

Use of clinical scores to guide therapeutic decisions in patients with rheumatoid arthritis in daily care

O. Malysheva¹, A. Bedrich¹,
J.G. Kuipers², H. Kleine³,
B. Wolff³, C.G. Baerwald¹

¹University Hospital Leipzig, Department for Gastroenterology and Rheumatology, Rheumatology Unit, Leipzig, Germany;

²Rotes Kreuz Hospital Bremen, Department for Internal Rheumatology, Bremen, Germany;

³AbbVie Deutschland GmbH & Co. KG, Wiesbaden, Germany.

Olga Malysheva, MD

Anne Bedrich, MD

Jens G. Kuipers, MD, PhD

Henning Kleine, MD

Björn Wolff, MD

Christoph G. Baerwald, MD, PhD

Please address correspondence to:

Dr Olga Malysheva,
Rheumatology Unit, Department for
Medicine, Neurology and Dermatology,
Liebigstrasse 20,
04103 Leipzig, Germany.

E-mail:

olga.malysheva@medizin.uni-leipzig.de

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ABSTRACT

Objective. *This study focuses on the application and impact of different clinical scores for treatment changes in daily practice in patients with rheumatoid arthritis (RA), as achieving remission is a feasible aim due to considerable improvements in therapeutic options.*

Methods. *In this prospective study, 1467 RA patients aged 15 to 88 years (72.5% female, 27.5% male) who had undergone treatment change or were treated with a disease-modifying anti-rheumatic drug (DMARD) for the first time were analysed. At three consecutive visits (T-1, T0, T1), scores were used to assess disease activity, loss of function, quality of life and imaging. In addition, the impact of the scores on treatment change was addressed (numerical rating scale, 1–10).*

Results. *The most commonly used scores were the DAS28 (65% of all visits), the Hanover functional ability questionnaire (FFbH, 36%) and the HAQ (11%). Other scores for evaluating RA are of little relevance in daily practice. No scores were calculated in only 10% of visits. Among the commonly used scores, the DAS28 had the highest influence on therapy decisions, followed by HAQ and FFbH (mean weight 6.62, 4.99 and 4.41, respectively).*

Conclusion. *In daily practice, rheumatologists very often take scores for disease activity (especially DAS28) and loss of physical function into consideration when deciding on treatment for patients with RA. However, scores for measuring structural changes or quality of life, are not yet very well established with German rheumatologists.*

Introduction

The primary goal of rheumatoid arthritis (RA) therapy is to achieve remission. The path to achieving this goal is based on, amongst other things, the *Treat-to-Target* recommendations of an international research group (1). The regular monitoring disease activity with validated instruments and the recording of structural and functional changes is recommended to guide treatment. A variety of scores is available for objectively recording these

parameters (2-5). The German Rheumatology Association (*Deutsche Gesellschaft für Rheumatologie, DGRh*) recommends the DAS28, SDAI or CDAI for documenting disease activity, and the FFbH (Funktionsfragebogen Hannover = Hanover functional ability questionnaire) for documenting physical functional ability (6). How often these and other scores commonly used in clinical trials with RA patients are actually used in routine care in Germany has not been widely studied. This study aims to provide information on which scores are used in daily practice and how much significance physicians working in rheumatology ascribe to these scores.

Methods

As part of a nationwide prospective study from 2010 to 2012 (the ScoRA study), use of scores by rheumatologists in 77 practices and 10 hospitals was documented using a questionnaire. A total of 1838 patients with RA who had undergone treatment change were included (T0). First-time treatment with a DMARD, change within the DMARD group, initiation or change of combination therapy or change to or within the biologics group constituted treatment change. At T0, patient demographics and the use of scores were recorded. At the same time, the retrospective documentation of scores used at the previous visit was carried out (T-1). At the patient's next visit for treatment monitoring, score usage was recorded again (T1). The use of the following scores for different aspects of RA was recorded: Disease activity (28-joint Disease Activity Score (DAS28) (2), 44-joint Disease Activity Score (DAS44) (7), Simplified Disease Activity Index (SDAI) (2), Clinical Disease Activity Index (CDAI) (2), Rheumatoid Arthritis Disease Activity Index (RADAI-5) (2)), loss of physical function (Health Assessment Questionnaire (HAQ) (5), Hanover functional ability questionnaire (FFbH) (3)), quality of life (12-item short form health survey (SF-12) (4), 36-item short form health survey (SF-36)) and imaging (7-joint ultrasound score (US7) (8), modified Total Sharp Score (TSS) (9), Ratingen Score

(10), Steinbrocker Score (11). Furthermore, an assessment was made in each case on a scale from 1 to 10 to determine how much the calculated scores contributed to a decision regarding treatment change (1=little contribution to 10=very high contribution). After study initiation, an additional question was included at the T0 visit to investigate how much the decision to change the treatment was driven by the physician or the patient. Both the physician and patient were requested to estimate the impact of their assessment on the treatment decision on a scale from 1 to 10 (1=little contribution to 10=very high contribution) which was obtained in a subgroup of cases at time point T0 only (n=472).

