Performance of the Ankylosing Spondylitis Disease Activity Score (ASDAS) in patients under biological therapies in daily practice – results from the Portuguese register Reuma.pt

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Background/Purpose

- The Ankylosing Spondylitis Disease Activity Score (ASDAS) is the new index to measure disease activity in Ankylosing Spondylitis (AS).
- Our aim was to address validity and discriminatory aspects of the ASDAS, as well as to analyse the performance of the ASDAS disease activity states and response criteria in the setting of an observational cohort of patients with AS starting biological therapies.

Methods

- Patients with AS under biological therapy and followed in the Portuguese register of rheumatic diseases (Reuma.pt) were included in this analysis. Reuma.pt is used as an electronic medical record (linked to a SQL server database) and assessments are performed by rheumatologists.
- All patients with baseline data were used for cross-sectional analysis (n= 264). For the longitudinal analyses, follow-up visits at 12 and 24 weeks and with an ASDAS-CRP available were required (n = 109).
- Pearson coefficients were calculated to establish the correlation between disease activity measurements at baseline.
- Discrimination between patients with low versus high disease activity according to the patient's global assessment (PGA) was analysed as the standardised mean difference (SMD).
- The percentage of patients within each ASDAS disease activity state at each time point and the percentage of patients achieving ASDAS improvement criteria at 12 and 24 weeks were determined and the latter were compared with other response measures.

Reuma.pt
Registo Nacional de Doentes Reumáticos
Rheumatic Diseases Portuguese Register

Results

- The ASDAS showed a good correlation with the PGA (0.66), and simultaneously a good correlation with acute phase reactants (CPR 0.61; ESR 0.52).
- The ASDAS was discriminatory, with similar SMDs to the ones from BASDAI. Results were consistent for the whole population as well as in subgroups of baseline CRP (at a cutoff of 5mg/l) and disease duration (at a cutoff of 5 years).
- ASDAS disease activity in states showed a clinically meaningful shift from high to low over time. The same pattern was found in the subgroups of CRP and disease duration.
- The ASDAS improvement criteria identified more patients with clinically meaningful improvement than the classical criteria did, and the same results were also found in the subgroups of CRP and disease duration.

Table 1 - Correlations between the different instruments (N = 202 – 264)

	ASDAS	Patient's global assessment	BASDAI
ASDAS	1	0.66	0.73
Patient's global assessment	0.66	1	0.66
BASDAI	0.73	0.66	1
BASFI	0.61	0.53	0.66
CRP	0.61	0.15	0.08
ESR	0.52	0.21	0.08

Conclusions

- **The ASDAS is a discriminatory instrument for disease activity in the setting of usual clinical practice.**
- **The ASDAS discriminatory properties are maintained, independently of the level of baseline CRP and the disease duration.**

Table 3 – Longitudinal distribution of ASDAS disease activity states

Time point	N	ASDAS < 1.3 N (%)	1-3 ≤ ASDAS < 2.1 N (%)	2.1 ≤ ASDAS < 3.5 N (%)	ASDAS > 3.5 N (%)
Baseline	109	0 (0%)	3 (2.8%)	46 (42.2%)	60 (55.0%)
12 weeks	109	33 (30.3%)	25 (22.9%)	42 (38.5%)	9 (8.3%)
24 weeks	109	30 (27.5%)	29 (26.6%)	40 (36.7%)	10 (9.2%)

Table 4 - Percentage of patients achieving different improvement criteria

	12 weeks (n = 91)	24 weeks (n = 91)
Δ ASDAS ≥ 1.1	57 (62.6%)	55 (60.4%)
Δ ASDAS ≥ 2.0	36 (39.6%)	34 (37.4%)
Δ BASDAI ≥ 2.0	46 (50.6%)	46 (50.6%)
BASDAI50	40 (44.0%)	37 (40.7%)
ASAS20	51 (56.0%)	51 (56.0%)
ASAS40	42 (46.2%)	44 (48.4%)

