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Disclosure of Interests: Richard Furie Grant/research support from: AstraZeneca, Biogen, Consultant of: AstraZeneca, Biogen, SV Parikh Grant/research support from: Aurinia Pharmaceuticals, EMD-Serono, Consultant of: Aurinia, BMS, GSK, Adonis Maiquez: None declared, Amber Khan: None declared, Orlando Moreno: None declared, Miguel Soneira: None declared, Christopher Kirk Shareholder of: Kezar Life Sciences, LLC, Employee of: Kezar Life Sciences, LLC, Darrin Bomba Shareholder of: Kezar Life Sciences, LLC, Employee of: Kezar Life Sciences, LLC, Ken Harvey Shareholder of: Kezar Life Sciences, LLC, Employee of: Kezar Life Sciences, LLC, Mary Katherine Farmer Shareholder of: Kezar Life Sciences, Employee of: Kezar Life Sciences
DOI: 10.1136/annrheumdis-2020-eular.2700

AB0374

LUPUS LOW DISEASE ACTIVITY STATE AND MAINTAINING DRUG THERAPY: A RETROSPECTIVE INVESTIGATION

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Background: Systemic lupus erythematosus (SLE) is a chronic autoimmune multisystemic disease, that can begin with a wide range of clinical manifestations, and requires immunosuppressive therapies (1). A treat-to-target strategy leads to a high rate of clinical remission among patients (2). Several "remission" definitions have been provided in the last years and Lupus Low Disease Activity State (LLDAS) seems one of the best tools to evaluate it in clinical practice (3).

Objectives: To evaluate the prevalence of SLE signs and symptoms at onset and the drugs used to induce and maintain the clinical remission, evaluated by LLDAS, in a real-life cohort of SLE patients.

Methods: Thirty female SLE patients (mean age 52±15 years; mean age at disease onset 34±16 years, mean disease duration 18±13 years) in clinical remission have been enrolled (EULAR/ACR 2019 criteria) (4). Remission was defined by LLDAS (SLEDAI-2K < 4 and no activity in major organ systems, no hemolytic anemia; no new features of activity compared with previous assessment, physician global assessment (PGA) ≤ 1, prednisone dose ≤ 7.5 mg/day, well tolerated and stable therapy with maintenance doses of immunosuppressive drugs). Clinical and serological manifestations, SLEDAI-2K and pharmacological treatments were recorded at baseline and during follow-up.

Results: Mucocutaneous involvement (57%), arthritis (30%), serositis (30%), nephritis (27%), leukopenia (23%), thrombocytopenia (20%), hemolytic anemia (13%), antiphospholipid syndrome manifestations (16%), neuro-psychiatric lupus symptoms (6%) were present in various combinations at disease onset. Baseline mean SLEDAI-2K was 10.5±2.5. Patients were treated with different dosages of glucocorticoids (100%), hydroxychloroquine (HCQ, 73%), cyclofosfamide (20%), mycophenolate mofetile (MMF, 13%), azathioprine (AZA, 13%), methotrexate (MTX, 13%), cyclosporine A (CSA, 6%), rituximab (3%), abatacept (ABA, 3%). Glucocorticoids were prescribed together with a single DMARD in 50% of cases and with two DMARDs in the remaining 50% of patients. Patients reached LLDAS remission after a mean time of 14±12 years, with a mean remission duration of 4.2±3.2 years (mean SLEDAI-2K at last visit 1±1; Mean PGA 0.4±0.1). Maintenance therapies during remission were prednisone ≤ 5 mg/day and/or HCQ ≤ 400 mg/day and/or CSA ≤ 200 mg/day and/or MTX ≤ 10 mg/weekly and/or MMF ≤ 2 g/day and/or AZA ≤ 100 mg/day. In particular, only prednisone 7%, only HCQ 3%, prednisone + HCQ 53%, prednisone + single DMARD (different from HCQ) 7%, prednisone + HCQ + DMARDs 30%.

Conclusion: After reaching the clinical remission by a treat to target strategy, the administration of low dose of prednisone and HCQ in the majority of SLE patients (63%) seems useful to prevent new SLE flares. The retrospective design and the absence of a control group of patients with active disease limit this study.

