

prevention of the rejection of some transplants. Mycophenolate mofetil was found to be associated with a lower risk of toxic adverse events such as ovarian failure, alopecia and leucopenia, compared with cyclophosphamide (1).

Objectives: To describe the population of patients with SLE receiving mycophenolate during a five year period.

Methods: We conducted a retrospective observational study, extracting information from a database in our rheumatic diseases center; we reviewed the clinical record of each patient with diagnosis of SLE and receiving mycophenolate. Descriptive epidemiology was performed for each variable presented.

Results: 1989 patients were diagnosed with Systemic Lupus Erythematosus (SLE) during 2011 and 2016 and 287 were receiving mycophenolate. Regarding demographic characteristics 94% were woman and 6% men, mean age was 49 years \pm 15. 41% of patients were employed, 40% were housekeepers, 11% students and 8% retired. The indication for mycophenolate was mainly for lupus nephritis 62%, SLE in overlapping with systemic sclerosis 30% and only for SLE in 8% of cases. 36% of patients received a daily dose of 2000 mg, 30% 1500 mg, 20% 1000 mg, 8% 3000 mg, 3.5% 4000 mg and 1.5% 6000 mg and 1% 500mg. The mean value for 24 hour urine protein was 792 mg/dl \pm 140 and for creatinine was 0.84 mg/dl \pm 0.36. In our population patients were taking mycophenolate during a median of 24 months with a minimum of 6 and a maximum of 132. In combination with mycophenolate 28% of the patients were taking corticoids, 21% hydroxychloroquine, 20% chloroquine, 17% antihypertensive drugs, 7% other medications and only 4% were taking the mycophenolate alone.

Conclusions: Despite of the absence of a license for mycophenolate for the management of Systemic Lupus Erythematosus, the use off-label of this drug continues to be frequently as an alternative and effective treatment in patients with lupus nephritis and other conditions associated to SLE.

References:

[1] National Institute for Health Care Excellence. NICE. Systemic lupus erythematosus: oral mycophenolate. England: NICE 2014.

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AB0454 CLINICAL AND IMMUNOLOGICAL ACTIVITY IN POLISH COHORT OF SYSTEMIC LUPUS ERYTHEMATOSUS PATIENTS TREATED WITH GLUCOCORTICOIDS

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Background: Nowadays the lupus treatment strategy is based on background therapy, immunosuppressive drugs and glucocorticoids (GC). Using minimal effective dose of GC only in flares is a recommendation for preventing complications which increase mortality.

Objectives: To evaluate SLE clinical and immunological activity in lupus patients during the standard clinical care and analyze GC treatment

Methods: We observed Polish cohort of patients with SLE 127 patients (118 female and 9 male) with average age 43 \pm 6 years, average disease duration 7,8 \pm 5,6 years. All of them were treated with oral and pulse GC and standard immunosuppressive therapies (CTX, MMF, AZT,MTX, CsA). As a background therapy 77% of these patients were on chloroquine or hydroxychloroquine. All patients were assessed according to Systemic Lupus Erythematosus Disease Activity Index assessed by SLEDAI (version 2000) and divided into 5 groups: no GC, low dose, medium dose, high dose and puls GC therapy group. Immunological activity was assessed by anti-dsDNA and C3 and C4 complements levels.

Results: In analyzed group 28 of patients without GC the average SLEDAI score was 7 and 50% of this pts not revealed any immunological activity. Low dose of GC was used in 50 pts with average SLEDAI score 13 and in 24 pts of this group anti-dsDNA and C3 or C4 levels upper limit were not observed. Medium dose of GC was used in 20 pts with average SLEDAI score 19 and it was contained with high immunological activity in 55% (n=11) of pts. In 27 of pts, high doses of GC including puls therapy were needed, the average SLEDAI score was very high 30 and most of pts from this group 70% were immunologically active.

Conclusions: In this Polish cohort lupus patients GC doses depended on lupus activity. Minimizing glucocorticoid exposure is an important part of appropriate management of lupus patients. Proper assessment of clinical and immunological lupus activity is critically for treatment decisions, especially for long-term GC use.

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AB0455 SURVIVAL OF PREDNISONE-FREE REMISSION IN SLE PATIENTS WITH SEROLOGICALLY ACTIVE CLINICAL QUIESCENT DISEASE

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Objectives: To evaluate survival of prednisone (PDN) – free remission in systemic lupus erythematosus (SLE) patients and to investigate the potential predictors of disease flares.

Methods: Inclusion criteria were: (1) Diagnosis of SLE according to American College of Rheumatology (ACR) Classification Criteria of SLE; (2) Caucasian

ethnicity; (3) Clinical remission (clinical SLEDAI-2K=0) at the time of PDN-withdrawal; (4) Stop of PDN treatment between 2010 and 2016; (5) At least two visits per year between January 2010 and April 2016.

