

ABSTRACT NUMBER: 0818

Defining BASDAI Cut-offs for Disease Activity States in Axial Spondylarthritis – Results from the EuroSpA Collaboration

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Meeting: [ACR Convergence 2024](#)

Keywords: [Disease Activity](#), [Outcome measures](#), [Patient reported outcomes](#)

SESSION INFORMATION

Date: [Saturday, November 16, 2024](#)

Session Type: Abstract Session

Title: [Abstracts: SpA Including PsA –
Diagnosis, Manifestations, & Outcomes I](#)

Session Time: 1:00PM-2:30PM

Background/Purpose: While the Axial Spondyloarthritis Disease Activity Score based on C-reactive protein (ASDAS) is recommended for assessment of disease activity in patients with axial spondyloarthritis (axSpA), the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) is still widely used, particularly in settings where inflammatory laboratory markers are unavailable. BASDAI values of < 2, < 4 and >6 have been applied as cut-offs for remission, between low disease activity (LDA) and high disease activity (HDA) and for very high disease activity (VHDA), respectively, although these cut-offs remain unvalidated. We aimed to (i) determine BASDAI cut-offs for disease activity states against predefined external criteria, and (ii) assess the level of agreement *between* BASDAI and ASDAS *disease activity states*.

Methods: Prospectively collected real-world data from patients with axSpA initiating a first tumour necrosis factor inhibitor or an interleukin-17A inhibitor from registries participating in the European Spondyloarthritis (EuroSpA) collaboration were analyzed. We applied the same approach as previously used by Machado *et al.* [1] to define the endorsed ASDAS cut-offs for disease activity states against external criteria, i.e., ASAS partial remission, and patient and physician global assessments. Follow-up data at 6 months were used to select the cut-offs between BASDAI remission and LDA, and between LDA and HDA, while baseline data were used to select the cut-off for VHDA. Receiver operating characteristic analyses were performed to determine the optimal BASDAI cut-offs. The level of agreement between disease activity states based on BASDAI and ASDAS cut-offs was assessed using proportion of discordance and weighted kappa coefficient.

Results: We analyzed data from 2,791 patients from seven European registries with available data on BASDAI and the above-mentioned external criteria. Mean (standard deviation) BASDAI (on a 0-10 scale) and ASDAS were 6.1 (1.9) and 3.8 (0.9) at baseline, and 3.0 (2.3) and 2.0 (1.0) at 6-month follow-up, respectively. The optimal BASDAI cut-off values against external criteria were estimated to be < 1.4, < 2.8 and >5.9 (Table 1). Analyses on the level of agreement between BASDAI and ASDAS disease activity states demonstrated that the proportions of discordance decreased from 32.6% to 27.8% in baseline data and from 36.4% to 32.9% in follow-up data, when the estimated BASDAI cut-offs (< 1.4, < 2.8 and >5.9) were applied instead of the unvalidated BASDAI cut-offs (< 2, < 4 and >6) (Figure 1). The corresponding weighted kappa values increased slightly, but only a fair level of agreement was observed. The level of agreement between BASDAI and ASDAS disease activity states was superior at baseline compared to follow-up.

Conclusion: We estimated BASDAI cut-offs for the disease activity states against predefined external criteria to be < 1.4, < 2.8 and >5.9 in a large European observational cohort of patients with axSpA. Moderate agreement between disease activity states according to BASDAI and ASDAS was observed, which reflects that the underlying domains of BASDAI and ASDAS are not identical.

References:

1. Machado *et al.* (2011). *Ann Rheum Dis*, 70(1), 47-53.

	90% Spec (Sens/Spec)	Youden (Sens/Spec)	(0,1) (Sens/Spec)	AUC
Cut-off between remission and LDA				
ASAS partial remission	<1.2 (0.89/0.92)	<1.3 (0.91/0.90)	<1.3 (0.91/0.90)	0.96
Patient global ≤1	<1.5 (0.78/0.90)	<1.8 (0.84/0.85)	<1.8 (0.84/0.85)	0.92
Physician global ≤1	<1.4 (0.45/0.91)	<2.6 (0.68/0.72)	<2.6 (0.68/0.72)	0.76
Cut-off between LDA and HDA				
Patient global ≤3	<2.7 (0.78/0.90)	<3.2 (0.87/0.84)	<3.2 (0.87/0.84)	0.94
Physician global ≤3	<2.8 (0.60/0.90)	<3.3 (0.68/0.83)	<3.8 (0.74/0.76)	0.82
Cut-off between HDA and VHDA				
Patient global ≥6	>6.8 (0.50/0.90)	>5.7 (0.75/0.74)	>5.7 (0.75/0.74)	0.82
Physician global ≥6	>7.9 (0.24/0.90)	>6.0 (0.64/0.55)	>6.2 (0.60/0.59)	0.64
Bold indicates the optimal BASDAI values according to which the overall cut-offs were calculated as their average. Patient global and physician global were on a 0-10 integer scale.				
(0,1): cut-off according to the closest point to (0,1) criterion; 90% Spec: cut-off according to the 90% specificity criterion; ASAS: Assessment of SpondyloArthritis international Society; AUC: area under the curve; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; Sens: sensitivity; Spec: specificity; Youden: cut-off according to the Youden index criterion.				

