Rheumatology Advances in Practice, 2025, **9(2)**, rkaf012
https://doi.org/10.1093/rap/rkaf012
Advance access publication 29 January 2025
Original Article

British Society for Rheumatology
RHEUMATOLOGY ADVANCES IN PRACTICE
OXFORD

Clinical science

BASDAI and ASDAS disease states in relationship to ASAS40 response: post hoc analysis of ixekizumab in radiographic axial spondyloarthritis

Martin Rudwaleit [1,*], Victoria Navarro-Compán [2], Hagen Russ [3], Tommaso Panni [3], Erica Filippi [3], Mani Haschemi Nassab [3], Soyi Liu-Leage [3], Vincent Goëb [4], Francesco Ciccia [5], Jean Dudler [6]

[1]Department of Rheumatology, Klinikum Bielefeld, Medical School and University Center OWL, Bielefeld University, Bielefeld, Germany
[2]Department of Rheumatology, University Hospital La Paz, IdiPAZ, Madrid, Spain
[3]Eli Lilly and Company, Indianapolis, IN, USA
[4]Department of Rheumatology, Centre Hospitalier Universitaire Amiens-Picardie, UPJV, Amiens, France
[5]Department of Rheumatology, University of Palermo, Sicily, Italy
[6]Department of Rheumatology, Hôpital Fribourgeois, Fribourg, Switzerland

*Correspondence to: Martin Rudwaleit, Department of Internal Medicine and Rheumatology, Klinikum Bielefeld, University of Bielefeld, An der Rosenhoehe 27, 33647 Bielefeld, Germany. E-mail: martin.rudwaleit@uni-bielefeld.de

Abstract

Objectives: To explore the relationship between Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and Axial Spondyloarthritis Disease Activity Score (ASDAS) used in clinical practice and the Assessment of SpondyloArthritis international Society 40% (ASAS40) response, the primary endpoint in clinical trials in axial spondyloarthritis (axSpA).

Methods: Data from COAST-V, a phase 3 trial of ixekizumab *vs* placebo in biologic-naïve radiographic axSpA (r-axSpA) patients, were analysed. Patients treated with ixekizumab every 4 weeks were categorized using the ASAS40 response at week 16 and 52. The association between BASDAI and ASDAS disease states, respectively, and ASAS40 response achieved/not achieved was investigated. Additionally, back pain, fatigue, Bath Ankylosing Spondylitis Functional Index, ASAS Health Index and 36-item Short Form Health Survey Physical Component Summary scores corresponding to these states were assessed. Results were reported descriptively.

Results: After 16 weeks, 48.1% (39/81) of patients achieved an ASAS40 response. Among them, 71.8% ($n=28$) and 43.6% ($n=17$) achieved BASDAI <3 and BASDAI <2, respectively; 76.9% ($n=30$) and 33.3% ($n=13$) attained ASDAS <2.1 and ASDAS <1.3, respectively. Among ASAS40 responders at week 52 [53.1% (43/81)], 83.8% ($n=36$) and 51.2% ($n=22$) of patients achieved BASDAI <3 and BASDAI <2, respectively; 93.1% ($n=40$) and 41.9% ($n=18$) attained ASDAS <2.1 and ASDAS <1.3. Lower BASDAI and ASDAS disease states corresponded well with less back pain, fatigue and functioning impairment and better health-related quality of life.

Conclusions: More than 70% of biologic-naïve r-axSpA patients who achieved an ASAS40 response, also attained low disease activity or inactive disease as measured by the BASDAI or ASDAS. Findings may help clinicians translate results from clinical trials into daily practice.

