Belimumab from September 2017 to January 2023. Demographic, clinical, laboratory, effectiveness and safety variables were collected. Effectiveness was evaluated according to changes from the baseline in SLEDAI-2K and disease activity markers (proteinuria, complement consumption and/or Anti DNAds). Safety data was collected including any adverse event (AE) due to any cause. AE was considered serious (SAE) if it was life-threatening or result in hospitalization, disability or in death.

Results Overall, 15 patients were included in the study, whose baseline characteristics are exposed in the table 1. Nine patients were still receiving the drug with a mean drug survival of 15.6 months. Belimumab allowed steroid tapering in all cases, but treatment was discontinued just in 1 patient (7%). Treatment also improved disease activity markers in all (100%) patients. Belimumab was well tolerated, and the AE reported were infection (14 events) and malaise in 1 patient. In 11 cases, infection was mild (9 upper respiratory tract infection, 1 urinary tract infection and 1 gastroenteritis). 3 severe infections were registered (1 pneumonia, 1 pyelonephritis and 1 meningitis).

Regarding LN patients, treatment exposure achieved was 10.85 patients/year. Renal Biopsy demonstrated class III in a patient (20%) and class IV in 4 patients (80%). Mean proteinuria at baseline was 6.66g/24h. In 3 cases, Belimumab was started in the first 6 months after LN diagnosis was established. In 4 cases (80%), Belimumab addition allowed significant reduction of proteinuria and corticosteroids. In 2 out 5 (40%) treatment was discontinued, one case due to an insufficient response and in the other, to a SAE (*Cryptococcus neoformans* meningitis).

Conclusion Belimumab maintained an acceptable safety profile and an adequate effectiveness. Intravenous and subcutaneous formulations showed similar performance. Belimumab addition resulted in reduction in proteinuria and corticosteroid use.

P159 SEVERE INFECTIONS IN SLE PATIENTS: A DESCRIPTIVE ANALYSIS FROM A SINGLE CENTRE

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Objective Infectious risk in immunocompromised patients, particularly if affected by Systemic Lupus Erythematosus (SLE), is associated with disease-related and treatment-related factors. We analyze the rate of severe infections (defined as severe if immunosuppressive therapy has to be interrupted and/or patient has to be hospitalized for intravenous/oral therapy) in our cohort of SLE patients to identify risk factors for the development of infections.

Methods In our cohort we have enrolled 74 SLE patients (8 M, 66 F), of which 54 (72.97%; 5 M, 49 F) in actual or previous immunosuppressive therapy, with a median age of 45.71 years (SD +- 15.59 years). Patients who discontinued immunosuppressive treatment for severe infections were 20 (38.46% of patients on immunosuppressive therapy, 27.02% of the total cohort, 17 F and 3 M).

11/20 (55%) patients experienced Herpes Zoster, 8/20 (40%) Covid19 infection and 8/20 (40%) other types of infections (enteritis, urinary tract infections, extra-pulmonary tuberculosis, pneumonia and cellulitis). Herpes zoster was the most frequent severe infection in our cohort.

All patients with severe infections required immediate discontinuation of immunosuppressive therapy; 4/20 experienced a disease flare (20%), 19/20 (95%) required specific therapy for infection treatment, 7/20 (35%) required hospitalization and intravenous antibiotic/antiviral therapy.

We have conducted a comparison with the cohort of patients on immunosuppressive therapy who did not experience severe infections; we have also analyzed the different types of immunosuppressive treatment and cardiovascular risk factors in the two cohorts.

Results From our data analysis, conducted with statistical tests (t-Test, Fisher exact test, p-value 0.05) with the R-project software, there is no significant difference about specific risk factors that could favour the occurrence of severe infectious disease between patients in immunosuppressive therapy. Data analysis also highlighted that mycophenolate or belimumab increase infective risk.

Conclusions In our cohort we did not identify specific risk factors for severe infections in immunosuppressed patients. Analysis of larger cohorts has to be encouraged to identify potential risk factors for severe infections, so that they could be treated or prevented without treatment discontinuation.

P160 DRUG SURVIVAL IN SLE: REAL WORLD DATA FROM THE VIENNA LUPUS COHORT

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Objective The heterogeneity of systemic lupus erythematosus (SLE) poses a challenge in clinical care. Several treatment options are available, but data on immunomodulating drug survival in SLE is limited, warranting further investigation to optimize treatment strategies.

Methods The Vienna Lupus Cohort encompasses SLE patients treated at the outpatient clinic of the Division of Rheumatology at the Vienna General Hospital. Patient data, including measures of disease activity, type of medication, start- and end-date as well as reason for discontinuation, were entered into a specified database. Every initiation of an immunomodulating medication was considered a treatment cycle. Drug survival analyses using a Kaplan-Meier estimator was done for treatment cycles as well as for individual drugs, however excluding Cyclophosphamide and integrating Chloroquine and Hydroxychloroquine into one group.

