Use of Rheumatic Scores to Guide Therapeutic Decisions in Patients with Ankylosing Spondylitis: Results of a Multicentre Study in Germany

Verwendung von Scores bei der Beurteilung der ankylosierenden Spondylitis: Ergebnisse einer multizentrischen Studie in Deutschland

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Key words
therapeutic decision making, daily care, assessment, use of scores, treat to target

Schlüsselwörter
therapeutische Entscheidungsfindung, alltägliche Praxis, Assesment, Anwendung von Scores, Treat to target

Bibliography
DOI https://doi.org/10.1055/s-0042-102955
Online-Publikation: 19.9.2017
Akt Rheumatol 2017; 42: 544–550
© Georg Thieme Verlag KG Stuttgart · New York
ISSN 0341-051X

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ABSTRACT
Summary Background Rheumatology practice has seen an increasing development and use of scores to assess disease activity, loss of physical function, quality of life and radiographic damage. Study results, in particular for rheumatoid arthritis, demonstrate that target-oriented treatment concepts using scores lead to improved treatment results (Treat-to-Target).

Objective To review how frequently scores are used in daily rheumatological practice to assess disease activity, loss of physical function and treatment response in patients with ankylosing spondylitis and how much treatment decisions are influenced by the use of these scores.

Methods A Germany-wide prospective multicentre study 74 sites (61 rheumatologists in private practice and 13 hospital-based rheumatologists) documented the use of scores for assessing disease activity, treatment response, quality of life and imaging results in patients with ankylosing spondylitis (AS) (18–83 years) over 3 consecutive visits. A total of 1476 fully evaluable visits of 492 patients [326 (66.26 %) men and 166 (33.74 %) women] were recorded.

Results The most commonly used scores were BASDAI (n = 1134, 84 % of all visits) and BASFI (n = 500, 37.5 %). At least one score was calculated in 1335 visits (90.45 %); a combination of several scores was calculated in 748 visits (50.68 %). Only in 141 visits (9.55 %) no scores were calculated at all. Scores were used independently of patients’ age, duration of treatment, medication, and treatment changes and region of the participating rheumatologist. Scores recording treatment response (ASAS response) or quality of life were recorded in a few cases only. The average influence of a score on a treatment decision was 5.67 on a scale from 0 to 10.

ZUSAMMENFASSUNG

Ziel Untersuchung, wie häufig Scores zur Messung von Krankheitsaktivität, Funktionseinschränkung und Therapieansprüchen bei Patienten mit gesicherter ankylosierender Spondylitis in der täglichen rheumatologischen Praxis angewandt werden und wie stark Therapieentscheidungen durch die Anwendung dieser Scores beeinflusst werden.

Methoden In einer deutschlandweiten, prospektiven, multizentrischen Studie mit 74 Zentren (61 niedergelassene Rheu-
Introduction

Treatment of inflammatory rheumatic diseases aims, through suppressing the inflammatory disease activity, to relieve symptoms – mainly pain and loss of physical function – and to prevent damage caused by the inflammatory process. Standardized treatment recommendations/guidelines, with the aim of achieving remission or low disease activity (Treat-to-Target), have been published for rheumatoid arthritis [1, 2]. Scores to assess disease activity such as DAS28 ≤ 2.6 or SDAI ≤ 3.2 are used to define this treatment goal.

Strategy studies have demonstrated that score-guided treatment leads to better treatment results (BeSt, CAMERA) [3, 4]. Both studies show that a target oriented strategy which uses assessment scores to define a treatment goal, lead to better results than not target oriented strategies. From our own experience scores are also used with increasing frequency for patients with ankylosing spondylitis. For example, the ASAS (Assessment of SpondyloArthritis international Society) [5] and DGRh (Deutsche Gesellschaft fuer Rheumatologie) [6] guidelines recommend a BASDAI score of ≥ 4 as a condition for the use of TNF-alpha blockers. Treatment response is defined not only by the assessment of the physician or the patient but also by a decrease of the BASDAI score by at least 50 % or by at least 20 points (on a numeric scale of 0 to 100) [7]. As for RA, international recommendations regarding target-oriented treatment are now available for AS [8].

It is not known how frequently scores for disease activity, loss of physical function or quality of life are used in the daily rheumatological care of patients with AS or whether the results of these scores are used to guide treatment. The aim of the present study was to assess the use and relevance of scores for evaluating patients with AS on a Germany-wide scale using a multicenter approach.

Materials and Methods

The use of scores for assessing disease activity, loss of physical function, quality of life, treatment response and radiographic changes in patients with diagnosed AS was recorded in a nationwide multicenter study.

For this purpose, 74 sites (61 rheumatologists in private practice and 13 hospital-based rheumatologists) in Germany were surveyed by means of a standardized questionnaire from November 2010 to May 2012 (▶ Table 1).

All patients with AS who began treatment with or were changed to a TNF-alpha blocker (T0) were documented. At the same time, the retrospective documentation for the previous visit was carried out (T-1), used were only the documented scores and the fact, if a treatment change was initiated or not. Upon the patient’s next return for treatment monitoring, data were recorded anew (T1).