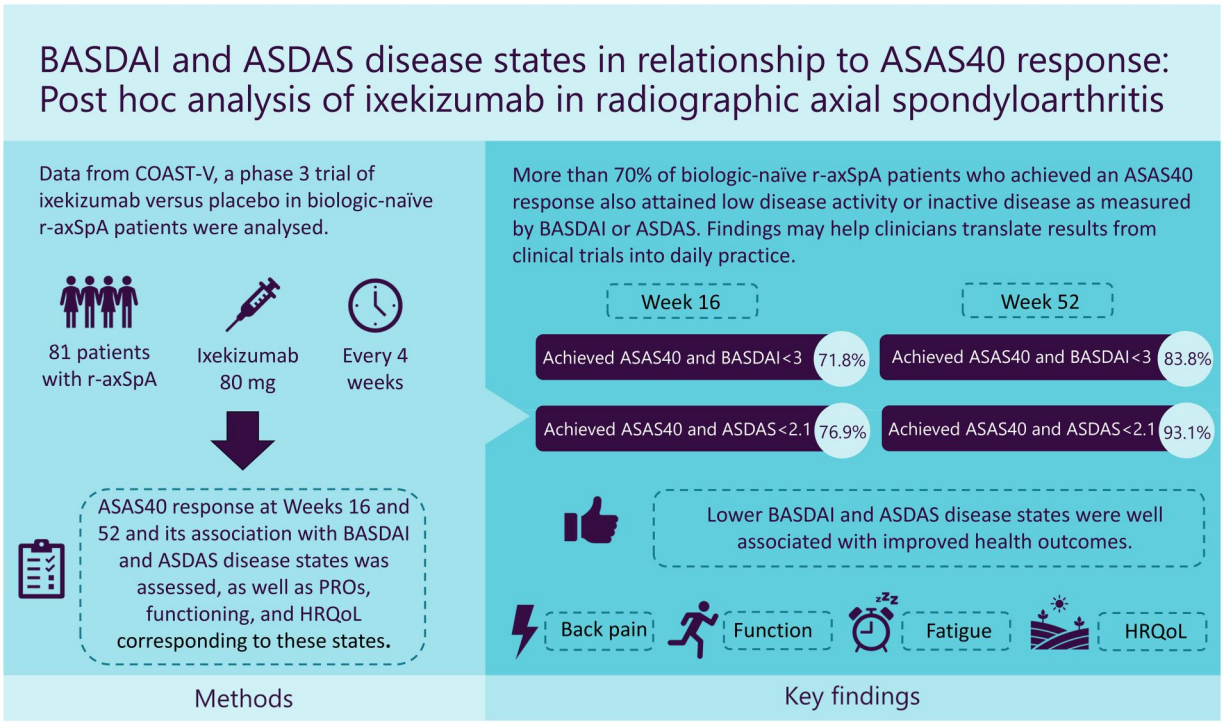
Lay Summary

What does it mean for patients?

This study explored how two measures of disease activity, the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Axial Spondyloarthritis Disease Activity Score (ASDAS), relate to improvements seen in patients with radiographic axial spondyloarthritis (r-axSpA) after treatment. Researchers used data from a trial involving ixekizumab, a medication for r-axSpA, to examine how well patients responded to treatment by achieving a 40% improvement based on the Assessment of SpondyloArthritis international Society (ASAS40) criteria. The results showed that >70% of patients who responded to treatment with ixekizumab using the ASAS40 criteria also had low disease activity or inactive disease according to BASDAI scores or ASDASs. Additionally, lower disease activity was linked to improvements in symptoms such as back pain, fatigue and physical function, leading to a better quality of life. These findings may help doctors understand how results from clinical trials can be applied to everyday care, offering a clearer picture of how treatments can lead to meaningful improvements in patients' disease management and overall well-being.

Received: 17 October 2024. **Accepted:** 31 December 2024

Graphical abstract



RHEUMATOLOGY ADVANCES IN PRACTICE

Rudwaleit et al. BASDAI and ASDAS disease states in relationship to ASAS40 response: Post hoc analysis of ixekizumab in radiographic axial spondyloarthritis. *Rheumatology Advances in Practice*.

Keywords: axial spondyloarthritis, ixekizumab, outcome, treatment response, disease activity.

Key messages

- Among ASAS40 responders, >70% of biologic-naïve r-axSpA patients achieved BASDAI <3 or ASDAS <2.1.
- Achieving lower disease activity was associated with better outcomes in clinical parameters, functioning and health-related quality of life.
- Findings may help clinicians translate results from randomised controlled trials into clinical practice.

Introduction

Axial spondyloarthritis (axSpA) is an immune-mediated chronic inflammatory disease primarily affecting young adults, causing chronic back pain, morning stiffness and fatigue, which often leads to impaired overall functioning and quality of life. It is generally characterized by inflammation of the sacroiliac joints and spine and in some patients by progressive spinal ankylosis due to new bone formation [1, 2]. The primary treatment goal is remission or low disease activity to improve health-related quality of life (HRQoL) [3]. However, persistent high disease activity in axSpA contributes significantly to radiographic progression and decreased physical functioning over time [4], making regular clinical assessment and disease activity recording essential for management [5].

Assessment indices, such as the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) and the Axial Spondyloarthritis Disease Activity Score (ASDAS), are key tools for monitoring disease activity and guiding treatment decisions [6]. The BASDAI, a widely used patient-reported outcome (PRO) measure, is especially helpful when CRP data are unavailable [3, 5, 7]. The ASDAS, introduced in 2009, combines PROs with inflammatory markers and has become the preferred tool for measuring disease activity in axSpA as per the 2022 ASAS-EULAR recommendations [5, 8, 9]. The ASAS40 response, commonly used in randomized clinical trials (RCTs), measures a ≥40% improvement and absolute improvement of ≥2 units in three of four domains: global assessment, back pain, physical function (BASFI) and morning stiffness [10].

Despite these tools, the relationship between ASAS40 response and BASDAI scores/ASDASs in biologic-naïve patients with radiographic axSpA (r-axSpA) treated with biologics is not fully understood. This highlights the need to better understand how ASAS40 relates to disease activity and patient outcomes to improve clinical decision-making. To address this, we conducted a post hoc analysis of the COAST-V phase 3 trial (NCT02696785), evaluating ixekizumab (IXE) efficacy and safety in biologic-naïve r-axSpA patients [11, 12].

We assessed the relationship between ASAS40 response at weeks 16 and 52 and BASDAI/ASDAS levels, as well as their correlation with PROs, functioning and HRQoL.

