The use of databases for quality assessment in rheumatoid arthritis

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ABSTRACT

As resources in health care systems become increasingly scarce, rheumatologists may need to provide evidence that their quality of care uses the allocated resources effectively by achieving a good outcome for patients with rheumatoid arthritis (RA). In order to assess quality, it has been recommended in other areas of medicine to gather data according to appropriate outcome measures, preferably in electronic databases, enabling identification of benchmarks to compare the outcome quality of different clinical settings.

Available electronic applications commonly comprise a database for data processing and storage, as well as a tool for regularly measuring and following disease activity in individual patients. Access to aggregated data makes it possible to monitor disease activity in individual patients over time in relation to treatment. In addition, electronic applications should allow the extraction of patient data according to special characteristics for analysis. In this way, such electronic applications can provide a central database that can be used for monitoring patients in routine care, case studies or general research, as well as facilitating comparisons of quality of care in different centres or in different countries for reference purposes.

Introduction

Rheumatoid arthritis (RA) is a chronic inflammatory disease that is known to result in pain, disability and joint destruction. It has already been recognized for many years that a poor prognosis, whether based on an evaluation of joint destruction, long-term functional disability or mortality, is associated with the degree of the cumulative inflammatory response (1-11). More recently, it has been suggested that acute phase reactant levels or swollen joint counts even at the time of initiation of disease modifying anti-rheumatic drugs (DMARD), or 3 months thereafter, are highly predictive of subsequent joint damage (12). Over time, increasing joint damage leads to increasing disability (13, 14).

As a consequence of these insights, the primary aim in treating patients with active RA is the rapid reduction of disease activity, the optimal goal being the achievement of remission. The success of tight control of the disease status in conjunction with the adjustment of therapy based on the results of control examinations has been clearly documented in three recent investigations (15-17). Therefore, to achieve optimal therapeutic effects in all RA patients, regular quantitative evaluation of disease activity must be regarded a necessity even in clinical practice.

A recent Europe-wide survey indicated that patients in different countries appear to exhibit distinct clinical activity and disability index values despite the use of similar therapies (18), but the reasons underlying these differences have not been evaluated. They may be linked to differences in baseline characteristics and/or the treatment response in specific patient populations (19) or to differences in the quality of patient care, including adherence to more or less intensive treatment strategies (15, 20). With dynamic treatment strategies and the optimal use of currently available therapies, low disease activity or remission should be an achievable goal in the majority of our patients (21).

Monitoring disease activity

Inherent in the strategy of intensive treatment with DMARDs (including biological agents) with the goal of preventing or slowing permanent structural joint damage and long-term disability in RA is the accurate monitoring

of disease activity (22, 23). Both the European League Against Rheumatism (EULAR) and the American College of Rheumatology (ACR) have defined core sets of disease activity measures for RA (22, 24) with the goal of providing a certain uniformity in the assessment of outcome (25-31).

Both in daily clinical practice and in clinical trials, many variables are recorded to monitor the course of the disease. A variety of factors can confound the process of measuring disease activity, however, including the unpredictable course of RA, the varied clinical presentation of the disease in different patients, and the variability and potential bias of individual measures. Because of these factors, it was suggested that monitoring disease activity in the form of a composite evaluation of core set variables might be more valid than the evaluation of single variables (2-4). In this respect, continuous composite scores for assessing disease activity in RA have been developed and validated, using more complex or simplified means of calculation and comprising core sets with the inclusion of an acute phase reactant (APR) such as the Disease Activity Score (DAS)28 (28) and the Simplified Disease Activity Index (SDAI) (30), with or without the addition of an APR measure such as the Clinical Disease Activity Index (CDAI) (6). These composite indices are preferable to measuring single variables (23, 32-34), as they comprise both the physician's as well as the patient's perspectives.