Table 1. BASDAI cut-offs for disease activity states against external criteria

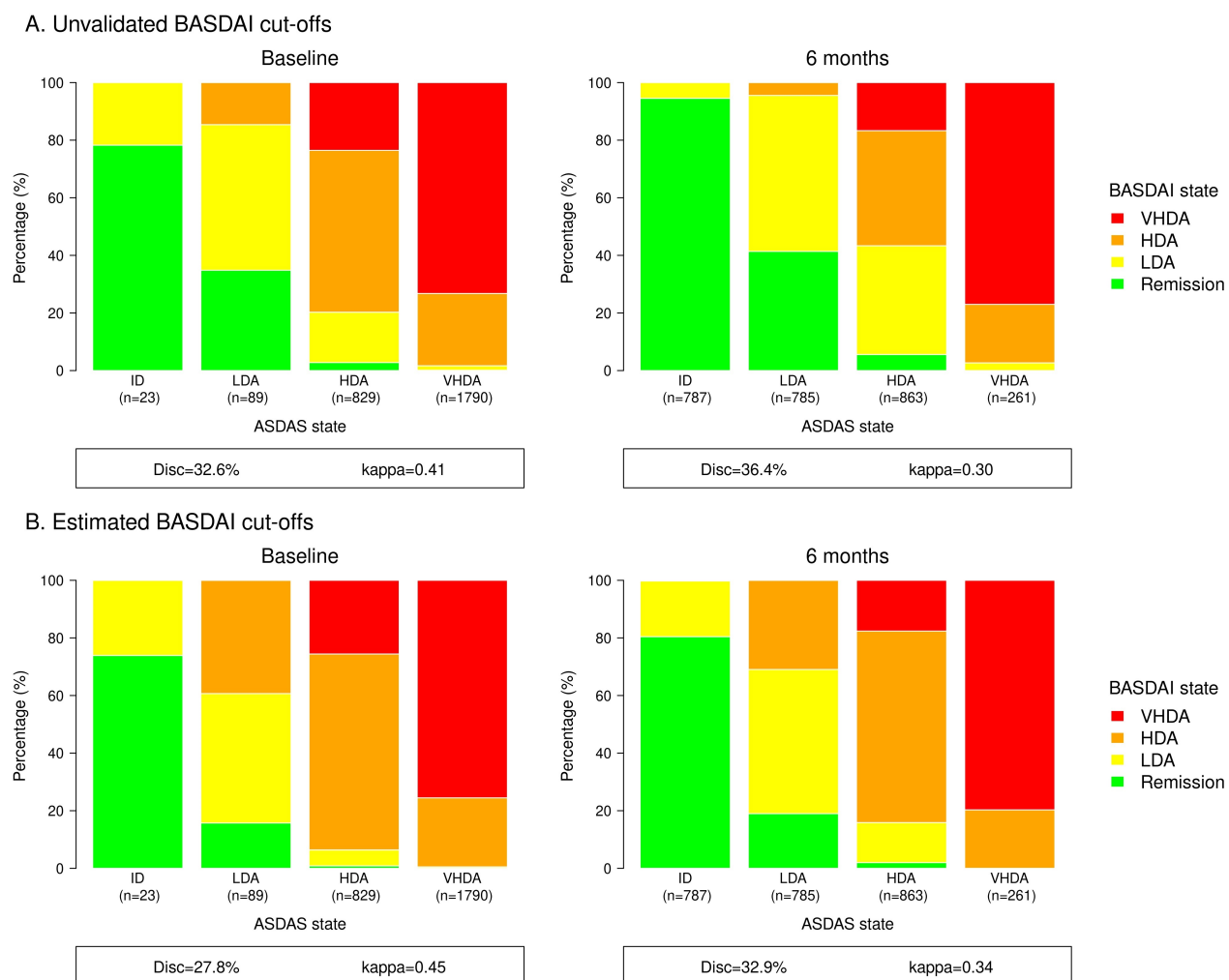


Figure 1. Stacked bar charts of BASDAI states according to estimated cut-offs dependent on ASDAS states according to A. unvalidated cut-offs (<2, <4 and >6), and B. estimated cut-offs: <1.4, <2.8 and >5.9. ASDAS states: ID (ASDAS<1.3), LDA (1.3≤ASDAS<2.1), HDA (2.1≤ASDAS≤3.5) and VHDA (ASDAS>3.5). ASDAS: Ankylosing Spondylitis Disease Activity Score based on C-Reactive Protein; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; Disc: proportion of discordance; HDA: high disease activity; ID: inactive disease; LDA: low disease activity; VHDA: very high disease activity; kappa: weighted kappa coefficient.

Disclosures: **S. Georgiadis:** Novartis, 5, UCB, 5; **L. Oernbjerg:** Novartis, 5, UCB, 5; **B. Michelsen:** Novartis, 5, 6; **T. Kvien:** AbbVie/Abbott, 1, 2, 5, Bristol-Myers Squibb(BMS), 5, Galapagos, 5, Gilead, 2, Grünenthal, 6, Janssen, 2, 6, Novartis, 2, 5, Pfizer, 2, 5, Sandoz, 2, 6, UCB, 2, 5; **S. Rasmussen:** Novartis, 5; **J. Závada:** AbbVie/Abbott, 1, AstraZeneca, 6, Eli Lilly, 6, Sanofi, 6, Sobi, 6, UCB, 6; **K. Bubová:** None; **B. Glintborg:** AbbVie/Abbott, 5, Bristol-Myers Squibb(BMS), 5, Pfizer, 5, Sandoz, 5; **A. Loft:** AbbVie/Abbott, 2, 6, Eli Lilly, 2, 6, Janssen, 2, 6, Novartis, 2, 5, 6, Pfizer, 2, 6, UCB, 2, 6; **A. Rodrigues:** AbbVie/Abbott, 5, Amgen, 5, AstraZeneca, 5, Boehringer-Ingelheim, 5, Eli Lilly, 5, Merck/MSD, 5, Novartis, 5, Pfizer, 5; **M. Santos:** None; **A. Ciurea:** None; **M. Nissen:** AbbVie/Abbott, 2, 6, Amgen, 2, 6, Janssen, 2, 6, 12, Support for conference participation, Novartis, 2, 2, 5, 6, 6, Pfizer, 2, 