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Disclosure of Interests: Emanuele Gotelli: None declared, Alberto Sulli Grant/research support from: Laboratori Baldacci, Giorgia Ferrari: None declared, Greta Pacini: None declared, Carlotta Schenone: None declared, Massimo Patanè: None declared, Pietro Francesco Bica: None declared, Carmen Pizzorni: None declared, Maurizio Cutolo Grant/research support from: Bristol-Myers Squibb,

Actelion, Celgene, Consultant of: Bristol-Myers Squibb, Speakers bureau: Sigma-Alpha, Sabrina Paolino: None declared

DOI: 10.1136/annrheumdis-2020-eular.5268

AB0375

SAFETY AND BENEFICIAL EFFECTS OF HYDROXYCHLOROQUINE ON PREGNANCY OUTCOMES IN WOMEN WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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Background: The use of hydroxychloroquine (HCQ) has long been established in Systemic Lupus Erythematosus (SLE) and especially as applicable drug during pregnancy. Recently, beneficial effects and safety of HCQ have been re-discussed in the light of a change in the summary of product characteristics in some countries. More current studies are required to provide patients with evidence-based advice regarding this essential drug when counselling for pregnancy.

Objectives: To examine the impact of HCQ on pregnancy outcomes of SLE women.

Methods: Pregnancies of women with SLE from an outpatient pregnancy clinic were prospectively evaluated before and throughout gestation. Maternal and fetal outcomes in women without HCQ therapy (group A) were compared to pregnancies under HCQ treatment from 1st trimester on (group B). A multiple logistic regression was performed with adjustment for confounding factors.

Results: We enrolled 184 live births from singleton pregnancies in 145 women (n=77 with HCQ and n=107 w/o HCQ). One neonatal death (group B) occurred after severe preeclampsia at 24 weeks of gestation (w/g) linked to noncompliance in a woman with high-risk aPL profile. One child (group B) was born with mycophenolate mofetil embryopathy.

Women in the HCQ group had a significantly lower rate of preterm births [aOR 0.31 (95%-CI: 0.15-0.64), p = 0.026]. Regarding preeclampsia, we found a tendency towards less incidence with the use of HCQ [aOR 0.49 (95%-CI: 0.23-1.03), p = 0.24]. These improved outcomes are opposed by a higher frequency of risk factors in group B (lupus nephritis, high-risk aPL profile, slightly more hypertension) and a tendency towards more severe SLE (expressed in terms of increased use of Azathioprine) (Table 1). Nevertheless, women with HCQ

Table 1. Patient characteristics & pregnancy outcomes

		All pregnancies (n=184)	No HCQ in pregnancy (n=107)	HCQ during pregnancy (n=77)
SLE disease & therapy characteristics	Age (years), median (IQR)	31.0 (28.0-34.0)	31.0 (29.0-34.0)	30.0 (27.0-33.0)
	Hypertension, n (%)	29 (15.8%)	16 (15.0%)	13 (16.9%)
	Preconception counselling, n (%)	122 (66.3%)	69 (64.5%)	53 (68.8%)
	Disease duration (years), median (IQR)	6.7 (2.9-10.3)	7.0 (3.0-10.0)	6.7 (2.1-11.0)
	Lupus nephritis ¹ , n (%)	51 (27.7%)	25 (23.4%)	26 (33.8%)
	High-risk aPL profile ² , n (%)	39 (21.3%)	21 (19.8%)	18 (23.4%)
	SLEDAI ¹ , median (IQR)	2.0 (0-4.0)	2.0 (0.0-4.0)	2.0 (2.0-4.0)
	Anti-dsDNA, n (%)	102 (55.7%)	47 (44.3%)	55 (71.4%)
	Anti-SSA/Ro and/or Anti-SSB/La, n (%)	91 (49.7%)	55 (51.9%)	36 (46.8%)
	Azathioprine ¹ , n (%)	38 (20.7%)	18 (16.8%)	20 (26.0%)
Obstetrical history	Low dose Aspirin ³ , n (%)	74 (41.1%)	34 (32.7%)	40 (52.6%)
	Nulliparous, n (%)	113 (61.4%)	63 (58.9%)	50 (64.9%)
	Previous fetal loss, n (%)	39 (21.2%)	22 (20.6%)	17 (22.1%)
	Previous (pre-)eclampsia or HELLP, n (%)	14 (7.6%)	8 (7.5%)	6 (7.8%)
	Previous congenital heart block, n (%)	1 (0.54%)	-	1 (1.3%)
Pregnancy outcome	(mild-moderate) flare ⁴ , n (%)	44 (29.5%)	30 (34.9%)	14 (22.2%)
	Preterm birth ⁵ , n (%)	46 (25%)	30 (28.0%)	16 (20.8%)
	Preeclampsia, n (%)	24 (13%)	15 (14.0%)	9 (11.7%)
	Intrauterine growth restriction, n (%)	3 (1.7%)	1 (1.0%)	2 (2.6%)
	Congenital heart block, n (%)	1 (0.54%)	-	1 (1.3%)