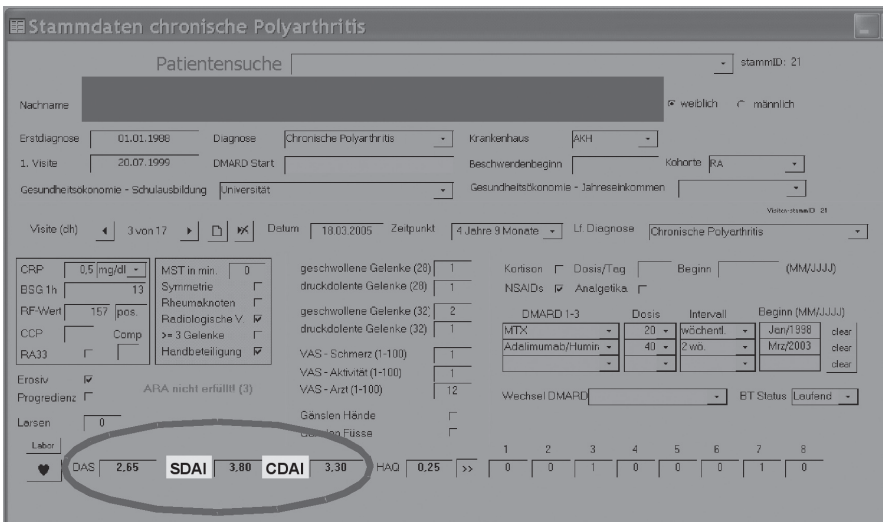

Fig. 1. Screenshot from the CARAbase.
This screenshot shows the variables which are recorded for the CARAbase. The 3 disease activity measures calculated (DAS28, SDAI and CDAI) are circled in blue. CDAI values can be calculated during the patient's visit, even if the acute phase reactant result is not yet available. Because in our center the acute phase reactant values are available for entry one day later into the electronic application, the DAS28 and SDAI values are usually calculated with a delay of one working day.

Quality assessment in electronic databases

With the advent of biological therapies and the consequential increase in the direct costs of care (35, 36), a thorough assessment of disease activity is especially mandated to justify the use of expensive treatments. As resources in health care systems become increasingly scarce, rheumatologists may need to provide evidence that their quality of care makes use of the allocated resources effectively by achieving a good outcome for patients with RA. In order to assess outcome quality, it has been recommended in other areas of medicine to gather data according to appropriate outcome measures, preferably in electronic databases (37), which allow benchmarks to be set and the outcome quality of different units or organizations to be compared (38-42).

Variables recorded in electronic databases should include the following information on the patient: demographic data, disease duration, 28 to 64/66 tender (TJC) and swollen joint counts (SJC), patient VAS for pain (PPA) and global disease activity (PGA), physician VAS for global disease activity (MDGA), morning stiffness (MST), HAQ scores, the presence of rheumatoid factor (and, eventually, anti-CCP), APR (such as ESR and CRP), and medications used (including side effects) (Fig. 1). Clinical assessments should be performed by trained assessors.

Requirements for electronic applications

Available electronic applications commonly comprise a database for data processing and storage, as well as an electronic tool for regular measurement and to calculate the disease activity scores in individual patients. DAS28 (28), SDAI (30) or CDAI (6) values (Table I) may be calculated automatically by the electronic application and are then displayed to the rheumatologist. The advantage of using the CDAI is that values can be calculated at the time of the visit to the rheumatology clinic while the patient being seen by the rheumatologist, even if the laboratory test results, such as APR, are not yet available (Fig. 1).

Equally important is that aggregated data can be accessed in order to monitor disease activity in individual patients over time in relation to treatment (Fig. 2). This may help rheumatologists to set goals and chart treatment progress in a visual form that can be shared with the individual patient (43). In addition, electronic applications should be able to aggregate patient data based on specific characteristics and extract them for data analysis. Such electronic applications would provide a central database that can be used to organize patient information for routine follow-up, for case studies or research studies, or for the comparison of quality of care between centres and countries for reference purposes.

