

Response to: 'Belimumab and the measurement of fatigue' by Mazzoni

We agree that fatigue is a common and important symptom of patients with active systemic lupus erythematosus (SLE), and that it is multidimensional, as has been elegantly described in patients with rheumatoid arthritis.¹ In fact, randomised controlled trials in SLE have assessed fatigue, as early as the prasterone dehydroepiandrosterone (DHEA) studies (published in 2002–2004) that employed the (Krupp) Fatigue Severity Scale (FSS), developed for SLE and multiple sclerosis.^{2–3}

We agree that belimumab treatment does reduce fatigue, particularly in Systemic Lupus Erythematosus Responder Index (SRI) responders as reported in a more recent publication. In a combined analysis of BLISS-52 and BLISS-76, SRI responders, across all three treatment groups, reported statistically significant and clinically meaningful improvements compared with non-responders in Functional Assessment of Chronic Illness Severity (FACIT), SF-36 summary and all domain scores.⁴ That neither FACIT nor SF-36 data were statistically significant at the predefined 24-week time point is likely due to the fact that the protocol allowed increases in glucocorticoid doses until 24 weeks and immunosuppressive/antimalarial agents up to 16 weeks following baseline—thereby 'rescuing' placebo patients.

FACIT is a unidimensional scale and has been validated in SLE across many studies.^{5–8} The belimumab data that you are querying were analysed in 2010–2011, presented to the Food and Drug Administration Arthritis Advisory Committee in November 2011 and subsequently published.^{4,9} To our knowledge, the second Cella paper had not yet been published when these detailed analyses were completed. It is an interesting idea to segregate items of the FACIT into experience and impact scores; however, this would necessarily require validation in SLE as well as 'qualification' that this is relevant and clinically meaningful to patients with SLE. Unfortunately, the sponsorship of this database has changed (from HGS to GSK) and much time has passed, and we are unable to undertake further analyses to address your question.

V Strand,¹ R A Levy,² R Cervera,³ M Petri⁴

¹Division Immunology/Rheumatology, Stanford University School of Medicine, Palo Alto, California, USA

²Department of Medicine, Universidade do Estado do Rio de Janeiro, Brazil

³Department of Autoimmune Diseases, Hospital Clinic, Barcelona, Spain

⁴Department of Rheumatology, Johns Hopkins University, Baltimore, Maryland, USA

Correspondence to Dr Vibeke Strand, Division Immunology/Rheumatology, Stanford University School of Medicine, Palo Alto, California 94028, USA; vstrand@aol.com

Competing interests None declared.

Provenance and peer review Commissioned; internally peer reviewed.



CrossMark

To cite Strand V, Levy RA, Cervera R, *et al.* *Ann Rheum Dis* 2015;**74**:e54.

Received 29 April 2015

Accepted 1 May 2015

Published Online First 19 May 2015



► <http://dx.doi.org/10.1136/annrheumdis-2015-207693>

Ann Rheum Dis 2015;**74**:e54. doi:10.1136/annrheumdis-2015-207700

REFERENCES

- Hewlett S, Chalder T, Choy E, *et al.* Fatigue in rheumatoid arthritis: time for a conceptual model. *Rheumatology* 2011;**50**:1004–6.
- Petri MA, Lahita RG, van Vollenhoven RF, *et al.* Effects of prasterone on corticosteroid requirements of women with systemic lupus erythematosus: a double-blind, randomized, placebo-controlled trial. *Arth Rheum* 2002;**46**:1820–9.
- Petri MA, Mease PJ, Merrill JT, *et al.* Effects of prasterone on disease activity and symptoms in women with active systemic lupus erythematosus: results of a multicenter randomized, double-blind, placebo-controlled trial. *Arth Rheum* 2004;**50**:2858–68.
- Furie R, Petri MA, Strand V, *et al.*, BLISS-52 and -76 study groups. Clinical, laboratory and health-related quality of life correlates of Systemic Lupus Erythematosus Responder Index response: a post hoc analysis of the phase 3 belimumab trials. *Lupus Sci Med* 2014;**1**:e000031.
- Ad Hoc Committee on Systemic Lupus Erythematosus Response Criteria for Fatigue. Measurement of fatigue in systemic lupus erythematosus: a systematic review. *Arth Care Res* 2007;**57**:1348–57.
- Golliger EC, Pouchot J, Brant R, *et al.* Minimal clinically important difference for 7 measures of fatigue in patients with SLE. *J Rheumatol* 2008;**35**:635–42.
- Lai JS, Beaumont JL, Ogale S, *et al.* Validation of the functional assessment of chronic illness therapy-fatigue scale in patients with moderately to severely active systemic lupus erythematosus, participating in a clinical trial. *J Rheumatol* 2011;**38**:672–9.
- Kosinski M, Gajria K, Fernandes AW, *et al.* Qualitative validation of the FACIT-fatigue scale in systemic lupus erythematosus. *Lupus* 2013;**22**:422–30.
- Strand V, Levy R, Cervera R, *et al.*, for the BLISS-52 and -76 Study Groups. Improvements in health related quality of life with belimumab, a B-lymphocyte stimulator-specific inhibitor, in patients with autoantibody-positive systemic lupus erythematosus. *Annals Rheum Dis* 2014;**73**:838–44.