Supplementary Material

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Video abstract transcript

Simplified Ankylosing Spondylitis Disease Activity Score (SASDAS) Versus ASDAS: A Post Hoc Analysis of a Randomized Controlled Trial

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Slide 1:

The ASDAS tool is to be considered the gold standard for assessment of axial spondyloarthritis, but its use in daily practice is limited by its complexity and need for scientific calculation. The SASDAS index is a simple alternative to ASDAS and is calculated as the linear sum of the 5 ASDAS components. It is available in two versions – one using erythrocyte sedimentation rate or another using C-reactive protein. It doesn't require a calculator or an electronic application and it may be quicker and easier to use in routine practice.

Slide 2:

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Slide 3:

The objective of our study is to compare SASDAS with ASDAS for measuring and categorizing axSpA disease activity using data from the EMBARK trial in patients with active, non-radiographic disease. We decided to use the CRP version because it is a more specific acute-phase reactant.

Slide 4:

EMBARK is a multicenter, double-blind, placebo-controlled, randomized, study evaluating the efficacy between etanercept versus placebo. In double-blind phase, patients received etanercept 50 mg or placebo once weekly (1:1) for 12 weeks and then they were followed by a 92-week open-label phase in which all the patients took etanercept 50 milligrams weekly. ASDAS & SASDAS were calculated at baseline, 12, and 24 weeks.

Slide 5:

For statistical analysis the continuous SASDAS and ASDAS were evaluated by Spearman's correlation and ICC coefficients at baseline, and at Weeks 12 and 24. We used Cohen's weighted kappa for agreement in ASDAS versus SASDAS disease categories. The magnitude of treatment difference was evaluated using treatment effect size. It is the capacity to differentiate between treatments: etanercept versus placebo at Week 12, and etanercept versus placebo/etanercept at Week 24 for both ASDAS and SASDAS. The sensitivity to change from baseline at Week 12 and 24 was assessed by effect size for change.

Slide 6:

At baseline, the mean age of our patients was 32 years. 61% of them were male, 72% had HLA-B27 positive, and 81% had sacroiliitis confirmed by MRI. The mean BASDAI score was 6, indicating moderate-to-severe disease. 215 patients were randomized into the double-blind phase: 106 to etanercept and 109 for placebo.

Slide 7:

And here are the results. We found a strong linear relationship between standardized ASDAS and SASDAS at baseline and at Week 12. The Spearman correlation and ICC coefficients were very similar between etanercept and placebo at Week 12. At least 0.82 for pooled treatments and each treatment group at all the time points.

Slide 8:

The between-treatment effect size was numer¬ically higher by ASDAS (-0.74) than SASDAS (-0.51). In regarding to the within-treatment effect size for sensitivity to longitudinal changes for ASDAS versus SASDAS, the etanercept arms were similar, but it was slightly larger for SASDAS in placebo group at Week 12 and in placebo/etanercept group at Week 24.

Slide 9:

In this table, as you can see, the SASDAS as a category placed almost 70% of the patients in the same disease activity categories as ASDAS. The Cohen's weighted kappa was 0.58 at baseline, suggesting a moderate to substantial agreement. However, there were 38 patients corresponding to 17.9% in low and high disease activity in ASDAS who were categorized as having higher disease activity by SASDAS. Besides there were 26 patients (12.2%) that were categorized as having lower disease activity with SASDAS than with ASDAS. A similar pattern was seen post baseline.

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Slide 10:

As conclusions, it is the first time that SASDAS is validated in the context of a randomized clinical study. We observed a strong correlation between ASDAS and SASDAS for continuous variables and moderate-to-substantial agreement for categorical data. SASDAS places more patients with moderate activity into the high disease activity group. While our intention is not to replace ASDAS, we believe it's useful for everyday clinical practice as a faster, simpler tool. However, further evaluation of SASDAS is needed.

Slide 11:

If you would like to know more about this study, we invite you to read our full paper in the Journal of Rheumatology. We would like to thank the patients, the trial investigators and personnel at all the participating centers who made this study possible. The EMBARK trial was sponsored by Pfizer and medical writing support was provided by David Sunter of Engage Scientific Solutions. Thank you very much!

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