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POS0027

SECULAR TRENDS IN BASELINE CHARACTERISTICS, TREATMENT RETENTION AND RESPONSE RATES IN 27189 BIO-NAÏVE AXIAL SPONDYLOARTHRITIS PATIENTS INITIATING TNFI – RESULTS FROM THE EUROSPA COLLABORATION

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Background: Knowledge of changes over time in baseline characteristics and tumor necrosis factor inhibitor (TNFi) response in bio-naïve axial spondyloarthritis (axSpA) patients treated in routine care is limited.

Objectives: To investigate secular trends in baseline characteristics and retention, remission and response rates in axSpA patients initiating a first TNFi.

Methods: Prospectively collected data on bio-naïve axSpA patients starting TNFi in routine care from 15 European countries were pooled. According to year of TNFi initiation, three groups were defined a priori based on bDMARD availability: Group A (1999–2008), Group B (2009–2014) and Group C (2015–2018). Retention rates (Kaplan-Meier), crude and LUNDEX adjusted¹ remission (Ankylosing Spondylitis Disease Activity Score (ASDAS) <1.3, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI) <20) and response (ASDAS Major and Clinically Important Improvement (MI/CII), BASDAI 50) rates were assessed at 6, 12 and 24 months. No statistical comparisons were made.

Results: In total, 27189 axSpA patients were included (5945, 11255 and 9989 in groups A, B and C).

At baseline, patients in group A were older, had longer disease duration and a larger proportion of male and HLA-B27 positive patients compared to B and C, whereas disease activity was similar across groups.

Retention rates at 6, 12 and 24 months were highest in group A (88%/81%/71%) but differed little between B (84%/74%/64%) and C (85%/76%/67%).

In all groups, median ASDAS and BASDAI had decreased markedly at 6 months (Table 1). The ASDAS values at 12 and 24 months and BASDAI at 24 months were higher in group A compared with groups B and C. Similarly, crude remission and response rates were lowest in group A. After adjustments for drug retention (LUNDEX), remission and response rates showed less pronounced between-group differences regarding ASDAS measures and no relevant differences regarding BASDAI measures.

Conclusion: Nowadays, axSpA patients initiating TNFi are younger with shorter disease duration and more frequently female and HLA-B27 negative than previously, while baseline disease activity is unchanged. Drug retention rates have decreased, whereas crude remission and response rates have increased. This may indicate expanded indication but also a stable disease activity threshold for TNFi initiation over time, an increased focus on targeting disease remission and more available treatment options.

Table 1. Secular trends in baseline characteristics, treatment retention, remission and response rates in European axSpA patients initiating a 1st TNFi