Methods

Study design and patient eligibility criteria for the COAST-V trial have been described previously [11]. The study was approved by the ethical review board at each participating site before the start of the study. COAST-V was conducted in accordance with the ethical principles of the Declaration of Helsinki. All patients provided written informed consent before undergoing study-related procedures. Adult patients with an established diagnosis of r-axSpA and who fulfilled the ASAS 2009 criteria for axSpA (sacroiliitis on radiograph by the modified New York criteria and at least one SpA feature), inadequate response or intolerance to NSAIDs, a baseline score of BASDAI ≥4 and back pain numeric rating scale (NRS) ≥4 were randomized (1:1:1:1) to IXE 80 mg every 2 weeks, IXE 80 mg every 4 weeks, adalimumab 40 mg every 2 weeks (reference arm) or placebo. After completing 16 weeks, the study entered a dose double-blind treatment period during which participants originally in the placebo or adalimumab group were randomized (1:1) to IXE at every 2- or 4-week treatment and originally randomized IXE patients continued their same regimens. To assess if treatment response rates were sustained, parameters were measured up to 52 weeks [12].

For this post hoc analysis, the patient data relevant to IXE 80 mg administration every 4 weeks were used, as this is the approved dosage [13, 14]. The COAST-V trial collected data on ASAS40 (primary endpoint), BASDAI, ASDAS, PROs, functioning and HRQoL.

In this analysis, those patients who achieved ASAS40 response at weeks 16 or 52 were referred to as ASAS40 responders and those who did not achieve ASAS40 response were referred to as ASAS40 non-responders at the respective timepoints.

The BASDAI comprises six questions that relate to five major symptoms: fatigue, total back pain, peripheral arthritis, enthesitis and both intensity and duration of morning stiffness. Each question is scored on an NRS. The final score is calculated by the addition of the first four questions and the average of the last two questions, divided by five. NRS scores range from 0 (no disease activity) to 10 (highly active disease). The most commonly used cut-off value for BASDAI is 4, above which a patient is considered to be in an active disease state [6]. Other BASDAI cut-off values have not been extensively validated [10]. However, researchers have applied BASDAI scores <3 or <4 for low disease activity [15, 16] and BASDAI scores ≤2 for very low disease activity/remission [16]. The BASDAI intervals derived from these cut-off values and applied in our analysis were <2, 2–2.99, 3–3.99 and ≥4.

The ASDAS is calculated from the assessment of the patient-reported global assessment of disease activity, total back pain (BASDAI question 2), peripheral joint pain and/or swelling (BASDAI question 3), duration of morning stiffness (BASDAI question 6) and objective measures of inflammation (CRP or ESR) [10]. The ASDAS disease activity states validated are <1.3 for inactive disease, ≥1.3–<2.1 for low disease activity, ≥2.1–≤3.5 for high disease activity and >3.5 for very high disease activity [17].

Total back pain (BASDAI question 2) and fatigue (Fatigue Severity NRS) were scored on a scale from 0 to 10, physical function was measured by applying the BASFI NRS 0–10, overall functioning and health were assessed by the ASAS Health Index (ASAS HI; NRS 0–17) and HRQoL parameters were evaluated using the 36-Item Short Form Health Survey Physical Component Score (SF-36 PCS; NRS 0–100).

Statistical analysis

ASAS40 achievement at weeks 16 and 52 compared with BASDAI and ASDAS disease activity states, as well as clinical outcomes, functioning and HRQoL measures, are presented descriptively as percentages of patients or mean (S.D.). For responder analysis, missing data were computed using non-responder imputation (NRI). For missing data on continuous parameters, the modified baseline observation carried forward (mBOCF) was used. Analysis of data was performed using Statistical Analysis System version 9.4 (SAS Institute, Cary, NC, USA).

Results

Baseline demographics and clinical disease characteristics of ASAS40 responders and non-responders at week 16

In the COAST-V trial, ASAS40 responders at week 16 [$n = 39$ (48.1%)] were younger (36.8 years) than non-responders (44.8 years) and had a shorter symptom duration (11.2 *vs* 20.1 years), higher CRP (15.5 *vs* 9.1 mg/l) and were more often positive for HLA-B27 (100% *vs* 85.7%) at baseline. Clinical disease characteristics were similar between the two groups (Table 1).

Change from baseline to week 52 in BASDAI scores and ASDASs in ASAS40 responders at weeks 16 and 52

The mean BASDAI score among ASAS40 responders at week 16 declined from 7.0 at baseline to 2.3 at week 16 and was maintained at 2.2 in week 52. The mean BASDAI score among ASAS40 responders at week 52 decreased from 6.9 at baseline to 2.6 at week 16 and slightly decreased further to 1.9 at week 52 (Fig. 1A). A similar pattern was observed for changes in mean ASDASs among ASAS40 responders at weeks 16 and 52, with a major decline in the first 16 weeks. The mean ASDAS among ASAS40 responders at week 16 decreased from 3.9 at baseline to 1.7 at week 16 and was maintained at 1.6 at week 52. The mean ASDAS among ASAS40 responders at week 52 declined from 3.8 at baseline to 1.8 at week 16 and slightly decreased further to 1.4 at week 52 (Fig. 1B).

