Optimisation of assessment for rheumatic diseases in clinical trials, observational studies and routine clinical care

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Patients with rheumatic diseases and their rheumatologists have been fortunate to see many important advances in therapies and therapeutic strategies, leading to improved outcomes over the last 3 decades. Accurate quantitative assessment of patient status has been prerequisite to these advances. While biomarkers have been critical in advances in understanding pathogenesis and developing new therapies, no single *gold standard* biomarker (such as blood pressure or serum cholesterol) can serve in diagnosis, prognosis and monitoring and outcomes of each *individual* patient.

Therefore, quantitative clinical assessment of patient status in rheumatic diseases requires a pooled index (1). Development of pooled indices has been critical to our golden age for rheumatology. Over the last 3 decades, indices have been developed for assessment, management, and documentation of changes in status in rheumatoid arthritis, systemic lupus erythematosus, ankylosing spondylitis, vasculitis, fibromyalgia, and other diseases.

One or more index has been incorporated into all clinical trials. Most specialised research centres include indices for long-term observational studies. However, indices are not necessarily applied by most rheumatologists in most routine care (2), unless required for access to therapies. Indeed, the only quantitative data in the medical records of many patients with rheumatic diseases are laboratory tests, the limitations of which have led to requirements for pooled indices to document improved clinical status for registration of new therapies.

A primary goal of this supplement is to explore directions toward use of feasible tools for rheumatologists in routine care, while recognising further development of specialised index which are required to better understand pathogenesis and progression of disease. It appears unfortunate that these indices often are not available to offer optical possible targets for our care of individual patients in routine settings. The clinical measures and indices document improved outcomes of patients with many rheumatic diseases at this time compared with earlier decades.

This supplement is the 16th in an annual series published by *Clinical and Experimental Rheumatology* concerning contemporary topics in rheumatology care. The previous 15 supplements, available at the Journal website without charge, have been directed to consolidate emerging but often disparate information in new areas to improve rheumatology care and outcomes, as noted below:

1999 – Combination DMARD therapy in rheumatoid arthritis
2000 – Bone mass in the rheumatic diseases
2001 – Controversies in COX-2 inhibitor therapy
2002 – Innovative therapies for spondyloarthritides
2003 – Early arthritis
2004 – Benefit/risk of new drugs for rheumatoid arthritis
2005 – Quantitative clinical assessment of rheumatic diseases
2006 – Remission in rheumatic diseases
2007 – Quality of care in rheumatology: opportunities and challenges
2008 – Mortality in rheumatic diseases
2009 – Rheumatoid arthritis and ankylosing spondylitis: similarities and differences
2010 – Methotrexate in rheumatic diseases
2011 – Low-dose glucocorticoids in rheumatic diseases
2012 – Treat to target in rheumatic diseases
2013 – Possible discontinuation of therapies in rheumatic diseases

This volume addresses *Optimisation of Assessment for Rheumatic Diseases in Clinical Trials, Observational Studies and Routine Clinical Care*, in 3 sections:

1. Optimisation of individual rheumatology measures, including joint counts, imaging methods, laboratory measures, and patient self-report scores, all of which are included in some indices for rheumatology care.

2. Optimisation of rheumatology indices, including disease activity score 28 (DAS28), simplified disease activity index (SDAI), clinical disease activity index (CDAI), rheumatoid arthritis disease activity index (RADAI), and routine assessment of patient index data (RAPID3) for rheumatoid arthritis (RA). Further articles present indices for systemic lupus erythematosus (SLE), ankylosing spondylitis (AS), psoriatic arthritis (PSA), vasculitis, juvenile arthritis (JIA), and comorbidities.

3. Successful strategies for data management which have resulted in very valuable information to monitor and document better results of rheumatology care from national and multi-national databases such as METEOR – an international database organised in the Netherlands, DANBIO in Denmark, OPAL in Australia, ARTIS Swedish rheumatology quality register, NOR-DMARD in Norway, ESPOIR in France, RABBIT in Germany, CORRONA in the USA, BIOBADASER in Spain and Latin American countries, and remote collection of data.

We hope that this supplement will add to optimal strategies for quantitative assessment, leading to better care and outcomes for our patients.

References

1. GOLDSMITH CH, SMYTHE HA, HELEWA A: Interpretation and power of pooled index. *J Rheumatol* 1993; 20: 575-8.
2. ANDERSON J, CAPLAN L, YAZDANY J *et al*.: Rheumatoid arthritis disease activity measures: American College of Rheumatology recommendations for use in clinical practice. *Arthritis Care Res* (Hoboken) 2012; 64: 640-7.