Baseline characteristics	Group A (1999–2008)			Group B (2009–2014)			Group C (2015–2018)		
Age, years, median (IQR)	57 (49–66)			51 (42–60)			46 (37–56)		
Male, %	66			60			57		
HLA-B27, %	87			77			72		
Years since diagnosis, median (IQR)	5 (1–12)			2 (0–8)			2 (0–7)		
Smokers, %	23			24			25		
ASDAS, median (IQR)	3.5 (2.8–4.1)			3.4 (2.8–4.1)			3.5 (2.8–4.1)		
BASDAI, median, (IQR)	57 (42–71)			59 (43–72)			57 (41–71)		
TNFi drug, % (Adalimumab / Etanercept / Infliximab / Certolizumab / Golimumab)	22 / 35 / 43 / 0 / 0			37 / 21 / 20 / 4 / 18			27 / 28 / 24 / 8 / 13		
Follow up	6 months			12 months			24 months		
	Gr A	Gr B	Gr C	Gr A	Gr B	Gr C	Gr A	Gr B	Gr C
Retention rates, %, (95% CI)	88 (88–89)	84 (83–85)	85 (84–86)	81 (80–82)	74 (74–75)	76 (75–76)	71 (70–72)	64 (63–65)	67 (66–68)
ASDAS, median, (IQR)	1.8 (1.2–2.8)	1.9 (1.2–2.8)	1.8 (1.2–2.6)	1.9 (1.3–2.6)	1.7 (1.2–2.5)	1.6 (1.1–2.4)	1.9 (1.4–2.6)	1.7 (1.1–2.4)	1.5 (1.1–2.2)
ASDAS inactive disease, %, c/L	28 / 25	28 / 24	30 / 26	24 / 19	32 / 24	34 / 26	23 / 16	34 / 20	39 / 23
ASDAS CII, %, c/L	57 / 51	59 / 50	63 / 54	61 / 50	63 / 47	67 / 51	59 / 41	68 / 40	74 / 45
ASDAS MI, %, c/L	31 / 27	32 / 27	37 / 32	32 / 26	37 / 27	41 / 31	30 / 20	42 / 25	46 / 28
BASDAI, median, (IQR)	23 (10–40)	26 (11–48)	24 (10–44)	21 (10–38)	23 (10–42)	20 (8–39)	22 (9–40)	20 (8–39)	16 (6–35)
BASDAI remission, %, c/L	44 / 40	40 / 34	43 / 36	45 / 36	45 / 34	50 / 38	44 / 30	48 / 29	56 / 34
BASDAI 50 response, %, c/L	53 / 47	50 / 42	53 / 45	57 / 46	56 / 42	58 / 44	57 / 39	60 / 35	63 / 38

Gr, Group; c/L, crude/LUNDEX adjusted.

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POS0028

DEFINING THE PREVALENCE OF UNMET NEED IN SLE: DATA FROM A LARGE MULTINATIONAL LONGITUDINAL SLE COHORT

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Background: The recent prospectively validated definition of the lupus low disease activity state (LLDAS) allows characterisation of patients not achieving a treatment goal, providing impetus for an analysis of unmet needs in SLE using formal definitions. Other recently described definitions of high disease burden include disease activity over time, high disease activity status (HDAS) episodes, and the combination of high disease activity, serological activity and glucocorticoid (GC) use (HDAS+SA+GC).

Objectives: To determine the prevalence of formal categories of unmet need, and the association of these with adverse outcomes, in SLE.

Methods: Data from a 13-country longitudinal SLE cohort (ACR/SLICC criteria) were collected between 2013 and 19 using standard templates. Unmet need was defined as (i) patients never attaining LLDAS defined as in Golder *et al.*, 2019 [1], (ii) having persistently active disease (time adjusted mean SLEDAI-2K (AMS) > 4), (iii) ever exhibiting high disease activity status (HDAS; SLEDAI-2K ≥ 10[2]), or (iv) ever exhibiting all of SLEDAI ≥ 10, serological activity, and glucocorticoid use (HDAS+SA+GC)[3]. Health-related quality of life (HRQoL) was assessed using SF36 (v2) surveys and damage accrual using SLE Damage Index (SDI).

Results: 3,384 SLE patients were followed for 30,313 visits over median [IQR] 2.4 [0.4, 4.3] years. 53% of all visits were not in LLDAS; 813 patients (24%) never achieved LLDAS during observation. Median AMS was 3.0 [1.4, 4.9] and 34% of patients had AMS > 4 throughout the study. 25% of patients had at least one episode of HDAS, representing 8% of visits. 702 patients (21%) had at least one episode of HDAS+SA+GC, representing 8% of visits. Each of never-LLDAS, AMS>4, ever-HDAS, and ever-HDAS+SA+GC were associated with significantly greater number of physician visits, higher mean glucocorticoid dose, lower HRQoL and higher mortality. 31%, 58% and 83% of never-LLDAS, AMS>4, and ever-HDAS patients respectively were also HDAS+SA+GC on at least one occasion.

Conclusion: Data from a multinational longitudinal SLE cohort indicate that unmet need, defined by LLDAS-never, AMS>4, HDAS, or HDAS+SA+GC, is prevalent in SLE, and that these definitions are associated with poor outcomes.

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