BASDAI and ASDAS disease activity in ASAS40 responders and non-responders at weeks 16 and 52

Among patients who achieved an ASAS40 response at week 16 [48.1% (39/81)], 71.8% ($n = 28$) and 43.6% ($n = 17$) achieved a BASDAI <3 and BASDAI <2, respectively (Fig. 2A). Also, ASDAS <2.1 was attained by 76.9% ($n = 30$) and ASDAS <1.3 by 33.3% ($n = 13$) of ASAS40 responders (Fig. 2C). Among patients who achieved an ASAS40 response at week 52 [53.1% (43/81)], the proportion of patients who achieved a BASDAI <3 was 83.8% ($n = 36$) and the proportion of patients who achieved a BASDAI <2 was 51.2% ($n = 22$) (Fig. 2B). An ASDAS <2.1 was attained by 93.1% ($n = 40$) and ASDAS <1.3 was achieved by 41.9% ($n = 18$) of

Table 1. Baseline demographics and clinical characteristics by ASAS40 responders/non-responders at week 16

Characteristics	ASAS40 responders ($n = 39$)[a]	ASAS40 non-responders ($n = 42$)[a]	Total cohort ($n = 81$)[a]
Age, mean (S.D.), years	36.8 (9.8)	44.8 (12.9)	41.0 (12.0)
Males, *n* (%)	34 (87.2)	34 (81.0)	68 (84.0)
HLA-B27 positive, *n* (%)	39 (100.0)	36 (85.7)	75 (92.6)
Symptom duration, mean (S.D.), years	11.2 (7.8)	20.1 (12.2)	15.8 (10.8)
Duration since diagnosis, mean (S.D.), years	5.1 (6.7)	11.3 (11.0)	8.4 (9.8)
csDMARDs used, *n* (%)	15 (38.5)	19 (45.2)	34 (42.0)
BASDAI, mean (S.D.)	7.0 (1.4)	6.5 (1.2)	6.7 (1.3)
ASDAS, mean (S.D.)	3.9 (0.7)	3.5 (0.7)	3.7 (0.7)
CRP, mean (S.D.), mg/l	15.5 (15.4)	9.1 (10.3)	12.2 (14.2)
Total back pain (BASDAI question 2), mean (S.D.)	7.5 (1.5)	7.3 (1.2)	7.4 (1.3)
Fatigue severity (NRS), mean (S.D.)	7.0 (1.7)	6.4 (1.6)	6.7 (1.6)
BASFI, mean (S.D.)	6.3 (1.9)	5.8 (1.7)	6.1 (1.8)
ASAS HI, mean (S.D.)	7.4 (3.4)	7.5 (3.3)	7.5 (3.3)
SF-36 PCS, mean (S.D.)	36.2 (7.5)	36.7 (6.7)	36.5 (7.1)

[a] Intention-to-treat population who were initially randomized to IXE every 4 weeks.
ASAS40: Assessment of SpondyloArthritis international Society 40% response; ASDAS: Axial Spondyloarthritis Disease Activity Score; ASAS HI: Assessment of SpondyloArthritis international Society Health Index; NRS: numeric rating scale; SF-36 PCS: 36-Item Short Form Health Survey Physical Component Score; csDMARDs: conventional synthetic disease-modifying anti-rheumatic drugs.