For the assessment of quality of care, data on RA patients is currently being compared between different settings and different countries in two ongoing projects. It is desirable to use either the same electronic application or to capture exactly the same variables at each centre. Variables should include at least

Table I. Formulas for calculating DAS28, CDAI and SDAI values.

DAS28	= 0.56*SQRT(TJC) + 0.28*SQRT(SJC) + 0.7*ln(ESR) + 0.014*PGA (in mm)	0-10
CDAI	= SJC (28)+ TJC (28)+ PGA (VAS in cm) (10)+ MDGA (VAS in cm) (10)	0-76
SDAI	= CDAI + CRP (mg/dl)	0-86

SJC: 28 swollen joint count; TJC: 28 tender joint count; PGA: patient's global VAS assessment; MDGA: physician's global VAS assessment; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; SQRT: square root.

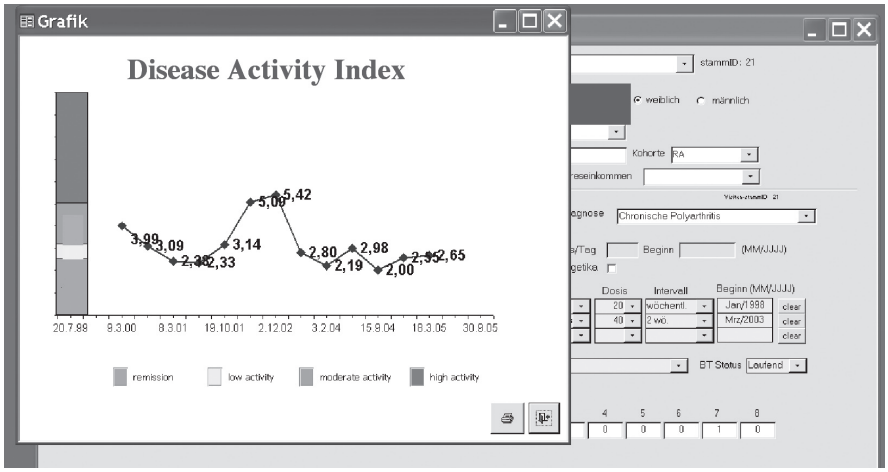

Fig. 2. Monitoring of disease activity scores over time.
This screenshot from the CARAbase shows the DAS28 values for one patient over time. The ranges for remission, or low, moderate or high disease activity are provided in the left margin. Similar graphs are available for the CDAI and SDAI.

Table II. Electronic applications currently available to monitor RA patients and assess the quality of treatment.

Application	Year of launch	Source
METEOR	2007	http://www.meteorfoundation.com/
Care for RA Database, CARAbase	2002	authors

This table provides an overview of the currently available electronic applications to monitor disease activity over time in patients with RA. The METEOR foundation is an ongoing project in which rheumatologists from various different European countries are participating.

the core set variables as detailed above and the use and side effects of medication. Preferably, the use of the same electronic application will provide an equal set of data without the need for adaptation, such as the recalculation of CRP values, because the units used may be different in different centres. In addition, one goal could be to standardise patient care and the measurement of variables in order to achieve the same process quality in different centres. In 2006 the ACR published a starter set of quality indicators for RA that has been applied in clinical studies (44, 45) to standardize and analyze the process of quality of care for RA. In terms of the standardized measurement of variables, joint counts should preferably be carried out by the same assessor blinded to treatments. Measurement of the ESR, if performed on the rheumatology ward, must be standardized. Finally, it is important that the same patient populations are compared, based on routine care data or data from specific cohorts, such as early arthritis.

In order to facilitate analysis, data should be stored anonymously with no need for informed consent or permission from the institutional review board (43). In addition, data storage needs to be safe and has to follow the legal requirements for processing patient data in each country.

Outlook

Table II provides an overview of the currently available electronic applications for monitoring disease activity in RA. Currently, a European initiative launched in 2007 – the Measurement of Efficacy of Treatment in the 'Era of Outcome' in Rheumatology (METEOR) – is undertaken to establish an international electronic application for patients with RA (43). In this project the same application, which can be slightly customized to the individual needs of each centre, will be used to produce comparable data. In Austria and The Netherlands, two ongoing projects are comparing data between 4 different centres. In Austria, the CARAbase application is used in some rheumatology centres.

