O21 IS SLE-DAS BETTER THAN BILAG-2004 TO IDENTIFY SEVERE SLE DISEASE ACTIVITY? POST-HOC ANALYSIS OF 438 SLE PATIENTS FROM THE ANIFROLUMAB CLINICAL TRIALS

[1,2]Diogo Jesus, [3,4]Carla Henriques, [3,5]Ana Matos, [6]Andrea Doria, [2,7]Luís Sousa Inês. *[1]Rheumatology Dept., Centro Hospitalar de Leiria, Leiria, Portugal; [2]Faculty of Health Sciences, University of Beira Interior, Covilhã, Portugal; [3]School of Technology and Management, Polytechnic Institute of Viseu, Viseu, Portugal; [4]Centre for Mathematics, University of Coimbra, Coimbra, Portugal; [5]Research Centre in Digital Services (CISeD), Viseu, Portugal; [6]Reumatology Unit, Dept. of Medicine, University of Padova, Padova, Italy; [7]CHUC Lupus Clinic, Rheumatology Dept., Centro Hospitalar e Universitário de Coimbra, Coimbra, Portugal*

10.1136/lupus-2024-el.31

Background A gold-standard definition of severe SLE disease activity is lacking for use both in clinical trials and daily clinical setting. The SLE-DAS is an easy to use, validated instrument, with high accuracy and sensitivity to change in SLE disease activity. The SLE-DAS definition for severe disease activity (SDA) was recently derived and validated.

Objectives To compare the disease features and health-related quality of life (HR-QoL) of patients fulfilling the SDA definition both by SLE-DAS and BILAG-2004 with those in SDA: (a) only by SLE-DAS (but not BILAG-2004); (b) only by BILAG-2004 (but not SLE-DAS).

Methods Post-hoc analysis of the aggregated intention-to-treat, placebo arm participants, in the anifrolumab versus placebo for moderate-to-severe SLE phase 2 and 3 RCTs [MUSE (NCT01438489), TULIP-1 (NCT02446912), TULIP-2 (NCT02446899)]. At the RCTs week 12, we analyzed the physicians' assessments (including clinical and analytical data, BILAG-2004, CLASI-A, SLEDAI-2K), and patient reported

Abstract O21 Table 1 Comparison of lupus features and health-related quality of life between patients classified in severe disease activity (SDA) by both SLE-DAS (>9.90) and BILAG-2004 (>11) versus patients classified in SDA only by SLE-DAS or BILAG-2004

	SDA by SLE-DAS and BILAG-2004	SDA only by SLE-DAS		SDA only by BILAG-2004	
	n=149 (34%)	n=55 (12.6%)	*p**	n=44 (10%)	*p**
SLE manifestations, n (%)					
- Neuropsychiatric	4 (2.68)	1 (1.82)	1.000	0 (0.00)	0.576
- Systemic vasculitis	1 (0.67)	0 (0.00)	1.000	0 (0.00)	1.000
- Mucocutaneous vasculitis	30 (20.13)	8 (14.55)	0.363	5 (11.36)	0.185
- Cardiopulmonary	1 (0.67)	0 (0)	1.000	0 (0.00)	1.000
- Serositis	19 (12.75)	5 (9.09)	0.471	1 (2.27)	**0.049**
- Lupus nephritis	24 (16.11)	7 (12.73)	0.551	0 (0.00)	**0.002**
- Arthritis	129 (86.58)	45 (81.82)	0.394	25 (56.82)	**<0.0001**
- 28-SJC	4 (2;8)	3 (1;7)	0.2668	1 (0;2)	**<0.0001**
- Myositis	6 (4.03)	2 (3.64)	1.000	0 (0.00)	0.340
- Mucocutaneous	142 (95.30)	51 (89.09)	0.117	41 (93.18)	0.698
- Thrombocytopenia	3 (2.01)	1 (1.82)	1.000	1 (2.27)	1.000
- Leukopenia	13 (8.72)	5 (9.09)	1.000	4 (9.09)	1.000
- Hypocomplementemia	72 (48.32)	28 (50.91)	0.743	19 (43.18)	0.548
- Increased anti-dsDNA	77 (51.68)	31 (56.36)	0.552	13 (29.55)	**0.01**
Severe CLASI-A, n (%)	9 (6.04)	0 (0.00)	0.117	2 (4.55)	1.000
SLEDAI-2K, Median (IQR)	12 (8;14)	10 (8;12)	0.0996	8 (6;9)	**<0.0001**
PtGA, Median (IQR)	53 (41.5;67)	50 (26;67)	**0.0388**	41 (21;59)	**0.0044**
FACIT-F, Median (IQR)	24 (14;32)	23 (16;35)	0.5031	33 (21;40)	**0.0015**
LupusQoL, Median (IQR)					
- Physical Health	56.3 (31.3;75)	50 (31.3;75)	0.8244	68.8 (46.9;81.2)	**0.0210**
- Pain	54.2 (25;75)	50 (25;75)	0.7944	66.7 (50;75)	**0.0153**
- Planning	58.33 (25;75)	50 (33.3;75)	0.7357	75 (50;83.3)	**0.0406**
- Intimate relationships	62.5 (25;75)	50 (25;75)	0.9453	75 (37.5;87.5)	0.2609
- Burden to others	50 (16.7;75)	58.33 (25;75)	0.1035	66.7 (25;83.3)	0.0792
- Emotional Health	62.5 (41.7;83.3)	70.8 (45.8;83.3)	0.4374	75 (62.5;83.3)	**0.0133**
- Body image	62.5 (35;80)	70 (55;80)	0.0737	70 (45;81.3)	0.3042
- Fatigue	43.8 (25;68.8)	50 (25;68.8)	0.3019	56.3 (37.5;81.3)	**0.0127**
EQ-5D Index, Median (IQR)	0.64 (0.48;0.74)	0.64 (0.54;0.78)	0.3985	0.71 (0.59;0.83)	**0.0087**
EQ-5D VAS, Median (IQR)	51 (38;70)	51 (40;73)	0.2579	68 (51;71)	**0.0132**