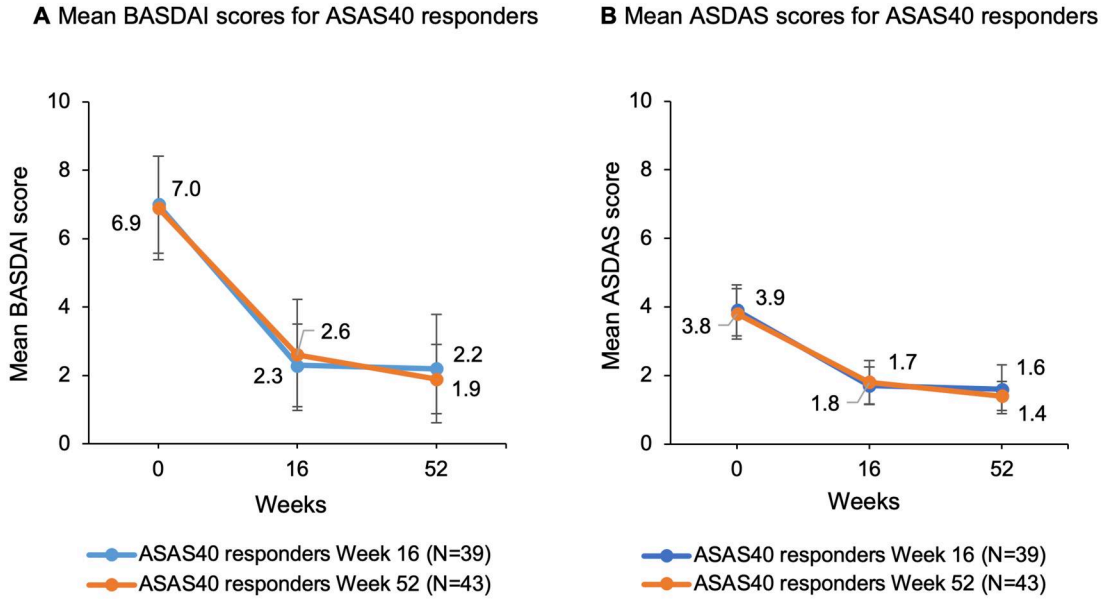


Figure 1. Line graphs show **(A)** mean BASDAI scores and **(B)** mean ASDASs in patients who achieved ASAS40 response at week 16 and 52, respectively, in the COAST-V trial. Error bars represent S.D.s from the mean. ASAS40: Assessment of SpondyloArthritis international Society 40% response; ASDAS: Axial Spondyloarthritis Disease Activity Score

ASAS40 responders at week 52 (Fig. 2D). The vast majority of ASAS40 non-responders at week 16 were in the BASDAI ≥4 (81.0%) and ASDAS ≥2.1–≤3.5 (73.8%) intervals, with slightly higher percentages noted at week 52.

Clinical outcomes, functioning and HRQoL by BASDAI and ASDAS intervals, irrespective of the ASAS40 response

We were also interested in analysing other clinical outcomes in relation to BASDAI and ASDAS intervals. Decreasing disease activity as measured by the BASDAI and ASDAS intervals outlined above was associated with low mean scores for back pain, fatigue, BASFI and ASAS HI and high mean scores for SF-36 PCS. The improvements at both time points were comparable for patients who achieved a BASDAI <2 or an ASDAS <1.3 as well as for patients who achieved a BASDAI 2.0–2.99 or an ASDAS ≥1.3–<2.1 (Table 2A and 2B).

BASDAI scores through 52 weeks in COAST-V irrespective of the ASAS40 response

The investigation of patients ($N = 81$) who achieved specific BASDAI cut-offs (<4, <3 and <2) for each of the 52 weeks revealed an early response to IXE treatment within the first 4 weeks. This trend was characterized by 53.1% ($n = 43$) of participants achieving BASDAI <4, 38.3% ($n = 31$) attaining BASDAI <3 and 22.2% ($n = 18$) meeting the threshold of BASDAI <2 at week 16. After week 16 through week 52, >50% of participants had a BASDAI <4, >40% a BASDAI <3 and >20% a BASDAI <2, as illustrated in Supplementary Fig. S1, available at *Rheumatology Advances in Practice* online.

Discussion

The objective of this post hoc analysis was to explore the relationship between BASDAI and ASDAS and the ASAS40