6, UCB, 2, 6, 12, Support for conference participation; **L. Kuusalo:** None; **J. Rutanen:** None; **Z. Rotar:** None; **K. Perdan-Pikmajer:** None; **B. Gudbjornsson:** None; **O. Palsson:** None; **D. DiGuseppe:** None; **M. Ostergaard:** Abbott, 2, 5, 6, BMS, 6, Centocor, 5, Merck, 2, 6, Mundipharma, 6, Pfizer, 2, 5, 6, Roche, 2, UCB Pharma, 2, 6; **M. Hetland:** AbbVie/Abbott, 5, 12, Paid to my institution, no personal fee, Bristol-Myers Squibb(BMS), 5, 12, Paid to my institution, no personal fee, Eli Lilly, 5, 12, Paid to my institution, no personal fee, Medac, 6, 12, Paid to my institution, no personal fee, Merck/MSD, 5, 12,

Paid to my institution, no personal fee, Novartis, 5, 6, Pfizer, 5, 6, 12, Paid to my institution, no personal fee, Sandoz, 5, 6, 12, Paid to my institution, no personal fee, UCB, 6, 12, Paid to my institution, no personal fee.

To cite this abstract in AMA style:

Georgiadis S, Oernbjerg L, Michelsen B, Kvien T, Rasmussen S, Závada J, Bubová K, Glintborg B, Loft A, Rodrigues A, Santos M, Ciurea A, Nissen M, Kuusalo L, Rutanen J, Rotar Z, Perdan-Pikmajer K, Gudbjornsson B, Palsson O, DiGuiseppe D, Ostergaard M, Hetland M. Defining BASDAI Cut-offs for Disease Activity States in Axial Spondylarthritis – Results from the EuroSpA Collaboration [abstract]. *Arthritis Rheumatol*. 2024; 76 (suppl 9). <https://acrabstracts.org/abstract/defining-basdai-cut-offs-for-disease-activity-states-in-axial-spondylarthritis-results-from-the-eurospa-collaboration/>. Accessed November 16, 2024.

ACR Meeting Abstracts - <https://acrabstracts.org/abstract/defining-basdai-cut-offs-for-disease-activity-states-in-axial-spondylarthritis-results-from-the-eurospa-collaboration/>