Table . Comparison of patients undergoing 2nd RB according to development of renal failure

	Renal failure (n=26)	No renal failure (n=69)*	p
Total FU (years), mean (SD)	21 (10.4)	16.5 (9.39)	0.002
SCr (mg/dl) at 2° RB, mean (SD)	1.7 (1)	0.98 (0.35)	0.001
Proteinuria (g/24h) at 2° RB, mean (SD)	4.7 (3.9)	2.99 (2.63)	0.022
Class IV and IV+V at 2° RB, %	76.9	54.5	0.07
Hypertension at onset, %	84.6	32.4	<0.001
HCO intake at 2° RB, %	9.5	52	<0.001
Glucocorticoids at 2° RB %	84	87	ns
Immunosuppressants at 2° RB %	40	58	ns
AI at onset, mean (SD)	7.14 (3.95)	7.02 (3.86)	ns
AI at 2° RB, mean (SD)	5.37 (4.12)	4.02 (3.71)	ns
CI at onset, mean (SD)	2.05 (1.88)	1.56 (1.64)	ns
CI at 2° RB, mean (SD)	3.87 (3.08)	3.52 (2.16)	ns
Years between 2° RB and end of FU, mean (SD)	14.1 (10.5)	9.3 (8.84)	ns

*Group 1 excluded

RB, renal biopsy; AI, activity index; CI, chronicity index; SCr serum creatinine; FU, follow-up; SD, standard deviation.

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THU0250 URINE AND SERUM S100 PROTEINS ASSOCIATE WITH LUPUS NEPHRITIS AND RESPONSE TO TREATMENT

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Background: Systemic lupus erythematosus (SLE) is a systemic autoimmune/inflammatory disease. Approximately 30% of SLE patients develop lupus nephritis (LN) that affects treatment and prognosis. Easily accessible biomarkers do not exist to reliably predict renal disease¹. Recently, calcium-binding S100 proteins have been suggested as biomarkers in systemic inflammatory conditions, including SLE^{2,3}.

Objectives: The MASTERPLANS Consortium aims to identify indicators of treatment responses in SLE. This study tested the applicability of S100 proteins in serum and urine as biomarkers for disease activity and response to treatment with rituximab in LN.

Methods: S100A8/A9 and S100A12 proteins were quantified in the serum and urine of 243 SLE patients from the BILAG-BR study and 48 matched controls using MSD technology to determine whether they perform as biomarkers for active LN (n=85 SLE patients) and/or may be used to predict response to treatment with rituximab. Renal disease activity and response to treatment was based on BILAG-BR scores and changes in response to treatment^{4,5}.

Results: Serum S100A12 (p<0.001), and serum and urine S100A8/A9 (p<0.001) are elevated in SLE patients. While serum and urine S100 levels do not correlate with global SLE disease activity (SLEDAI), levels in urine and urine/serum ratios are elevated in SLE patients with active LN (S100A8/A9: urine p>0.005, urine/serum p<0.05; S100A12: urine p<0.05, serum/urine p<0.005). S100 proteins perform better as biomarkers for active LN involvement in SLE patients positive for anti-dsDNA antibodies. Lastly, binary logistic regression and AUC analysis suggests the combination of serum S100A8/A9 and S100A12 to predict response to RTX treatment in LN after 6 months.

Conclusion: Findings from this study show promise for clinical application of S100 proteins to predict active renal disease in SLE and response to treatment with rituximab. Significantly overlapping values between groups currently prohibit the definition of cut-off values and prospective studies are required to validate findings.

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THU0251 IMMUNOPHENOTYPIC CLUSTERS OF SLE PATIENTS REVEAL SUBGROUPS WITH SEVERE DISEASE RESISTANT TO CONVENTIONAL THERAPY

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Background: Biomarkers to predict response to rituximab include plasmablasts and, in the current MASTERPLANS consortium, Sm/U1RNP antibodies and high expression of IFN Score B (a subset of interferon-stimulated genes that predict more clinical outcomes than a classic interferon signature). The relationships amongst these biomarkers and their association with response to conventional therapies are less well described.

