Comment on: Factors associated with fatal outcome of leflunomide-induced lung injury in Japanese patients with rheumatoid arthritis: reply

Sir, We would like to thank McLaren and Dawson [1] for their attention to our article [2] and for raising important issues. We would like to make the following comment. McLaren and Dawson pointed out that the association between pre-existing interstitial pneumonia and mortality of LEF-induced lung injury was not shown. As they pointed out, the P-value of pre-existing interstitial pneumonia between patients who died and who recovered from LEF-induced lung injury was 0.07, which was not of statistical significance. We agree with their comment that ‘it is crucial to properly define risk factors with statistical significance’, but we considered that pre-existing interstitial pneumonia should be noted and described because the P-value was close to 0.05 and the lowest among clinical background features.

It is important to distinguish drug-induced lung injury from rheumatoid lung or infectious diseases, although it is often difficult. In order to distinguish LEF-induced lung injury from other lung diseases to a maximum extent, and to compare the clinical and laboratory data between patients who died and who recovered from LEF-induced lung injury, the committee members examined post-marketing surveillance sheets and chest images of patients. In this process, committee members excluded 14 patients due to lack of data, and a further 25 patients because they included those who might have had lung injury other than LEF-induced lung injury and also those who might have had LEF-induced lung injury but died from complex causes including multiple organ failure. There were difficulties and limitations in the diagnosis of LEF-induced lung injury and judging the cause of their death in the excluded 25 patients.

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Takeo Sato1 and Shigeko Inokuma1

1Department of Allergic Diseases and Rheumatology, Japanese Red Cross Medical Center, Tokyo, Japan.

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Correspondence to: Takeo Sato, Department of Allergic Diseases and Rheumatology, Japanese Red Cross Medical Center, 4-1-22 Hiroo, Shibuya-ku, Tokyo 150-8935, Japan.

E-mail: satotk-rheumatol@umin.ac.jp

References


4 years’ time we shall be in a much stronger position to state whether or not MMF is effective in early dcSSc.

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Ariane L. Herrick1, Mark Lunt1, Alan J. Silman2 and Christopher P. Denton3
1Arthritis Research UK Epidemiology Unit, University of Manchester, Manchester Academic Health Science Centre, Manchester, 2Arthritis Research Campaign, Chesterfield and 3Centre for Rheumatology, Royal Free Hospital, London, UK.
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Correspondence to: Ariane L. Herrick, Arthritis Research UK Epidemiology Unit, Stopford Building, University of Manchester, Manchester M13 9PL, UK.
E-mail: ariane.herrick@manchester.ac.uk

References

Comment on: A prospective open-label study of mycophenolate mofetil for the treatment of diffuse systemic sclerosis: reply
Sir, in response to the comments by Herrick et al. [1] on our recent paper [2], we completely agree that spontaneous skin score improvement is part of the natural progression of dcSSc and we specifically comment on this on p. 1598 of our paper. SSC is a heterogeneous disease with geographical variations in disease phenotype [3], which may play a role in the different results of treatment studies. Detailed demographics of the population studied are very important when comparing data from different studies. As much as randomized, controlled clinical trials are difficult to perform in rare diseases, truly observational studies, as is described by Herrick et al. [4], also suffer from their limitations, such as loss to follow-up, inadequate data, bias in treatment allocation and differences in data collection, which makes it difficult to come to firm conclusions.

We agree with Herrick et al. that any treatment studies that are feasible in dcSSc, those being observational, retrospective, open-label or randomized, double-blind, placebo-controlled can provide us with useful information in this disease. We look forward to the results of the EULAR-funded observational study of treatment outcomes in dcSSc.

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Chris T. Derk1, Elizabeth Grace1, Max Shenin1, Manisha Naik1, Steffan Schulz1 and Wen Xiong1
1Division of Rheumatology, Thomas Jefferson University, Philadelphia, PA 19107, USA.
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Correspondence to: Chris T. Derk, Department of Medicine, Division of Rheumatology, Thomas Jefferson University, 613 Curtis Building, 1015 Walnut Street, Philadelphia, PA 19107, USA. E-mail: chris.derk@jefferson.edu

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