Each patient’s age, sex, disease duration and medication was recorded in completely anonymized form. The nature of the collected data and the complete anonymization required no ethic vote.

The documentation took data collected between August 2004 and December 2012 (Baseline visits where recorded retrospective) into account.

It was documented as to which of the following scores (BASDAI, SASSS, BASFI, mSASSS, BAS-G, MASES, BASMI, ASAS20 response, SF 12, ASAS40 response, SF 36, ASAS70 response, ASQol, ASAS5/6 response, EQ-SD, BASRI) or any other scores were used (> Table 2, 3).

Furthermore, the participating rheumatologists were requested to evaluate on a scale of 1 to 10 as to how far the recorded scores influenced their decision regarding treatment change.

For this purpose, the physician was asked “How much did the recorded scores influence your decision to change or continue the therapy. Please rate the influence on a scale of 1 to 10 (1 = little influence to 10 = very strong influence)”.

After study start an additional question was included at the T0 visit investigating as to how far physicians and patients regarded a change of treatment as necessary. Since this question had been added after study start, this information could be collected only for a subgroup of patients at time point T0 (n = 145).

All patients for whom no complete data at T0 were available were excluded from the analysis. The data were analyzed using descriptive statistics. The Mann-Whitney-U test was applied to compare score use with and without treatment change. On the basis of the median age of 43 years, subjects were divided into 2 age groups (≤ 43 years and > 43 years); the score frequencies in both groups were compared using the Mann-Whitney-U-Test.

Results

Data, considering the influences of assessment scores on the treatment decision, was obtained from 507 patients aged 18–83 with diagnosed ankylosing spondylitis.

A total of 1 476 fully evaluable visits of 492 patients [326 (66.26 %) men and 166 (33.74 %) women] were recorded.

It could be demonstrated that an assessment was performed using scores in a total of 90 % of all visits. To assess the influence of collected scores on treatment change, the influence of the scores...
Table 1  Location of the participating institutions.

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The most commonly used score (used in 84% of all visits) was BASDAI for documenting disease activity (as lone score in 42%, in combination in 42% of visits) which, with a mean influence of 6.1 (SD 2.7) can also be regarded as a relevant factor influencing treatment decisions.

BASFI for documentation of physical function was used in 38% of visits and evaluated with a relevance of 5.3 (SD 2.6) regarding treatment decisions.

The third most commonly used score was BASMI, used in 14% of visits, which was regarded as having a mean relevance of 4.5 (SD 2.8).

BAS-G was the fourth most commonly used score, used in 3% of all visits. BAS-G was attributed with a relevance of 5.4 (SD 3.8).

The scores which were used only in very few cases were SF-12 (once), MASES (twice), mSASSS (twice), SASSS (4 times) and EQ-5D (6 times). SF36, ASQoL, ASAS40/70 response and ASAS5/6 were not used.

The following scores which were not listed in the questionnaire were also recorded:

- HAQ (n = 22)
- FFbH (n = 62)
- DAS28 (n = 7)
- FACIT (n = 1)
- WPAI-SHP (n = 6)
- FFBM (n = 1)
- EQ-5D (n = 3)

More than one score was used in 45% of all visits. The combination of BASDAI and BASFI was the most common one and used in 25% of all visits. The triple combination of BASDAI, BASFI and BASMI was the second most commonly used combination, used in 9% of all visits, the simultaneous use of BASDAI and BASMI, used in 2% of all visits, constituted the third most common combination.

A mean number of 1.5 (SD 0.8) scores was determined per patient and visit. In the median split of 43 years, no age-related difference was found with regard to the use of scores in patients younger than the median as compared to older patients (Mann-Whitney-U test p = 0.734).

If the use of scores is analyzed according to whether a treatment change was initiated, it becomes apparent that scores were determined independently of whether treatment change took place.

If the patient’s and physician’s influence on the decision to change treatment are compared on a scale from 1–10 (little to very
strong), a low degree of correlation between the 2 parameters is observed (Spearman’s rank correlation coefficient r = 0.330). In total, the physician’s assessment had substantial influence on treatment decision with a mean relevance of 8.0 (SD 1.7). The patient’s assessment was also attributed with a relevance of 7.1 (SD 2.0), thus having more relevance than the BASDAI, the score most commonly used and given the highest marks for influence.

In the 145 patients, where an assessment, if the therapy should be changes, was obtained from physician and patient, only 30 % were concordant. Of the remaining 70 % the physicians assessment was more influential on the treatment decision.

Discussion

Treatment strategies and guidelines in rheumatology follow score-defined treatment goals (Treat-to-Target) more and more often. The aim of the present study was to evaluate the current situation regarding the use and significance of disease scores in the care of AS patients in Germany.

For the treatment of patients with an ankylosing spondylitis clearly defined targets are not yet consented, like it has been done for other disease entities [9].

