Reviewer’s report

Title: Use of a “critical difference” statistical criterion improves the predictive utility of the Health Assessment Questionnaire-Disability Index score in patients with rheumatoid arthritis

Version: 0 Date: 23 Jul 2019

Reviewer: David L Scott

Reviewer's report:

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This paper, from a leading group of clinical investigators, makes several interesting points. My comments are as follows:

1. Aims: the present aim is to "report the derivation and evaluation of the HAQ-DI-dcrit as an assessment of improved function during therapy". I think this is not well defined and I would suggest the aim is described more precisely. I believe this will make it easier to interpret the findings and their strengths and limitations.

2. Rasch Analysis: the report currently ignores the issues raised by Alan Tennant over many years about the nature of HAQ scores in RA. These views are summarised in a review form OMERACT (Doganay Erdogan B, Leung YY, Pohl C, Tennant A, Conaghan PG. Minimal Clinically Important Difference as Applied in Rheumatology: An OMERACT Rasch Working Group Systematic Review and Critique. J Rheumatol. 2016; 43: 194-202). I do not have a view on the importance of this particular approach but I think it is mistaken to overlook it entirely. One way or another the perception of HAQ as an ordinal scale is a relevant consideration.

3. Random Variation: the report implies this is commonplace and is generally accepted as an issue. But I think the problem is somewhat different. There is an extensive research literature on short-term fluctuations in blood pressure and the consensus is that these are both common and not due to random factors; the issue is outlined by Parati et al (Parati G, Ochoa JE, Lombardi C, Bilo G. Assessment and management of blood-pressure variability. Nat Rev Cardiol 2013; 10: 143-55). I have no doubt there are similar changes in many measures in RA, including potentially HAQ. I suggest the possible nature of these short-term within individual changes in HAQ are considered somewhat differently.

4. Predictors Of Change In HAQ: the regression model summarised in Table 4 mixes baseline variables with changes in clinical assessments. I think this is mistaken. Baseline and change measures are very different things. I would prefer to see baseline predictors treated together without confusing them with changes in clinical assessments. It is also regrettable that the components of DAS28 have not been considered separately in relation
to change. I anticipate patient global assessments and pain would relate closely to changes in HAQ whilst changes in the ESR may have little impact.

5. Impact Of Baseline HAQ: the analysis shows that high baseline HAQ was associated with higher changes in HAQ. This finding is inevitable. But the group as a whole had high initial HAQ scores of 1.44 to 1.60. I suspect that short term variations in HAQ also reflect baseline HAQ scores; if the investigators had studied a group with mild RA they may well find that the HAQ-DI-dcrit would have been less in such patients. Whilst this does not invalidate the approach taken in these patients, starting adalimumab, it means the findings may not be generalisable. I appreciate that the authors mention this issue in passing, but I think they somewhat underplay its importance.

6. Stability Of Response: the authors present some data to show that patients who achieve HAQ-DI-dcrit responses at 6 month continue to have these at 12 and 24 months. I appreciate this is one aspect of stability. But there may be the same extent of short-term variability in these patients as in all others. I believe it preferable to be more cautious about such a claim. I accept that HAQ-DI-dcrit responses are mainly retained over 24 months in patients on stable therapy, but I think this is all that is shown.

7. Discussion: I found the discussion covered a variety of relevant themes in a somewhat disorganised manner, without any clear perspectives on the strengths and limitations of the study. I think it would benefit from a more defined order and listing the limitations. The authors are also rather too critical of MCID approaches to changes in HAQ. The HAQ-DI-dcrit measures an important change, rather than a minimal change, and both seem useful in assessing the impact of biological and other intensive treatments.

Are the methods appropriate and well described?
If not, please specify what is required in your comments to the authors.

Yes

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