Rapid changes in available medications may lead to reductions in disease activity as well as the possibility of achieving remission in patients with RA. As resources in health care systems become increasingly scarce, rheumatologists may need to provide evidence that their quality of care exploits the allocated resources effectively by achieving well-documented outcomes for patients with RA. In order to facilitate data processing and comparisons between centers, electronic applications may be preferable. However, where electronic databases are not available, even such simple tools as the CDAI, which do not require any type of electronic device for their calculation, will be helpful for following patients in routine care, demonstrating the pertinent use of health care resources, informing patients on their disease status, and helping clinicians to adapt treatment in a dynamic manner based on state of the art knowledge.

References

1. CHOI HK, HERNAN MA, SEEGER JD, ROBINS JM, WOLFE F: Methotrexate and mortality in patients with rheumatoid arthritis: A prospective study. *Lancet* 2002; 359: 1173-7.
2. WOLFE F, SHARP JT: Radiographic outcome of recent-onset rheumatoid arthritis: A 19-year study of radiographic progression. *Arthritis Rheum* 1998; 41: 1571-82.
3. DROSSAERS-BAKKER KW, DE BUCK M, VAN ZEBEN D, ZWINDERMANN AH, BREEDVELD FC, HAZES M: Long-term course and outcome of functional capacity in rheumatoid arthritis: The effect of disease activity and radiologic damage over time. *Arthritis Rheum* 1999; 42: 1854-60.
4. WELSING PM, VAN GESTEL AM, SWINKELS