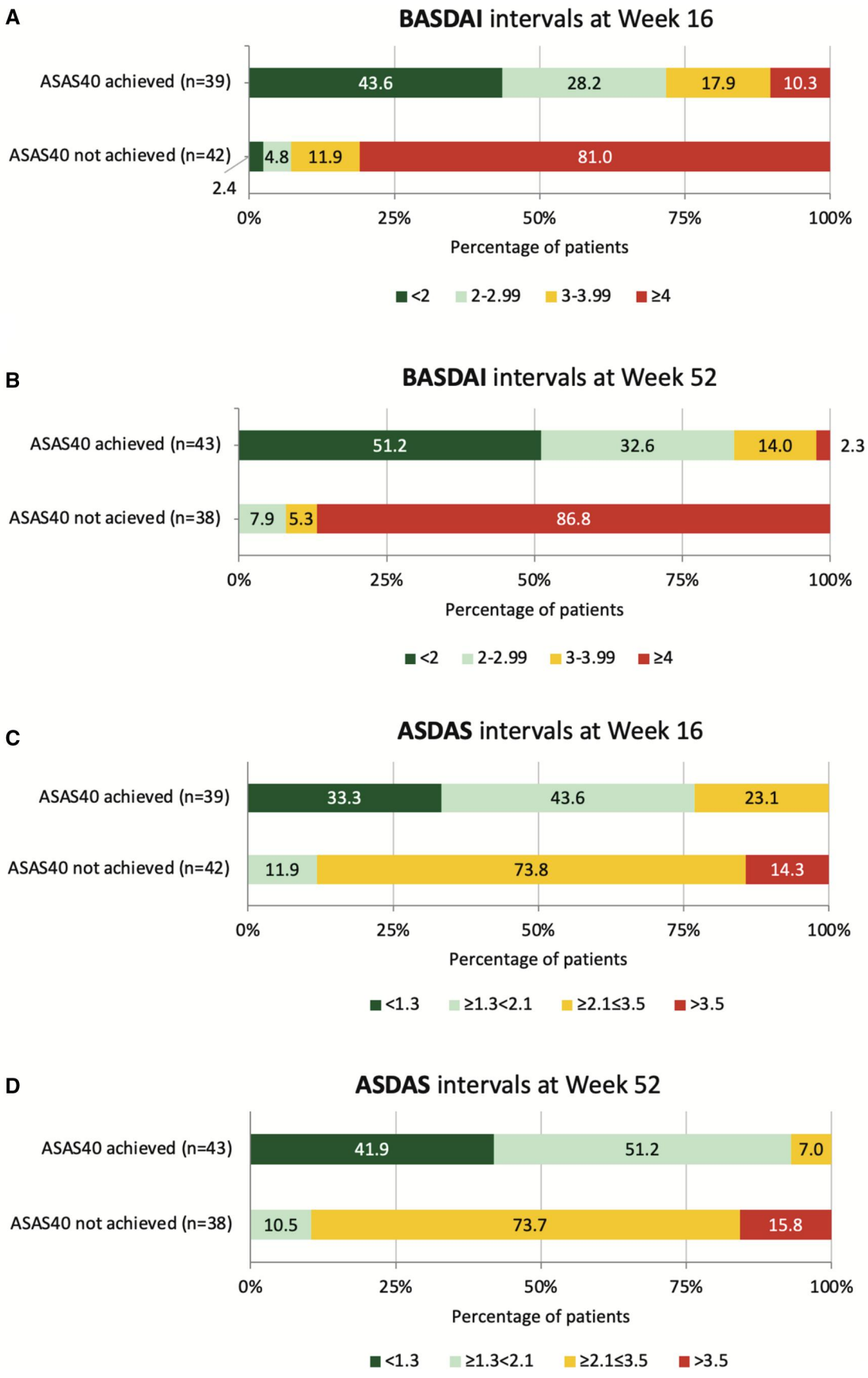


Figure 2. (**A** and **B**) BASDAI and **(C** and **D)** ASDAS intervals in relation to ASAS40 achievement. Stacked bar graphs show BASDAI and ASDAS intervals in ASAS40 responders/non-responders at week 16 (**A** and **C**) and week 52 (**B** and **D**) in the COAST-V trial. ASAS40: Assessment in SpondyloArthritis international Society 40% response; ASDAS: Axial Spondyloarthritis Disease Activity Score

Table 2. PROs, BASFI, ASAS HI and SF-36 PCS mean scores by BASDAI and ASDAS intervals.

BASDAI intervals ($N = 78$)				
Week 16				
	BASDAI <2 ($n = 18$)	BASDAI 2–2.99 ($n = 13$)	BASDAI 3–3.99 ($n = 12$)	BASDAI ≥4 ($n = 35$)
Back pain	1.2	2.6	4.2	5.7
Fatigue	1.8	3.1	4.4	6.1
BASFI	1.2	3.1	3.2	5.3
ASAS HI	2.1	4.4	5.3	7.0
SF-36 PCS	51.2	43.7	45.0	39.4
Week 52				
	BASDAI <2 ($n = 22$)	BASDAI 2–2.99 ($n = 17$)	BASDAI 3–3.99 ($n = 8$)	BASDAI ≥4 ($n = 31$)
Back pain	1.3	2.9	3.4	6.1
Fatigue	1.6	3.0	4.5	6.1
BASFI	1.0	2.4	3.3	5.0
ASAS HI	2.2	4.1	4.6	6.9
SF-36 PCS	51.7	46.7	47.3	39.6
ASDAS intervals ($N = 81$)				
Week 16				
	ASDAS <1.3 ($n = 13$)	ASDAS ≥1.3–<2.1 ($n = 22$)	ASDAS ≥2.1–≤3.5 ($n = 40$)	ASDAS >3.5 ($n = 6$)
Back pain	1.1	2.8	5.1	7.2
Fatigue	2.0	3.4	5.3	7.5
BASFI	1.2	2.4	4.7	7.1
ASAS HI	1.8	4.4	6.3	8.7
SF-36 PCS	51.7	46.6	40.3	36.1
Week 52				
	ASDAS <1.3 ($n = 18$)	ASDAS ≥1.3–<2.1 ($n = 26$)	ASDAS ≥2.1–≤3.5 ($n = 31$)	ASDAS >3.5 ($n = 6$)
Back pain	1.1	2.8	5.6	7.2
Fatigue	1.8	3.2	5.6	7.2
BASFI	0.8	2.4	4.7	5.6
ASAS HI	2.5	3.6	6.5	8.7
SF-36 PCS	52.4	47.6	39.7	34.9

ASAS HI: Assessment in SpondyloArthritis international Society Health Index; ASDAS: Axial Spondyloarthritis Disease Activity Score; Back pain: total back pain (BASDAI question 2); Fatigue: Fatigue Severity Numeric Rating Scale; PRO: patient reported outcomes; SF-36 PCS: 36-Item Short Form Health Survey Physical Component Score.

response. This is relevant for routine patient care, as the ASAS40, a measure of relative improvement, is currently the recommended primary endpoint in clinical trials in axSpA, while BASDAI and ASDAS, both of which reflect absolute disease activity levels, are the instruments to manage patients towards treatment targets in clinical practice.