Objectives: To analyse the inter-relationships amongst immune biomarkers in two independent SLE cohorts in association with disease activity and stage of therapeutic pathway.

Methods: CONVAS is a cohort of unselected SLE patients; data available include current and historic disease activity, use of biologic therapy, flow cytometry, gene expression (IFN Score A and IFN Score B), and immunoprecipitation for autoantibodies (n=91). BILAG-BR is a British registry study for SLE patients commencing biologics; data available include current and historic disease activity, gene expression (IFN Score A and IFN Score B) and immunoprecipitation for autoantibodies (n=112). In both cohorts, biologics were only prescribed to patients with active disease (BILAG 1 x A or 2 x B) and failure of either cyclophosphamide or mycophenolate. Given the mixture of continuous and categorical variables, data were clustered using Gower distance and Partitioning Around Medoids. K was chosen using silhouette coefficient and clusters visualised with t-Distributed Stochastic Neighbor Embedding (t-SNE).

Results: There were 6 clusters. In rituximab-naïve patients:

1. Sm/U1RNP+, Ro60-, highest IFN Score A, low CD4⁺ T cells, low NK cells, high plasmablasts
2. Sm/U1RNP-, Ro60+, medium IFN Score A, low CD4⁺ T cells, high NK cells, high plasmablasts
3. Sm/U1RNP-, Ro60-, lowest IFN Score A, high CD4⁺ T cells, low NK cells, low plasmablasts

Other antibody subtypes and flow cytometric markers did not improve the accuracy of clustering. In rituximab-treated patients, 3 equivalent clusters for antibody subtypes and IFN Score A were observed but differentiated due to flow cytometry findings, as expected after rituximab treatment. Overall, the patients in the cluster defined by Sm/U1RNP antibodies and high IFN Score A were notable for a higher rate of prior disease activity in the renal, neurological and general BILAG domains (Table 1).

Table 1 : Clinical features in unselected SLE patients (CONVAS)

System affected (ever)	Sm/U1RNP & high IFN Score A (n=27)	Other (n=92)	p value
General	14/27 (52%)	24/92 (26%)	0.02
Mucocutaneous	23/27 (85%)	73/92 (79%)	0.50
Neuro	10/27 (37%)	17/92 (19%)	0.04
MSK	25/27 (93%)	83/92 (90%)	0.71
Cardiorespiratory	9/27 (33%)	20/92 (22%)	0.22
Renal	12/27 (44%)	15/92 (16%)	0.005
Haematology	25/27 (93%)	67/92 (73%)	0.03

Analysis of autoantibody status and interferon scores only in BILAG-BR confirmed similar clustering. Across both cohorts, the prevalence of the Sm/U1RNP and high IFN Score A cluster was associated with inadequate response to conventional immunosuppressive treatment (Table 2).

Table 2 : Prevalence according to stage of therapy

Treatment group	Sm/U1RNP & high IFN Score A	Other	p value
Antimalarial or conventional IS-treated (CONVAS) (n=90)	16/90 (17.8%)	74/90 (82%)	0.02
Conventional IS inadequate response, Previous rituximab (CONVAS) (n=38)	14/38 (36.8%)	24/38 (63.2%)	
Conventional IS inadequate response, starting rituximab (BILAG-BR) (n=163)	51/163 (31.2%)	112/163 (68.7%)	N/A

Conclusion: A cluster of 23% of unselected SLE patients had more severe immune abnormalities, more severe clinical disease activity and were less likely to be maintained on conventional therapies, with twice as many requiring biologic therapy. Other data in MASTERPLANS have demonstrated that Sm/U1RNP antibodies and IFN Scores predict better response to rituximab. This subgroup of patients may therefore be more appropriate for first-line biologic therapy.