Patients with incomplete data were excluded from the analysis. The data were analysed using the Mann-Whitney-U test to compare score use with and without treatment change across all visits.

Results

A total of 1838 patients were included in this study with 371 patients being excluded from evaluation due to incomplete documentation at the baseline visit (T0); therefore 1467 patients (72.5% female, 27.5% male) aged 15 to 88 were evaluated. The mean age was 55.9 years and the median age 56 years. The mean disease duration was 79.5±90.7 months. Scores for disease activity were most commonly used (76% of all visits at T-1, T0, T1), followed by those for loss of physical function (54%) and imaging (4%). The DAS28 was by far the most commonly used score (65% of all visits) and had a significant impact on treatment decisions, with a mean weight of 6.62±2.19 on a scale from 1–10. The FFbH was the second most commonly used score (36%) and contributed moderately to treatment decisions with a mean relevance of 4.41±2.20. The same relevance was ascribed to the HAQ (mean weight 4.99±2.30), but this score was only applied in 11% of all visits. The CDAI was found to have the highest relevance for treatment decisions (mean weight 8.67±2.44), but this score is very rarely used (1%). In 10% of all visits, no score was used to assess the disease (Fig. 1).

Fig. 1. Frequency of applied scores in all visits (n=4401) [in %]. Black bars show the categories of the applied scores, shaded bars show the use of individual scores in percent.

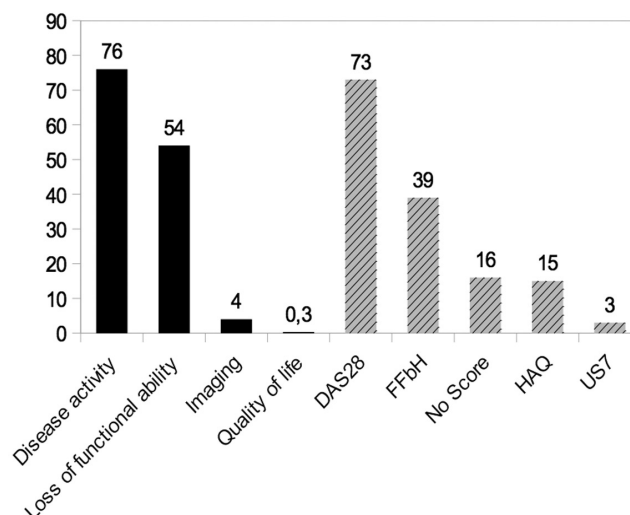
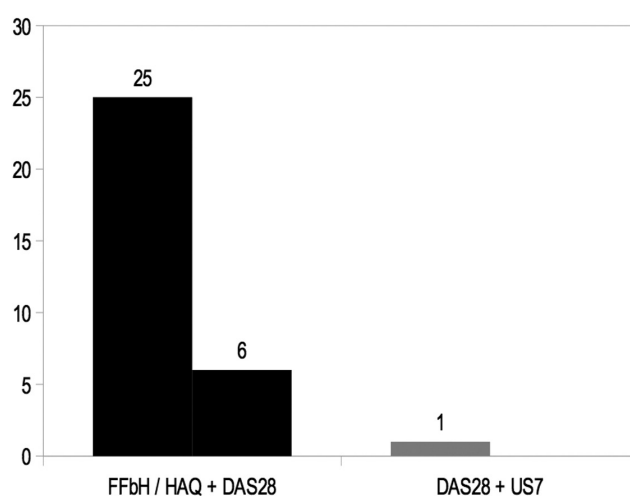


Fig. 2. Most common score combinations [% of visits]. The combination of scores for disease activity (DAS28) with those assessing functionality (FFbH and HAQ, black) is more common than the combination with imaging scores (US7, grey). In the case of two bars, the first represents the combination with FFbH, the second represents the combination with HAQ.