Our findings demonstrated that >70% of biologic-naïve r-axSpA patients who attained an ASAS40 response at week 16 when treated with IXE 80 mg every 4 weeks achieved low disease activity or inactive disease as assessed by BASDAI <3 and ASDAS <2.1, respectively. This proportion increased to 84% of ASAS40 responders at week 52 who achieved BASDAI <3 and 93% who achieved ASDAS <2.1. At the group level, the mean BASDAI among ASAS40 responders was 2.3 and 2.2 in weeks 16 and 52, respectively, and the mean ASDAS was 1.7 and 1.6 at these two timepoints, suggesting overall low disease activity on average among ASAS40 responders.

Our analysis demonstrates the relationship of ASAS40, which serves as a clinical improvement response criterion, with BASDAI and ASDAS, which are used to measure current disease activity. We also showed improvements in patient outcomes by several BASDAI and ASDAS intervals.

Although there is no consensus on the ideal cut-off for BASDAI low disease activity and inactive disease/remission in axSpA, the cut-off of ≥4 has been widely recognized in the literature for the definition of active axSpA [5, 6]. A few studies have estimated BASDAI cut-off values that can discriminate the four disease activity states (inactive, low, high and very high), separated by the validated ASDAS cut-off values 1.3, 2.1 and 3.5. The results of three recent studies [18–20] were reported as BASDAI values 1.9, 2.1 and 1.6 corresponding to ASDAS 1.3; BASDAI values 3.5, 3.1 and 2.9 corresponding to ASDAS 2.1; and BASDAI values 4.9, 3.7 and 3.8 corresponding to ASDAS 3.5, which largely supports the BASDAI cut-off values we applied to match the corresponding ASDAS disease activity states.

Irrespective of the ASAS40 response, this study also showed that gradually lower disease activity levels as measured by BASDAI and ASDAS were associated with continuously greater improvements in back pain, fatigue, functioning and HRQoL. Interestingly, achieving BASDAI <3 or ASDAS <2.1 reflected almost similar improvements in these outcomes. Improvements achieved by week 16 were maintained through week 52 at all disease activity levels.

While this analysis focused on r-axSpA, similar considerations likely apply to non-radiographic axSpA. Also, in psoriatic arthritis, where ACR 20%, 50% and 70% responses as primary endpoints in RCTs present comparable challenges in translation to clinical practice, careful interpretation and alignment with clinically meaningful outcomes and treat-to-target measures like Clinical Disease Activity Index for Psoriatic Arthritis and minimal disease activity are required. This study did not identify baseline predictors of response to treatment; these factors have been previously published [21].

Conclusion

This post hoc analysis of data from biologic-naïve patients with r-axSpA treated with IXE 80 mg every 4 weeks (COAST-V trial) revealed a substantial relationship between an ASAS40 response and the achievement of low disease activity as indicated by BASDAI <3 and ASDAS <2.1 or inactive disease as indicated by BASDAI <2 and ASDAS <1.3. Therefore, these results may help rheumatologists translate an ASAS40 response reported in clinical trials into their disease assessment tools in daily practice.

Moreover, achieving low BASDAI or ASDAS disease activity levels upon treatment is associated with low scores for back pain and fatigue, better functioning and higher HRQoL, indicating BASDAI and ASDAS measurements broadly covering other clinical outcomes that are relevant in axSpA. This is of particular interest considering the recent treat-to-target recommendations for axSpA that define treatment targets as clinical remission/inactive disease or low disease activity to achieve better patient outcomes.

Supplementary material

Supplementary material is available at *Rheumatology Advances in Practice* online.

Data availability

The data underlying this article are available in the article and in its online supplementary material.

Funding

This work was supported by Eli Lilly and Company.

Disclosure statement: M.R. declares consultancy/speaking fees from AbbVie, Boehringer Ingelheim, Eli Lilly, Janssen, Novartis, Pfizer and UCB Pharma. V.N.-C. declares speakers' bureau fees from AbbVie, Eli Lilly, Fresenius Kabi, Janssen, MSD, Novartis, Pfizer and UCB Pharma; consultant fees from AbbVie, Eli Lilly, Galapagos, Moonlake, MSD, Novartis, Pfizer and UCB Pharma and grant/research support from AbbVie and Novartis. V.G. declares advisory board fees from AbbVie, MEDAC, MSD, Eli Lilly, GSK and Galapagos. F.C. has served as a consultant, speaker and/or has received research grants from AbbVie, AstraZeneca, BMS, Celgene, Eli Lilly, GSK, Janssen, Novartis, Pfizer, Sanofi-Aventis and UCB Pharma. J.D. declares consultancy fees and occasional interventions from AbbVie, GSK, Janssen, Novartis and Eli Lilly. H.R., S.L.L., M.H.N., T.P. and E.F. are employees of Eli Lilly.

Acknowledgements

The sponsor acknowledges the participation of all study participants and the study site personnel involved in the original COAST-V clinical trial. Medical writing support was provided by Clare Koning and Francisco López de Saro (Rx Communications, Mold, UK), funded by Eli Lilly.