Disease activity was assessed according to SLE Disease Activity Index-2000 (SLEDAI-2K). Damage was measured by the SLICC/American College of Rheumatology Damage Index (SDI). Flares were defined according to Safety of Estrogens in Lupus Erythematosus National Assessment (SELENA)-SLEDAI criteria.

We evaluated whether gender, age, age at PDN-stop, disease duration, duration of corticosteroid therapy, duration of remission before PDN withdrawal, time to flare, SLICC/American College of Rheumatology Damage Index (SDI) – score >3, positive anti-dsDNA antibodies (abs) and/or low C3/C4, type of SLE-involvement and concomitant immunosuppressive treatment could be predictors of flare. Multivariate logistic regression analysis was run to investigate the predictors of flare. Covariates included in the analysis were all variables reaching p<0.20 in the univariate analyses.

Results: Among 400 patients evaluated, 104 (26%) fulfilled inclusion criteria. Baseline characteristics are reported in table 1. Twenty-two (21.2%) patients flared. Mean time to flare was 19.91 \pm 13.14 months. Types of flare were 7 renal, 7 articular, 4 cutaneous, 2 haematological, 1 serositis and 1 neurological. Variables included in the multivariate logistic regression analysis were: positive anti-dsDNA abs and/or low C3/C4, skin, articular and haematological involvement. Skin involvement resulted predictive of flare (OR 3.07, 95% CI 1.11–8.53, P 0.031) as reported in table 2.

Demographic and clinical variables in all patients and according to survival of prednisone-free remission

	All patients	Patients maintaining PDN-free remission	Patients who flared	p Value
Patients, N	104	82	22	-
Female, N (%)	91 (87.5%)	69 (84.1%)	22 (100.0%)	0.046
Age in 2016, years, mean \pm SD	41.25 \pm 10.95	41.46 \pm 11.13	40.45 \pm 10.46	0.723
Age at PDN-stop, years, mean \pm SD	39.08 \pm 11.2	39.32 \pm 11.27	38.18 \pm 10.68	0.844
Disease duration, months, mean \pm SD	188.54 \pm 101.57	187.61 \pm 97.96	192.0 \pm 116.52	0.817
Duration of corticosteroid therapy, months, mean \pm SD	131.77 \pm 69.74	128.34 \pm 68.3	140.73 \pm 96.16	0.607
Duration of remission before PDN-withdrawal, months, mean \pm SD	36.80 \pm 33.01	38.24 \pm 34.95	31.91 \pm 23.51	0.765
Time to flare, months, mean \pm SD	-	-	19.91 \pm 13.14	-
SDI >3, N (%)	10 (9.6%)	8 (9.8%)	2 (9.1%)	0.925
Positive anti-ds-DNA abs and/or low C3/C4, N (%)	89 (85.6%)	68 (82.9%)	21 (95.5%)	0.138
Skin rashes, N (%)	35 (37.7%)	22 (26.8%)	13 (59.1%)	0.004
Arthritis, N (%)	69 (66.3%)	51 (62.2%)	18 (81.8%)	0.084
Serositis, N (%)	16 (15.4%)	13 (15.9%)	3 (13.6%)	0.790
Glomerulonephritis, N (%)	65 (62.5%)	53 (64.6%)	12 (54.5%)	0.385
Neuropsychiatric manifestations, N (%)	10 (9.6%)	8 (9.8%)	2 (9.1%)	0.925
Vasculitis, N (%)	6 (5.8%)	4 (4.9%)	2 (9.1%)	0.452
Haematological involvement, N (%)	25 (24.0%)	17 (20.7%)	8 (36.4%)	0.128
Concomitant immunosuppressive treatment, N (%)	41 (39.4%)	32 (39.0%)	9 (40.9%)	0.872

PDN: prednisone; SD: standard deviation; SDI: SLICC/American College of Rheumatology Damage Index

Risk of flare in prednisone-free remission. Logistic regression analysis

	OR (95% CI)	p Value
Skin involvement	3.07 (1.11-8.53)	0.031
Articular involvement	2.75 (0.80-9.44)	0.108
Haematological involvement	1.89 (0.62-5.73)	0.261
Positive anti-ds-DNA abs and/or low C3/C4	3.17 (0.37-27.05)	0.292

OR: Odds Ratio; CI: Confidence Interval

Conclusions: In SLE patients who stopped corticosteroid therapy, previous skin involvement resulted to be a predictor of disease flare.

Disclosure of Interest: None declared

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AB0456 SAFETY AND RETENTION RATE OF BELIMUMAB: DATA FROM A MULTICENTRIC ITALIAN STUDY

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Background: Belimumab is used in the treatment of systemic lupus erythematosus (SLE), but few data on its safety in daily clinical practice are available to date.

Objectives: To investigate safety, retention rate (RR), reasons and predictors of belimumab discontinuation in a prospective multicentric Italian study.

Methods: A total of 188 active SLE patients refractory to standard therapy were treated with belimumab as add-on-therapy in 11 Italian centers. Adverse events (AEs) were defined as "any untoward medical occurrence in a patient