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THU0252

CORRELATION BETWEEN DISEASE ACTIVITY AND MENTAL HEALTH IN SLE PATIENTS: A CROSS-SECTION STUDY WITH SELF-ASSESSMENTS BASED ON SMART SYSTEM OF DISEASE MANAGEMENT (SSDM) MOBILE TOOLS

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Background: WHO survey showed that the prevalence of anxiety and depression in Chinese population and Chinese patients with chronic diseases were between 3.1% - 4.2% and 3.1% - 7.3%, respectively. SLEDAI-2K and Hospital Anxiety and Depression Scale (HADS) are commonly used to evaluate SLE patients' disease activity and mental health. All the Assessments were mainly performed by health professionals (HCPs) with paper questionnaire previously. SSDM is a novel smart disease management tool that allows patients to do self-assessments on SLEDAI-2K and HADS by mobile App.

Objectives: To investigate the prevalence of anxiety and depression in Chinese patients with SLE and to analyze the potential association between disease activity of SLE and mental health.

Methods: Under the guidance and training by HCPs, SLE patients downloaded SSDM and performed self-assessments bundle of SLEDAI-2K and HADS with SSDM. SLEDAI-2K <=4, 5-9, 10-14 and >=15 are defined SLE inactive, low (LDA), moderate (MDA) and high (HDA) disease activity, respectively. SLEDAI-2K score <= 4 is set as the main criteria for Lupus Low Disease Activity State (LLDAS) and achievement of T2T. HADS score >=8 can be diagnosed with anxiety or depression.

Results: From June 2016 to Jan 2020, 3,332 SLE patients (199 male, 3,133 female) with a mean age of 36.34 ± 12.80 (10-91) years and the median disease duration of 3.43 years from 216 hospitals performed bundle

self-assessments for 4,967 times in total. According to the HADS and SLEDAI-2K Assessment results, the prevalence of anxiety and depression in all patients was 36.7% and 39.3% respectively, which was significantly higher than that in the WHO survey in Chinese population and chronic disease patients. The proportion of patients achieved and failed on LLDAS was 53% and 47%, respectively. The prevalence of anxiety (A) and depression (D) was 19% and 27% among LLDAS achievers; 41% and 47% among LLDAS failures, respectively (pA<0.01, pD<0.01).

According to SLEDAI-2K, in LLDAS, LDA, MDA and HDA subgroups, the prevalence of anxiety and depression was 19%, 30%, 37%, 54% and 27%, 36%, 44%, 61%, respectively. The correlation coefficients of anxiety (A) and depression (D) with SLEDAI-2K were rA=0.9957 and rD=0.9819. It suggested that with the increase of disease activity, the proportion of SLE patients with anxiety and depression increased significantly. (Figure 1)

Conclusion: Conclusion: Higher prevalence of anxiety and depression were Associated with higher levels of disease activity in SLE patients. SSDM is an effective mobile interface to monitor and study entanglement of disease activity and mental health in SLE patients, which build a foundation for proactive interventions physically and mentally in future.

References:

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THU0253

FATIGUE AND PAIN REMAIN PROMINENT AND IMPACTFUL IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): A CROSS-SECTIONAL SURVEY OF SLE PATIENTS IN THE UNITED STATES

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Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune inflammatory condition impacting multiple organ systems.^{1,2} SLE affects approximately 1.5 million Americans, disproportionately females of reproductive age, and is more prevalent in non-Caucasian populations.³ Fatigue and pain are some of the most prominent symptoms of SLE, contributing to the heavy disease burden and disruption to daily life.⁴ This study aimed to further understand the burden of SLE. Lilly worked with the Lupus Foundation of America (LFA) and Evidera to develop the SLE-UPDATE (Understanding Preferences, Disease Activity and Treatment Expectations) survey.

Objectives: To understand the patient-perceived symptom burden of SLE, in particular pain and fatigue, within the current landscape of therapeutic options. This study also focused on current treatment patterns in SLE patients.

Methods: This was a cross-sectional, non-interventional, online survey study conducted in partnership with the LFA. English-speaking United States patients aged ≥18 years with a self-reported diagnosis of SLE completed the survey following online screening and informed consent. Descriptive data are presented by means (standard deviation [SD]) for continuous measures, and frequency (n, %) for dichotomous measures. Demographic, clinical, and patient-reported outcomes were collected including the FACIT-Fatigue (range 0-52, higher scores