References

1. Navarro-Compán V, Sepriano A, El-Zorkany B, van der Heijde D. Axial spondyloarthritis. Ann Rheum Dis 2021;80:1511–21.
2. Boonen A, van der Linden SM. The burden of ankylosing spondylitis. J Rheumatol Suppl 2006;78:4–11.
3. Smolen JS, Schöls M, Braun J *et al.* Treating axial spondyloarthritis and peripheral spondyloarthritis, especially psoriatic arthritis, to target: 2017 update of recommendations by an international task force. Ann Rheum Dis 2018;77:3–17.
4. Ramiro S, van der Heijde D, van Tubergen A *et al.* Higher disease activity leads to more structural damage in the spine in ankylosing spondylitis: 12-year longitudinal data from the OASIS cohort. Ann Rheum Dis 2014;73:1455–61.
5. Ramiro S, Nikiphorou E, Sepriano A *et al.* ASAS-EULAR recommendations for the management of axial spondyloarthritis: 2022 update. Ann Rheum Dis 2023;82:19–34.
6. Landewé R, van Tubergen A. Clinical tools to assess and monitor spondyloarthritis. Curr Rheumatol Rep 2015;17:47.
7. Garrett S, Jenkinson T, Kennedy LG *et al.* A new approach to defining disease status in ankylosing spondylitis: the Bath Ankylosing Spondylitis Disease Activity Index. J Rheumatol 1994;21:2286–91.
8. Lukas C, Landewé R, Sieper J *et al.* Development of an ASAS-endorsed disease activity score (ASDAS) in patients with ankylosing spondylitis. Ann Rheum Dis 2009;68:18–24.
9. Machado P, Landewé R, Lie E *et al.* Ankylosing Spondylitis Disease Activity Score (ASDAS): defining cut-off values for disease activity states and improvement scores. Ann Rheum Dis 2011;70:47–53.
10. Brandt J, Listing J, Sieper J *et al.* Development and preselection of criteria for short term improvement after anti-TNF alpha treatment in ankylosing spondylitis. Ann Rheum Dis 2004;63:1438–44.
11. van der Heijde D, Cheng-Chung Wei J, Dougados M *et al.* Ixekizumab, an interleukin-17A antagonist in the treatment of ankylosing spondylitis or radiographic axial spondyloarthritis in patients previously untreated with biological disease-modifying anti-rheumatic drugs (COAST-V): 16 week results of a phase 3 randomised, double-blind, active-controlled and placebo-controlled trial. Lancet 2018;392:2441–51.
12. Dougados M, Wei JC-C, Landewé R *et al.* Efficacy and safety of ixekizumab through 52 weeks in two phase 3, randomised, controlled clinical trials in patients with active radiographic axial spondyloarthritis (COAST-V and COAST-W). Ann Rheum Dis 2020;79:176–85.
13. US Food and Drug Administration. Ixekizumab prescribing information [updated July 2022]. https://www.accessdata.fda.gov/drugsatfda_docs/label/2022/125521s024lbl.pdf (9 October 2023, date last accessed).
14. European Medicines Agency. Ixekizumab summary of product characteristics [updated 17 December 2020]. https://www.ema.europa.eu/en/documents/product-information/taltz-epar-product-information_en.pdf (9 October 2023, date last accessed).
15. Baraliakos X, Listing J, Fritz C *et al.* Persistent clinical efficacy and safety of infliximab in ankylosing spondylitis after 8 years—early

clinical response predicts long-term outcome. Rheumatology (Oxford) 2011;50:1690–9.
16. Ramonda R, Lorenzin M, Sole Chimenti M *et al.* Effectiveness and safety of secukinumab in axial spondyloarthritis: a 24-month prospective, multicenter real-life study. Ther Adv Musculoskelet Dis 2022;14:1759720X221090310–8.
17. Machado PM, Landewé R, Heijde DV, Assessment of SpondyloArthritis International Society. Ankylosing Spondylitis Disease Activity Score (ASDAS): 2018 update of the nomenclature for disease activity states. Ann Rheum Dis 2018;77:1539–40.
18. Kwon OC, Park MC. BASDAI cut-off values corresponding to ASDAS cut-off values. Rheumatology (Oxford) 2022;61:2369–74.
19. Chen Y-H, Huang W-N, Chen Y-M *et al.* The BASDAI cut-off for disease activity corresponding to the ASDAS scores in a Taiwanese cohort of ankylosing spondylitis. Front Med (Lausanne) 2022;9:856654.
20. Cui R, Du Y, Tian N *et al.* Equivalent cut-off values of Bath Ankylosing Spondylitis Disease Activity Index corresponding to Ankylosing Spondylitis Disease Activity Score cut-off values. Clin Exp Rheumatol 2023;41:1163–9.
21. van der Heijde D, Østergaard M, Reveille JD *et al.* Spinal radiographic progression and predictors of progression in patients with radiographic axial spondyloarthritis receiving ixekizumab over 2 years. J Rheumatol 2022;49:265–73.

Rheumatology Advances in Practice, 2025, 9, 1–8
https://doi.org/10.1093/rap/rkaf012
Original Article