In 37% of all cases, several scores were used at the same examination time point. The combination of DAS28 and FFbH constituted the most common combination (25% of all visits). The second most common combination, DAS28 and HAQ, was used in 6% of all visits. Other score combinations were negligible. (Fig. 2). Imaging scores such as the sonographic US7 score (3%) or a radiological score (1%) are also seldom used.

In a subgroup of 472 patients, there was no significant correlation between physician and patient judgement regarding the necessity of treatment change was observed (Spearman's rank correlation coefficient $r=0.189$). Overall, the physician's assessment strongly contributed (mean scale value 7.70±1.58) to the decision of treatment change to the patient's assessment (mean scale value 6.42±2.15).

Comparing score use between primary rheumatological centres, *i.e.* practices and hospitals, at time point T0 revealed a significant difference in the use of the HAQ score (27.3% vs. 17.2%; $p=0.004$) and the EULAR response (1.2% vs. 15.2%; $p<0.001$). However, the number of patients from hospitals was low (n=132). Furthermore, there was a significant higher score usage in patients switching to biologics at T0 compared to patients not receiving biologics (DAS28 88.6% vs. 81.4% and HAQ 22.7% vs. 15.4%; $p<0.001$, respectively). Stratifying the patients for disease duration (DD) revealed an increased usage of the FFbH with long standing disease (DD <2 years 39.2%, DD 2–6 yrs. 43.8%, DD >6 yrs. 50.4%, $p=0.001$). Of interest, there was a significant difference in the utilisation of scores between various regions in Germany. In the eastern parts of Germany

DAS28 (87.9% vs. 83.1%, $p=0.04$), FFbH (62.1% vs. 40.3%, $p=0.001$) and EULAR (9.1% vs. 0.8%, $p<0.001$) were significantly more often used compared to the rest of Germany.

Discussion

This study demonstrates that scores for assessing rheumatoid arthritis disease activity, mainly the DAS28, are widely used in daily practice. The FFbH is the only other score which was used relatively often. Newer scores such as CDAI, SDAI or RADAI-5 are not yet used routinely.

There may be several reasons for only certain scores being used. One potential explanation may be that, in daily clinical practice, biologics can only be prescribed if DMARD therapy did not have the desired effect (1). To measure this effect, disease activity must be regularly documented, e.g. with the DAS28. Therefore, DAS28 was used in nearly 90% of patients at the time point of initiation of a therapy with biologics (T0). Other scores have only been used within studies and are therefore calculated less often in daily practice (RADAI-5, SDAI, CDAI) (2). The German Rheumatology Association (*Deutsche Gesellschaft für Rheumatologie, DGRh*) recommends the DAS28, SDAI or CDAI for documenting disease activity, and the FFbH for documenting physical functional ability (6). In particular in long standing disease the functional score FFbH was used more frequently. Therefore, cultural differences make it necessary to adapt score systems to the respective country and culture (12). In this respect there was a significant difference in the utilisation of scores between eastern parts and the rest of Germany.

Imaging scores are only rarely used as they are relatively time-consuming (6, 9). Consequently, the radiological scores are of little importance for daily clinical practice, where the focus is on the patient's clinical symptoms (general state of health, tender and swollen joints).

Similarly, arthrosonography and the US7, an ultrasound-based score for assessing synovitis, tendosynovitis, paratendinitis and erosion of the affected

joints as an alternative imaging score is rather time consuming and therefore hardly used in our study (8). However, the data were obtained from a total of three sites only, so that the data pool is too small to adequately evaluate the relevance of US7 in general clinical use. It remains to be seen whether US7 will prevail against the radiological scores in daily clinical practice (13).

As shown in previous studies, patient outcomes tend to be better if treatment decisions follow a strict protocol (14-16). However, the physician and patient verdicts regarding the necessity of treatment change plays an important role in therapy. No good correlation between physician and patient assessments was observed in our study. Physicians usually considered treatment change to be more necessary than the patients did. Pyne *et al.* recently demonstrated that physicians' assessments, independently of any calculated scores, had a significant impact on treatment change decisions. In the same analysis, DAS28 was not classified as having relevant influence on treatment decisions (17). The results of our study show the same tendency, as the physician's assessment was rated as having a higher mean influence on treatment decision compared to the most commonly used scores DAS28 and FFbH.

In summary, the results of this study indicate that German rheumatologists mainly use the DAS28 and FFbH scores as additional instruments for treatment decisions while the additional recording of structural changes by means of scores is not yet established and should be given more emphasis in future.

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