAS-28 < 2.85 or SJC-28 = 0, TJC-28 = 0 and ESR ≤ 10 mm/h; ACR/EULAR remission defined as SJC-28 ≤ 1, TJC-28 ≤ 1, CRP ≤ 1 mg/dl and VAS GH ≤ 1. (B) Mean HAQ score in patients with MDA, DAS-28 <2.6 or ACR/EULAR remission.

(B) Mean HAQ score in patients with MDA, DAS-28 <2.6 or ACR/EULAR remission.
It is debatable whether or not a PtGA ≤ 1 is mandatory for remission of disease activity. Obviously, a low PtGA is aimed at when the goal is to restore health. According to the authors, a PRO should be included in the definition, as was shown by a CART analysis, however, the cut-point for PtGA was chosen for practical reasons [7]. However, there are reasons to regard the cut-point of 1 cm as inappropriately low. First, the cut-point of 1 assumes that PtGA in non-RA patients would be ≤ 1. However, 45% of the normal population aged ≥ 50 has a VAS GH score of > 2/10 [31]. Secondly, the PtGA might unjustly be interpreted as measuring only RA disease activity. The PRO is included in the definition of ACR/EULAR remission because it should convey morning stiffness, fatigue and other not objectively assessable disease activity. High correlations between VAS disease activity, pain and general health show that it is difficult for patients to distinguish RA activity from other ailments like accompanying OA or myalgia. Additionally, several mechanisms separated from arthritis do influence patients’ evaluation of their health, such as recalibration of the VAS after treatment (response shift), patients being more sensitive to losses than to gains (loss aversion) and the tendency of people not to rate extremes (end of scale aversion) and apparently are not considered in the choice for the cut-point [32]. Due to this unrealistically low cut-point, this variable has a very heavy weight in the ACR/EULAR definition of remission and remission is hard to achieve.

Remission as the ultimate goal in RA is questionable, because the definition of remission is still a matter of discussion. More important is to have reachable treatment targets based on disease outcomes such as functionality. When PtGA is modified in the criteria, prevalence increases considerably, but disability score also increases. This shows that it is desirable to include a PRO in the definition of remission. However, it is unknown to what extent variation in the VAS cut-point compromises the validity of the criteria.

The results presented concern a cohort of patients with established RA and a median disease duration of 6 years. However, from a treatment viewpoint it is highly relevant to try to reach remission in early RA. Moreover, remission, notably with the ACR/EULAR remission criteria, may be more easily reached in early RA [33]. The time point of 6 months that was chosen for our analyses may be perceived to be short. However, this time point was chosen because the largest decrease in disease activity in patients with established RA occurred in the first 6 months after starting anti-TNF treatment and the average level of disease activity stays stable after 6 months. Illustratively, occurrence of remission was not different between 6 and 12 months of follow-up. We also regarded that 6 months is a meaningful time point to show the much-wished-for beneficial effect of anti-TNF in RA patients failing DMARD therapy.

Due to the large amount of missing data of the variables Physician Global Assessment and PtGA for disease activity in the DREAM data set, we used only the DAS-28-based definitions of MDA and the ACR/EULAR remission criteria based on SJC-28, TJC-28, CRP and PtGA. This is a limitation of our study. Further, the PtGA rating was substituted by VAS GH in our calculation of ACR/EULAR remission criteria. The concept rated by the VAS GH is not the same as the concept rated by the VAS disease activity, because general health can also be caused by factors other than disease activity. However, VAS GH and PtGA by the patient were closely correlated and there was no systematic difference between the two variables. Therefore, we regard that at least in our study the ACR/EULAR remission criteria would not have performed differently with PtGA instead of general health.

In the definition of MDA, ESR is used as acute-phase reactant, whereas in ACR/EULAR remission CRP is chosen. Therefore, the criteria are difficult to compare on the acute-phase reactant. The aim of our study was to compare three different criteria, not to compare performance of CRP with that of ESR. We chose to present residual activity of both variables because of difference in common use or preference of rheumatologists.

In conclusion, MDA and DAS-28 <2.6 are reachable treatment targets in daily clinical practice for anti-TNF treatment of RA. However, both are associated with the presence of residual disease activity. In contrast, ACR/EULAR remission criteria show limited residual disease activity, but are not easily reached in clinical practice mainly because of the strict cut-point on PtGA ≤ 1 cm.

### Acknowledgements

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

### Supplementary data

Supplementary data are available at *Rheumatology* Online.
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