HL, KIEMENEY LA, VAN RIEL PL: The relationship between disease activity, joint destruction, and functional capacity over the course of rheumatoid arthritis. *Arthritis Rheum* 2001; 44: 2009-17.
5. VAN LEEUWEN MA, VAN RIJSWIJK MH, SLUITER WJ *et al.*: Individual relationship between progression of radiological damage and the acute phase response in early rheumatoid arthritis. Towards development of a decision support system. *J Rheumatol* 1997; 24: 20-7.
6. ALETAHA D, NELL VP, STAMM T *et al.*: Acute phase reactants add little to composite disease activity indices for rheumatoid arthritis: validation of a clinical activity score. *Arthritis Res Ther* 2005; 7: R796-R806.
7. MALLYA RK, DE BEER FC, BERRY H, HAMILTON ED, MACE BE, PEPYS MB: Correlation of clinical parameters of disease activity in rheumatoid arthritis with serum concentration of C-reactive protein and erythrocyte sedimentation rate. *J Rheumatol* 1982; 9: 224-8.
8. PINCUS T, BROOKS RH, CALLAHAN LF: Prediction of long-term mortality in patients with rheumatoid arthritis according to simple questionnaire and joint count measures. *Ann Intern Med* 1994; 120: 26-34.
9. SCOTT DL, GRINDULIS KA, STRUTHERS GR, COULTON BL, POPERT AJ, BACON BA: Progression of radiological changes in rheumatoid arthritis. *Ann Rheum Dis* 1984; 43: 8-17.
10. SMOLEN JS, ALETAHA D: The challenge of following process, damage and function of RA patients in clinical care. *Curr Rheumatol Rep* 2003; 5: 336-40.
11. WOLFE F, HAWLEY DJ, CATHEY MA: Clinical and health status measures over time: Prognosis and outcome assessment in rheumatoid arthritis. *J Rheumatol* 1991; 18: 1290-7.
12. SMOLEN JS, VAN DER HEIDE DM, ST CLAIRE W *et al.*: Predictors of joint damage in patients with early rheumatoid arthritis treated with high dose methotrexate with or without concomitant infliximab. *Arthritis Rheum* 2006; 54: 702-10.
13. SCOTT DL, PUGNER K, KAARELA K *et al.*: The links between joint damage and disability in rheumatoid arthritis. *Rheumatology (Oxford)* 2000; 39: 122-32.
14. ALETAHA D, SMOLEN J, WARD MM: Measuring function in rheumatoid arthritis: Identifying reversible and irreversible components. *Arthritis Rheum* 2006; 54: 2784-92.
15. GRIGOR C, CAPELL H, STIRLING A *et al.*: Effect of a treatment strategy of tight control for rheumatoid arthritis (the TICORA study): A single-blind randomised controlled trial. *Lancet* 2004; 364: 263-9.
16. GOEKOOP-RUITERMAN YP, VRIES-BOUWSTRA JK, ALLAART CF A *et al.*: Clinical and radiographic outcomes of four different treatment strategies in patients with early rheumatoid arthritis (the BeSt study): A randomized, controlled trial. *Arthritis Rheum* 2005; 52: 3381-90.
17. FRANSEN J, MOENS HB, SPEYER I, VAN RIEL PL: Effectiveness of systematic monitoring of rheumatoid arthritis disease activity in daily practice: A multicentre, cluster randomised controlled trial. *Ann Rheum Dis* 2005; 64: 1294-8.
18. ANTONI C, MAINI RM, GRUNKE M *et al.*: Cooperative on quality of life in rheumatic diseases: Results of a survey among 6000 patients across 11 European countries. *Arthritis Rheum* 2002; 46 (Suppl.).
19. DROSOS AA, LANCHBURY JS, PANAYI GS, MOUTSOPOULOS HM: Rheumatoid arthritis in Greek and British patients. A comparative clinical, radiologic, and serologic study. *Arthritis Rheum* 1992; 35: 745-8.
20. SMOLEN JS, SOKKA T, PINCUS T, BREEDVELD FC: A proposed treatment algorithm for rheumatoid arthritis: Aggressive therapy, methotrexate, and quantitative measures. *Clin Exp Rheumatol* 2003; 21 (Suppl. 31): S209-S210.
21. MIERAU M, SCHOELS M, GONDA G, FUCHS J, ALETAHA D, SMOLEN JS: Assessing remission in clinical practice. *Rheumatology (Oxford)* 2007; 46: 975-9.
22. FELSON DT, ANDERSON JJ, BOERS M: The American College of Rheumatology preliminary core set of disease activity measures for rheumatoid arthritis in clinical trials. *Arthritis Rheum* 1993; 36: 729-40.
23. VAN GESTEL AM, VAN RIEL P: Evaluation of early rheumatoid arthritis disease activity and outcome. *Ballieres Clin Rheumatol* 1997; 11: 63.
24. VAN RIEL PL, VAN GESTEL AM, VAN DE PUTTE LB: Development and validation of response criteria in rheumatoid arthritis: Steps towards an international consensus on prognostic markers. *Br J Rheumatol* 2004; 35 (Suppl. 2): 4-7.