The new EULAR Guidelines define these targets as a maximization of the disease associated quality of life, which has probably a high influence on the BASDAI.

The german AWMF-S3-Guidelines [10] “Axiale Spondyloarthritis inclusive M. Bechterew und Frühformen” (which was published only after completion of this study) defines the treatment target similar to the EULAR –Guidelines as an “Reduction of pain, preservation of the body function, reduction of stiffness, preventing structural lesions and preservation of the ability to work”.

The reduction of pain and the function is well represented in the documented scores.

But how far a prognostic assessment of long term therapy targets could be done with these scores can be doubted.

A surrogate parameter for the long term outcome hasn’t been defined when the study took place meanwhile the ASDAS has been suggested to predict outcome [14].

It was demonstrated that scores for assessing activity and physical function are frequently used in daily practice. At least one score was documented in 90 % of all visits.

However, amongst the variety of validated instruments, only one score, BASDAI [11, 12] is subject to widespread use. In addition, more detailed patient evaluation was documented using BASFI for loss of physical function and BASMI for spine mobility.

Both scores for documenting health-related quality of life and scores for estimating treatment response are used rarely.

The limitation to BASDAI and, to a certain extent, to the supplementary BASFI is probably due to the fact that the patient questionnaires BASDAI and BASFI are uncomplicated, not time-consuming and available free of charge. In addition, a BASDAI ≥4 is defined explicitly by the DGRh and the ASAS [13] as a requirement for the use of a TNF-alpha blocker in AS, which causes the BASDAI to also be regarded as a preventive measure with regard to potential checks by the healthcare payers. As the international Treat-to-Target recommendations for treating spondyloarthritis name the BASDAI as suitable for measuring disease activity in axial SpA [8], this score type’s almost ubiquitous use in Germany would appear to be reasonable.

The above-named scores can generally be documented even in tightly organized everyday practice and are already available at the time of examination and treatment discussion, as no laboratory parameters are needed for calculation. Scores requiring the use of laboratory values (e. g. ASDAS) were not used. Apart from reasons of practicability, this may be due to the fact that in AS, in contrast to rheumatoid arthritis, the extent of disease activity does not always correlate with an increase of laboratory inflammatory parameters in all patients. The use of scores requiring laboratory values for calculation delays the evaluation and only offers benefit to few patients over the above-named, more commonly used scores. Very recently presented data is suggesting that the ASDAS may indeed be predictive regarding the radiologic outcome.

At the moment the clinical use of the ASDAS (score, which consists of 3 of the 6 BADAI questions (2. Backpain, 3 joint swelling and 6 morning stiffness), CRP and the patient global assessment.) is growing [18].
At the time of the observational visits, this score was published just a short time and wasn’t established well in daily clinical practice.

Questionnaires which can be independently completed by the patient and often document quality of life, such as SF-12 and SF-36 are not available free of charge, which limits their use in daily practice.

Scores for assessing radiographic progression are used very infrequently. This can be explained, amongst other things, by the fact that an inhibition of radiographic processes in AS has been shown rarely in clinical studies, even with modern treatment options. Furthermore, in contrast to RA, regular radiological monitoring is not recommended for AS but is even limited to every 2 years at most [15].

Alongside the influence of scores on decisions regarding treatment changes, this study also addressed the question as to whether the physician’s or patient’s assessment has more influence on the treatment decision. Only a low correlation was observed between physician’s and patient’s assessment. Similar results were found in other studies for ankylosing spondylitis and other rheumatic diseases, [17, 18] even if the discordance we observed here was much higher than the one found in literature. This may result from the different questions studied. Our study did not focus on global health but on the question wether a treatment change should be initiated. Even if a patient is not satisfied by the current state of health, he or she may not want an intensified treatment. Furthermore, the physician’s assessment was attributed as being more decisive for the treatment decision than the patient’s assessment. This may be the case because the physician regards a treatment change as necessary as the treatment results are not yet satisfactory, whereas the patient is satisfied with the treatment result at that point. As the influence of physician’s and patient’s assessments on treatment change were evaluated only from the physician’s point of view, the result may be affected by methodical bias, as physicians could tend to regard their own assessment as more important than that of the patient. In addition, both the physician’s assessment as well as that of the patient had a larger influence on the treatment decision than any of the used scores. This indicates that the assessment of the disease status by the patient and the physician in charge can still be regarded as a decisive parameter for treatment decisions even in times of Treat-to-Target concepts. As to how far this is an obstacle to the implementation of such objective parameter-based concepts in Germany, or perhaps even promotes these in the sense of a joint decision process, remains to be seen.

In summary, it can be concluded that the BASDAI is generally used as an indicator of disease activity for treatment decisions and treatment monitoring in patients with ankylosing spondylitis; this score is used almost ubiquitously and has a moderate influence in treatment change decisions.

Acknowledgements

This study was supported by AbbVie Deutschland GmbH & Co. KG. We are grateful to Dr. Imma Fischer (Tübingen) for statistical support.

References