Table 2 – Discriminatory capacity of the various disease activity assessments, with the population stratified according to the patient's global assessment

	Patient's global assessment of disease activity at baseline			Patient's global assessment of disease activity at 12 weeks			Patient's global assessment of disease activity at 24 weeks		
	<4 (n = 52-73)	>6 (n = 113-143)	SMD	<4 (n = 96-113)	≥4 (n = 72-83)	SMD	<4 (n = 90-107)	≥4 (n = 75-88)	SMD
ASDAS	2.5 (1.1)	4.1 (0.9)	1.7 (1.3; 2.1)	1.4 (0.8)	3.0 (0.9)	2.0 (1.6; 2.4)	1.3 (0.8)	2.9 (0.8)	2.0 (1.6; 2.4)
BASDAI	3.4 (2.5)	6.8 (1.6)	1.7 (1.4; 2.0)	1.9 (1.5)	5.7 (1.9)	2.2 (1.9; 2.6)	2.0 (1.9)	4.9 (1.9)	1.6 (1.2; 1.9)
BASDAI 1 fatigue	3.6 (2.7)	6.6 (2.3)	1.2 (0.9; 1.6)	2.5 (2.1)	6.2 (2.1)	1.8 (1.4; 2.1)	2.3 (2.2)	5.3 (2.2)	1.3 (1.0; 1.7)
BASDAI 2 back pain	4.3 (3.0)	7.6 (1.9)	1.4 (1.1; 1.7)	2.0 (1.9)	6.6 (2.0)	2.4 (2.0; 2.8)	2.4 (2.4)	5.9 (2.0)	1.6 (1.2; 1.9)
BASDAI 3: pain/swelling peripheral joints	2.7 (3.0)	6.0 (2.9)	1.1 (0.8; 1.4)	1.5 (1.8)	5.0 (2.8)	1.5 (1.2; 1.8)	1.5 (2.0)	4.4 (2.8)	1.2 (0.9; 1.5)
BASDAI 4: enthesitis	3.3 (3.1)	6.9 (2.4)	1.4 (1.0; 1.7)	1.7 (1.9)	5.7 (2.7)	1.8 (1.4; 2.1)	2.0 (2.3)	4.7 (2.6)	1.1 (0.8; 1.4)
BASDAI 5: severity morning stiffness	3.3 (3.1)	7.4 (2.0)	1.7 (1.3; 2.0)	1.6 (1.7)	5.4 (2.5)	1.8 (1.5; 2.1)	1.6 (2.1)	4.7 (2.4)	1.4 (1.1; 1.7)
BASDAI 6: duration morning stiffness	2.8 (2.8)	6.0 (2.9)	1.1 (0.8; 1.4)	1.7 (2.0)	4.2 (2.8)	1.1 (0.8; 1.4)	1.6 (2.0)	4.0 (2.8)	1.0 (0.7; 1.3)
BASDAI 5/6: morning stiffness	3.1 (2.8)	6.7 (2.1)	1.5 (1.2; 1.9)	1.7 (1.7)	4.8 (2.3)	1.6 (1.2; 1.9)	1.6 (2.0)	4.3 (2.4)	1.3 (0.9; 1.6)
Patient global	2.0 (1.2)	7.8 (1.1)	--	1.4 (1.1)	6.0 (1.6)	--	1.5 (1.2)	5.6 (1.4)	--
CRP	18.5 (22.2)	26.5 (22.4)	0.2 (-0.1; 0.6)	5.6 (11.0)	7.8 (13.1)	0.2 (-0.1; 0.5)	4.7 (10.4)	10.2 (15.6)	0.4 (0.1; 0.7)
ESR	26.1 (34.3)	40.9 (33.7)	0.5 (0.2; 0.8)	14.2 (14.3)	14.6 (14.8)	0.0 (-0.3; 0.3)	11.9 (10.5)	20.4 (22.2)	0.5 (0.2; 0.8)