25. FELSON DT, ANDERSON JJ, BOERS M *et al.*: American College of Rheumatology. Preliminary definition of improvement in rheumatoid arthritis [see comments]. *Arthritis Rheum* 1995; 38: 727-35.
26. VAN GESTEL AM, PREVOO ML, 'T HOF MA, VAN RIJSWIJK M, VAN DE PUTTE LB, VAN RIEL P: Development and validation of the European League Against Rheumatism response criteria for rheumatoid arthritis. Comparison with the preliminary American College of Rheumatology and World Health Organization/International League Against Rheumatism Criteria. *Arthritis Rheum* 1996; 39: 34-40.
27. VAN DER HEIJDE DM, 'T HOF MA, VAN RIEL P, THEUNISSE LA, LUBBERTS EW, LEEUWEN MA: Judging disease activity in clinical practice in rheumatoid arthritis: First step in the development of a disease activity score. *Ann Rheum Dis* 1990; 31: 219-20.
28. PREVOO ML, 'T HOF MA, KUPER HH, VAN LEEUWEN MA, VAN DE PUTTE LB, VAN RIEL PL: Modified disease activity scores that include twenty-eight joint counts. Development and validation in a prospective longitudinal study of patients with rheumatoid arthritis [see comments]. *Arthritis Rheum* 1995; 38: 44-8.
29. VAN GESTEL AM, ANDERSON JJ, VAN RIEL P, BOERS M, HAAGSMA CJ, RICH B: ACR and EULAR improvement criteria have comparable validity in rheumatoid arthritis trials. *J Rheumatol* 1999; 26: 705-11.
30. SMOLEN JS, BREEDVELD FC, SCHIFF MH *et al.*: A simplified disease activity index for rheumatoid arthritis for use in clinical trials. *Rheumatology* 2003; 42: 1-14.
31. SMOLEN JS: The work of the EULAR Standing Committee on International Clnical Studies Including Therapeutic Trials (ESCISIT). *Br J Rheumatol* 1992; 31: 219-20.
32. BOERS M, TUGWELL P, BROOKS PM: Progress towards optimal end-points in rheumatoid arthritis. *Bio Drugs* 1997; 7: 40-50.
33. GOLDSMITH C, BOERS M, BOMBARDIER C, TUGWELL P: Criteria for clinically important changes in outcomes: Development, scoring and evaluation of rheumatoid arthritis patient and trial profiles. *J Rheumatol* 1993; 20: 561-5.
34. VAN DER HEIJDE DM, VAN'T HOF MA, VAN RIEL PL, VAN LEEUWEN MA, VAN RIJSWIJK MH, VAN DE PUTTE LB: Validity of single variables and composite indices for measuring disease activity in rheumatoid arthritis. *Ann Rheum Dis* 1992; 51: 177-81.
35. WARD MM, JAVITZ HS, YELIN EH: The direct cost of rheumatoid arthritis. *Value Health* 2000; 3: 243-52.
36. BANSBACK NJ, BRENNAN A, GHATNEKAR O: Cost effectiveness of adalimumab in the treatment of patients with moderate to severe rheumatoid arthritis in Sweden. *Ann Rheum Dis* 2005; 64: 995-1002.
37. HAAN CK, ADAMS M, COOK R: Improving the quality of data in your database: Lessons from a cardiovascular center. *Jt Comm J Qual Saf* 2004; 30: 681-8.
38. MEISSNER W, ULLRICH K, ZWACKA S: Benchmarking as a tool of continuous quality improvement in post-operative pain management. *Eur J Anaesthesiol* 2006; 23: 142-8.
39. MAUNE S, SCHMIDT C, KUCHLER T: [Measurement of the outcome quality as beginning of total quality management in otorhinolaryngology]. *Laryngorhinootologie* 2001; 80: 101-8.
40. SAINFORT F, RAMSAY JD, FERREIRA PL, MEZGHANI L: A first step in total quality management of nursing facility care: Development of an empirical causal model of structure, process and outcome dimensions. *Am J Med Qual* 1994; 9: 74-86.
41. VINCENT C, MOORTHY K, SARKER SK, CHANG A, DARZI AW: Systems approaches to surgical quality and safety: from concept to measurement. *Ann Surg* 2004; 239: 475-82.
42. DHINGRA H, LASKI ME: Outcomes research in dialysis. *Semin Nephrol* 2003; 23: 295-305.
43. THE METEOR FOUNDATION: METEOR (Measurement of Efficacy of Treatment in the 'Era of Outcome' in Rheumatology) http://www.meteorfoundation.com/ . 2007. 30-6-2007.
44. KAHN KL, MACLEAN CH, LIU H *et al.*: Application of explicit process of care measurement to rheumatoid arthritis: Moving from evidence to practice. *Arthritis Rheum* 2006; 55: 884-91.
45. KAHN KL, MACLEAN CH, WONG AL *et al.*: Assessment of American College of Rheumatology quality criteria for rheumatoid arthritis in a pre-quality criteria patient cohort. *Arthritis Rheum* 2007; 57: 707-15.