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CLUSTER PROFILING OF PATIENTS IN A REAL-WORLD DATA SET WITH SYSTEMIC LUPUS ERYTHEMATOSUS AND THEIR ASSOCIATED TREATMENTS

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Background: Previous systemic lupus erythematosus (SLE) studies have identified potential clusters of SLE clinical manifestations.

Objectives: To describe the presentation of SLE across different cohorts of patients and describe standard of care within clusters.

Methods: Cross-sectional study of 263 rheumatologists in the US and EU5. Data were collected from the Adelphi Real World 2015 Lupus Disease Specific Programme. Physicians completed patient record forms (PRFs) for the next 5 patients consulting with SLE; these patients completed patient self-completion (PSC) forms describing how SLE affected them. PRFs data include patient's characteristics and management history. PSCs focused on similar data collection, including patient reported outcome measures on the humanistic burden. Principal-component factor analysis reduced 39 unique SLE symptoms to 8 factors. These factors were used as covariates in latent class cluster analysis to provide discrete cohorts of patients. Chi-squared and Kruskal-Wallis tests compared patient outcomes across clusters.

Results: Data were extracted from 1376 PRFs. Factor analysis resulted in 8 clusters of concurrent symptoms; joint, haematological, constitutional/mental health, skin, circulatory, cardiovascular, renal, and muscular symptoms respectively. The four-cluster solution was selected.

Cluster 1 displayed the lowest symptom burden, characterised by low skin involvement. Cluster 2 is characterised by joint and skin involvement. Cluster 3 & 4 had a high frequency of all factors, with cardiovascular involvement high in cluster 3 and renal/constitutional involvement high in cluster 4 (table 1).

Significant between-cluster differences were observed when comparing clinical and humanistic outcomes; physician/patient satisfaction were greatest in cluster 1 (physician satisfied 94.2% vs. 2: 90.8%, 3: 85.2%, 4: 74.4%, p<0.0001; patient 94.7% vs. 2: 93.9%, 3: 91.5%, 4: 79.2%, p<0.0001), whilst disease progression (deteriorating slowly 2.5% vs. 2: 12.9%, 3: 9.8%, 4: 25.5%, p<0.0001) and flaring in the last 12 months (flared 30.0% vs. 2: 54.8%, 3: 62.2%, 4: 70.8%, p<0.0001) differed significantly with worst outcomes seen in cluster 4.

Significant differences were also observed between clusters in relation to treatment proportions; anti-malarials (highest cluster 1: 70.5%), biologic DMARD (highest cluster 3: 17.5%), glucocorticoid and immunosuppressants (highest cluster 4: 85.5%, 74.5%).

Conclusion: This study adds to the evidence demonstrating the heterogeneous nature of SLE experienced within distinct patient clusters. Significant proportions of SLE patients experience high symptom burden and low levels of satisfaction. Additional analysis to understand limited biologic use in more severe patients is needed.

Table 2 Cluster analysis

Factors, n (%)	Overall (n=276)	1 (n=123)	2 (n=92)	3 (n=43)	4 (n=118)	p-value
Joint	595 (91.5)	0	729 (98.1)	62 (95.4)	345 (100.0)	<0.0001
Haematological	289 (22.0)	17 (5.2)	112 (15.1)	48 (10.8)	112 (87.9)	<0.0001
Constitutional/mental	423 (50.0)	11 (1.6)	252 (55.8)	14 (3.8)	237 (98.6)	<0.0001
Skin	688 (50.0)	89 (21.2)	389 (52.4)	81 (56.4)	349 (98.3)	<0.0001
Circulatory	71 (5.2)	0	0	39 (9.1)	32 (10.4)	<0.0001
Cardiovascular	130 (8.4)	0	0	48 (57.6)	82 (57.6)	<0.0001
Renal	207 (22.4)	18 (5.1)	144 (10.7)	48 (10.8)	89 (51.1)	<0.0001
Muscular	268 (29.1)	6 (1.8)	109 (14.7)	38 (10.8)	115 (98.7)	<0.0001

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PREDICTION OF RESPONSE TO RITUXIMAB IN SLE USING A VALIDATED TWO-SCORE SYSTEM FOR INTERFERON

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Background: Rituximab (RTX) is used for resistant SLE but clinical response varies. We previously validated two interferon-stimulated gene expression scores (IFN-Score-A and IFN-Score-B) that improved prediction of clinical outcomes in SLE. IFN-Score-A included most commonly reported ISGs and predicted flares and glucocorticoid requirements. IFN-Score-B included ISGs that respond to multiple IFN subtypes and predicted development of SLE in At-Risk individuals. Diagnosis of SLE was associated with both scores, while only IFN-Score-B was elevated in RA. The British Society for Rheumatology Biologics Registry (BILAG-BR) collects samples for RTX-treated patients in the UK. MASTERPLANS is a consortium to identify predictors of drug response.

Objectives: To investigate whether IFN-Score-A and IFN-Score-B predict BILAG response to RTX at 6 months.

Methods: This is a preliminary analysis of the first RTX-treated patients in the BILAG-BR with complete data. Patients were recruited if they were starting a first cycle of RTX for active SLE (BILAG A or 2xBILAG B) despite previous cyclophosphamide or mycophenolate mofetil. Disease activity was measured using BILAG-2004. Clinical response was defined as improvement by ≥1 grade in active BILAG-2004 systems with no worsening in other systems. Whole blood was collected into TEMPUS tubes and RNA extracted. IFN-Scores were measured using a custom Taqman array as previously described [El Sherbiny et al., 2018]. Multivariate logistic regression was used to test IFN-Scores and baseline clinical covariates as predictors of BILAG response at 6 months.

Results: Samples were available from 147 patients, of whom 84 had complete baseline and 6 month clinical data available and were included in this analysis. 40/84 (47.6%) patients had BILAG response at 6 months. In univariate and multivariate analysis, high IFN-Score-B expression was significantly associated with clinical response (see table 1).

Predictor	Non-responders	Responders	Univariable OR (95% CI)	P	Multivariable OR (95% CI)	P
Age (mean, 95% CI)	40.5 (36.2,44.8)	40.9 (36.2,45.6)	1.015 (0.993,1.037)	0.188	0.994 (0.959,1.032)	0.765
Baseline organs affected	22/44	23/40	0.866 (0.468,1.601)	0.645	1.024 (0.381,2.750)	0.962
Mucocutaneous						
Musculoskeletal	21/44	18/40	0.728 (0.392,1.354)	0.728	0.424 (0.145,1.244)	0.118
Renal	21/44	16/40	0.869 (0.470,1.607)	0.654	0.290 (0.087,0.969)	0.044
Cardiovascular	9/44	5/40	1.250 (0.553,2.824)	0.591	0.627 (0.164,2.391)	0.494
Neurological	7/44	6/40	0.859 (0.358,2.065)	0.735	0.768 (0.170,3.473)	0.731
Antimalarial=Yes	41/44	39/40	1.458 (0.410,5.186)	0.560	0.073 (0.005,1.005)	0.050
IFN-Score-A (per unit)	2.49 (1.77,3.19)	1.74 (1.10,2.39)	0.845 (0.682,1.048)	0.126	1.601 (0.935,2.743)	0.086
IFN-Score-B (per unit)	2.36 (1.98,2.73)	1.76 (1.43,2.09)	0.606 (0.394,0.933)	0.023	0.267 (0.093,0.762)	0.014