Results 428 treatment cycles in 178 patients were analyzed. Patient were on average 35.1 (± 13.1) years old at initiation of their first DMARD therapy, and 158 (89%) were female. Time of observation ranged from 1987 to 2023. Overall, treatment cycle three and the following cycles had longer drug survival as treatment cycle one or two. Among the four most frequent treatments, Methotrexate (MTX), Azathioprine

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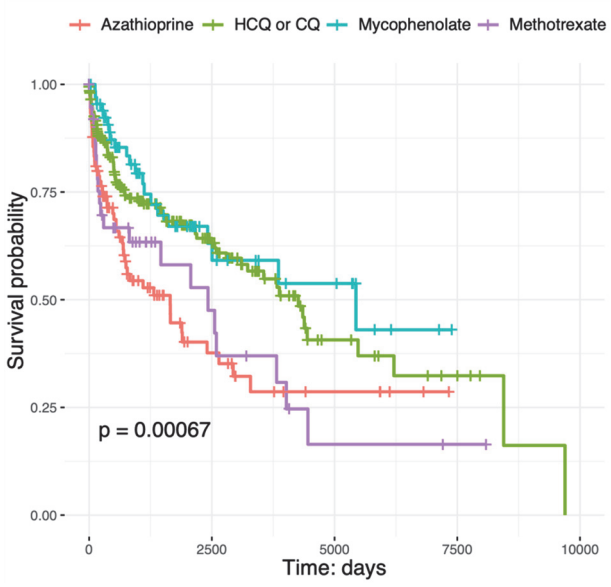
(AZA), Chloroquine/Hydroxychloroquine (H/CQ) and Mycophenolate (MMF), drug survival rates were higher for H/CQ and MMF compared to the other therapies **(figure 1)**. Most frequent reasons for drug discontinuation were objective side effects, insufficient efficacy, followed by subjective side effects and non-compliance **(table 1).**



Abstract P160 Figure 1 Drug survival by medications: Azathioprine (red), (Hydroxy)-chloroquine (green), Mycophenolate (blue), Methotrexate (purple)

Abstract P160 Table 1 Reason for drug discontinuation

Reason	n
Objective* AE	44 (23%)
Insufficient effect	33 (17%)
Subjective** AE	29 (15%)
no reason stated	23 (12%)
Other	20 (11%)
Incompliance	16 (8%)
Remission	11 (6%)
Child wish	6 (3%)
Comorbidity	4 (2%)
Pregnancy	4 (2%)

* Such as increase liver enzymes, decrease blood count or kidney function retinopathy,…; ** such as nausea, headache, dizziness,..

Conclusions This real-life data suggests favourable drug survival rates in SLE, especially with MMF and (H)CQ. The reasons for drug discontinuation in SLE are diverse. Further assessment of more recent treatment strategies, especially biologicals might offer additional insights.

Acknowledgements The SLE database was supported by AstraZeneca.

P161 SUCCESSFUL TREATMENT OF PULMONARY HYPERTENSION AND GRADE 3 LUPUS NEPHRITIS WITH TRIPLE COMBINATION TREATMENT FOR PULMONARY HYPERTENSION (MACITENTAN, TADALAFIL, SELEXIPAG) AND CYCLOPHOSPHAMIDE

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Background 28-year-old Goan lady presented with polyarthritis, positive ANA, RNP, dsDNA, low C4 and normal C3. She was diagnosed with SLE and received Hydroxychloroquine (HCQ), Prednisolone, and Azathioprine 150mg daily. Between 2011–2016, she had multiple flares with arthritis and serositis. She responded poorly to methotrexate, and developed a reaction to Rituximab, but improved on HCQ 400mg, mycophenolate mofetil 3 g and Prednisolone 7.5mg daily. (SLEDAI 4 in 2018).

Methods She presented in 2018 with fever, urine infection, and pericarditis; ESR-92, CRP-38, low C3, C4, and dsDNA-345. Examination revealed raised JVP, loud P2, and ECG findings consistent with pulmonary hypertension (PH). CT pulmonary angiogram showed an enlarged main pulmonary artery with no PE. Renal biopsy demonstrated class 3 lupus nephritis, protein-creatinine ratio (PCR) 362. She developed autoimmune haemolysis requiring blood transfusion. Apixaban was prescribed for positive anticardiolipin antibody and lupus anticoagulant. She was treated with Cyclophosphamide (CYC) (EUROLUPUS regime) and Prednisolone. Six-Minute-walk-distance was 356m, desaturating to 85%. Borg's score was 17. Lung function test showed FVC 1.31 litres- 40% predicted, TLCO 32% predicted. Echocardiogram showed significant pulmonary hypertension, dilated RV with impaired function, TAPSE 1.9cm, dilated right atrium, RVSP-71mmHg and normal LV function. Right Heart Catheter (RHC) confirmed mPAP 52mmHg (May 2019).

Results She was started on Tadalafil and Macitentan whilst receiving CYC. Within 4 months, mPAP improved to 34 mmHg. As she became more breathless in December 2020, Selexipag was added. In 2021, mPAP was 22mmHg. Echocardiogram in 2023 showed sinus rhythm, TAPSE 2.2cm, low probability of pulmonary hypertension, and no evidence of right heart strain.

Conclusions PAH is a rare but severe complication of SLE. The prevalence of clinical SLE-PAH is 0.5–17%.[1] Suggested pathogenic mechanisms include immune system dysregulation, inflammatory cell infiltrate deposition in pulmonary vasculature and endothelial dysfunction. Most patients are asymptomatic until the late stages. Studies suggest a better benefit with immunosuppressive therapy in SLE-PAH vs. SSC-PAH, the commonest CTD-PAH with a 3-year survival of 74% - 89.4% vs. 50% respectively.[1] [2] Meta-analysis and RCT reported that combination therapy with immunosuppression, pulmonary vasodilators, and prostacyclin analogues yielded a favourable outcome (2) and delayed disease progression.

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