Severe CLASI-A: CLASI activity score $\geq$ 21; 28-SJC: Number of swollen joints in 28-joint count.
* Comparison between patients in severe disease activity (SDA) by SLE-DAS+BILAG-2004 versus patients classified in SDA only by SLE-DAS or BILAG-2004, using Chi-squared, Fishers' or Mann-Whitney tests as appropriate.

outcomes (PROs) [LupusQoL, EQ-5D, FACIT-F, Patient Global Assessment (PtGA) scores]. The SLE-DAS was retrospectively scored. Active lupus features and PROs at week 12 were compared between the group of patients classified in SDA by both the SLE-DAS (>9.90) and BILAG-2004 (>11) *vs* patients classified in SDA only according to SLE-DAS or BILAG-2004. Chi-squared, Fishers' or Mann-Whitney tests were applied.

Results From 438 SLE patients, at week 12 were classified in SDA: 34% by both instruments (SLE-DAS+BILAG-2004), 12.6% by SLE-DAS only, and 10.05% by BILAG-2004 only. The groups in SDA according to SLE-DAS+BILAG-2004 and to SLE-DAS-only did not present any significant differences in active disease features and the HR-QoL PROs (table 1). In contrast, patients classified in SDA only by BILAG-2004 presented significantly lower SLEDAI-2K, less serositis, nephritis and arthritis. Notably, patients in SDA by BILAG-2004 alone presented significantly less severe impact in the HR-QoL PROs (table 1).

Conclusion Patients in SDA defined either by SLE-DAS +BILAG-2004 or by SLE-DAS only present similarly severe disease, both according to active lupus features and the HR-QoL PROs. Contrarily, those classified in SDA only by BILAG-2004 may present less severe disease, according both to the physician and patient assessments.

Acknowledgement This publication is based on research using data from data contributors AstraZeneca that has been made available through Vivli, Inc. Vivli has not contributed to or approved, and is not in any way responsible for, the contents of this publication.

O22 FACTORS ASSOCIATED WITH SLE PATIENT CONCORDANCE TO MEDICATION – DOES NURSE INITIATED THERAPY MAKE A DIFFERENCE?

[1]Rosaria Salerno, [1]Sasha Saadia Ali, [2]Flora Dell'Accio, [1]Heather Lapham, [3]Jo Dobson, [1]Patrick Gordon, [1]Chris Wincup. *[1]Kings College Hospital, London, UK; [2]University of Liverpool, UK; [3]University of Edinburgh, UK*

10.1136/lupus-2024-el.32

Objective Medication non-concordance in systemic lupus erythematosus (SLE) is associated with a higher risk of flares, hospitalisations and mortality. Patient non-concordance involves a complex interplay of both patient and physician factors including communication, nature and severity of disease, treatment and the clinician-patient relationship. We hypothesise that patients starting medication initiated by a specialist nurse would have higher medication concordance.

Methods A retrospective analysis of patients attending the tertiary lupus clinic at King's College Hospital was undertaken. Inclusion criteria included patients with a diagnosis of lupus being initiated on DMARD therapy (Mycophenolate, Methotrexate or Azathioprine) who had their medication prescribed and dispensed by the hospital pharmacy. Those starting biologics or receiving medication via Shared Care agreements were excluded. Patients were defined as concordant if they renewed all 3-monthly prescriptions over a 12 month period. Demographics, disease activity, employment status and ethnicity were recorded. We sought to assess differences in concordance between those initiated by Nurse Specialists versus doctors, and between those

Abstract O22 Table 1 Comparison of concordance between patients initiated of DMARDs by clinician

	Concordant (n=29)	Non-Concordant (n=16)	p-value
Age (mean ± SD years)	43.88 ± 11.32	36.95 ± 12.43	ns
Female, n (%)	26 (90%)	14 (88%)	ns
Ethnicity, n (%)			
Caucasian	1 (3%)	1 (6%)	ns
Black	19 (66%)	14 (88%)	ns
Asian	5 (17%)	0 (0%)	ns
Other	4 (14%)	1 (6%)	ns
Starting Mycophenolate, n (%)	**23 (79%)**	**7 (44%)**	**0.015**
Starting Azathioprine, n (%)	5 (17%)	7 (44%)	ns
Starting Methotrexate, n (%)	1 (3%)	2 (13%)	ns
Employed, n (%)	**23 (80%)**	**3 (20%)**	**<0.001**
SLEDAI-2K mean ± SD	**7.31 ± 1.99**	**6.25 ± 2.18**	**0.032**
Nurse : Doctor Initiated, n (%)	**28:1 (97:3)**	**0:16 (0:100)**	**<0.001**
Online : Paper Information, n (%)	**22:7 (76:24)**	**1:15 (6:94)**	**<0.001**