



# Patient Reported Outcomes Compared to Composite Indexes in Routine Disease Activity Assessment of Rheumatoid Arthritis

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## Editorial

Rheumatoid arthritis (RA) activity assessment has become increasingly important not only for documenting the disease course in clinical trials, but also on the individual level primarily for justifying potentially precarious and expensive treatments. The discussion whether and how intensively the patient should be involved into this process continues since decades. The approaches to clarify the situation, however, may be particularly dependent on the viewpoint, whether theoretical trialists or practicing rheumatologists, directly involved in daily patient care, are called to give an answer. In 2014, Austrian rheumatologists could show that the patient relevant course of RA cannot be simplistically regarded a linear connection between two observation points, as the Treat-to-Target concept, based on clinical trial results on the group level, does [1,2]. The disease course over two months fluctuated significantly in 80% of the surveyed patients, which understandably resulted in global uncertainty and compromised patients' quality of life [1].

The addressed Treat to Target approach, utilizing composite disease activity indexes, for example, the disease activity score including a 28-joint count (DAS28), is thought to result in a better outcome for the patients [2]. It is one of this approach's overarching principles that RA therapy should be based on a shared decision between patient and rheumatologist [2]. However, all composite indexes weigh the patient's global assessment lower, far inferior to the joint counts, which are in fact physician-dependent, and sometimes the acute phase reactants [3]. That is why, all the composite indexes utilized do not grant patients' wishes, beliefs, fears, coping mechanisms or morbid-gains a prominent status. The Viennese DAS clone scores, the simplified disease activity index (SDAI), and the clinical activity index (CDAI), reinforce the overemphasis of the physician's position, as his global assessment of disease activity was additionally incorporated [4]. This situation is further outbalanced by the fact that all the composite indexes including a 28-joint count, applied in clinical trials, leave out foot involvement, which often constitutes the primary problem of the patient. Although not of explicit importance on the group level, it is incidentally the case in daily routine, that the calculated index result indicates remission, while the individual is not able to leave the physician's office independently because of foot and/or ankle complaints. So, where can the interested clinical rheumatologist find a true shared decision as one partner in fact has no capability of exerting influence? However, from the viewpoint of theoreticians, who have small experience in treating patients, the issue seems to be the easier to handle the smaller the influence of the individual can be, and statisticians cheer enthusiastically as they are not obliged to make greater efforts than necessary to meet the overall goal — the golden cow — of clinical trials, namely significant findings irrespective of their clinical relevance. In this respect they deliberately forget that  $p < 0.05$  is five percent better than throwing a coin. Their primary interest lies in nice average results on the group level, which may be used as explanations for almost everything. The question is what does one learn from averages?

One cannot avoid the impression that managers and trialists may be happy for treatments to work on average, however, patients in every instance expect their doctors to do better than that [5]. Obviously, it is certainly less important whether the physician is satisfied with the disease outcome, but the patient, who must bear the disease consequences, in many cases for decades [6]. Patients' opinion with respect to improvement or worsening of RA has been shown to be asymmetric, in contrast to the physician's perspective, and clinical rheumatologists have learned about that in part painfully. Patients require greater improvement to be satisfied and less deterioration to be dissatisfied [7], which provides additional guidance for the application of PROs in defining response

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and non response in daily RA management. To repetitively question individual factors influencing the personal attitude, will contribute to approach the true target in daily routine, namely the best possible individual outcome. Such information may be captured only by asking and listening to the patient, which can be easily carried out by applying PROs [8].

However, given the individuality of all human beings, analyzing PROs on the group level will result in higher disparities and variances, which theoreticians and trial statisticians to a high percentage find disgusting, as it reduces the likelihood of significant results or require higher patient numbers to achieve those. So, the strengths of composite indexes lie in group level analyses with a minor focus on the individual, conversely, the weakness of PRO's can be found exactly in this respect. But, the situation, where a patient group requests improvement of their mean disease activity, regardless of the individual ones, does not exist in daily rheumatology. Normally, the individual longs for pain relief and functional improvement, and the physician is seldom successful for a longer time in convincing the patient, "you don't know how well you are!"

Instruments such as the Routine Assessment of Patient Index Data 3 (RAPID3), the Rheumatoid Arthritis Disease Activity Index-Five (RADAI-5) or the Rheumatoid Arthritis Impact of Disease (RAID) score, apart from the complicated calculation, have been shown to provide reliable information about disease activity, functionality, and other important aspects of daily life [9-11]; from a statistical viewpoint, the internal consistency of the RAPID-3 and RADAI-5, was shown significantly higher than the one of the composite indexes [3], underlining their importance for assessing the individual situation. It may be anticipated that the better the patient's position about benchmarks and thresholds for decisions with respect to the disease is accepted, the more likely an optimal treatment outcome can be expected [6].

Many practicing rheumatologists appear to agree increasingly that short and easy instruments providing reliable information and alarming in case of deterioration could help to improve and standardize daily routine care significantly. PROs will also give the opportunity for monitoring the disease course by electronic media, which probably will constitute a future perspective in routine medical care and in rheumatology. As the compatibility of all assessment tools is limited, always the same instrument should be applied in the individual patient [3]. The therapeutic options for patients with RA or other arthritides have improved a great deal; disease monitoring and treatment should be performed in an optimally targeted — in an individualized — approach [12].

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