¹last visit before pregnancy, ²according to the 2019 EULAR recommendations, ³until 16 w/g,

⁴increase in SLEPDAI ≥ 4 or increase in prednisolone ≥ 5mg/d, ⁵< 37 w/g

therapy experienced significantly less flares during pregnancy [aOR 0.18 (95%-CI: 0.09-0.38), $p = 0.013$].

Conclusion: In our cohort, SLE women with additional risk factors achieved a favourable pregnancy outcome. This encouraging result is in part attributable to pregnancy counselling with the advice to continue HCQ throughout gestation.

Disclosure of Interests: Isabell Haase Grant/research support from: Abbvie, Medac, Hexal, Pfizer, Ralph Brinks: None declared, Matthias Schneider Grant/research support from: GSK, UCB, Abbvie, Consultant of: Abbvie, Alexion, Astra Zeneca, BMS, Boehringer Ingelheim, Gilead, Lilly, Sanofi, UCB, Speakers bureau: Abbvie, Astra Zeneca, BMS, Chugai, GSK, Lilly, Pfizer, Sanofi, Rebecca Fischer-Betz Consultant of: UCB, Speakers bureau: Abbvie, Amgen, Biogen, BMS, Celgene, Chugai, GSK, Janssen, Lilly, Medac, MSD, Novartis, Roche, UCB, Pfizer.

DOI: 10.1136/annrheumdis-2020-eular.3567

AB0376

DETERMINANTS AND PROTECTIVE EFFECTS OF A LOW DISEASE ACTIVITY STATE IN SYSTEMIC LUPUS ERYTHEMATOSUS: RESULTS FROM A PROSPECTIVE CHINESE COHORT

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Background: The concept of treat to target in systemic lupus erythematosus has moved forward in recent years. The Lupus low disease activity state (LLDAS) defined by the Asia-Pacific Lupus Collaboration (APLC) in 2016 has been validated prospectively in the APCL cohort itself and retrospectively in multiple other cohorts.

Objectives: The concept of treat to target in systemic lupus erythematosus has moved forward in recent years. The Lupus low disease activity state (LLDAS) defined by the Asia-Pacific Lupus Collaboration (APLC) in 2016 has been validated prospectively in the APCL cohort itself and retrospectively in multiple other cohorts. The aim of this study was to investigate the frequency and determinants of achieving LLDAS, and the influence of LLDAS on short term outcomes including disease flare and damage accrual in Chinese lupus patients.

Table 1-Determinants of achieving LLDAS for at least 50% of follow-up time by univariate and multivariate logistic regression analysis^{a,b}

Variables ^c	Univariate analysis ^d			Multivariate analysis ^d		
	OR ^e	95% CI ^e	P value ^e	OR ^e	95% CI ^e	P value ^e
Gender-Female ^c	5.25 ^c	0.94-24.02 ^c	0.057 ^c			
Onset age<30 years old ^c	0.54 ^c	0.28-0.99 ^c	0.047 ^c	0.05 ^c	0.01-0.59 ^c	0.017 ^c
Disease duration at recruitment ^{a,c}	0.98 ^c	0.94-1.03 ^c	0.434 ^c			
Organ involvements ^{a,c}						
Skin & mucous involvement ^c	0.75 ^c	0.38-1.47 ^c	0.403 ^c			
LN ^c	0.62 ^c	0.32-1.21 ^c	0.162 ^c			
NPSLE ^c	0.84 ^c	0.27-2.64 ^c	0.764 ^c			
AIHA ^c	0.38 ^c	0.10-1.44 ^c	0.157 ^c			
Thrombocytopenia ^c	0.94 ^c	0.44-1.98 ^c	0.866 ^c			
PAH ^c	1.15 ^c	0.25-5.34 ^c	0.857 ^c			
Laboratories at recruitment ^c						
Anti-dsDNA positive ^c	0.67 ^c	0.27-1.64 ^c	0.382 ^c			
C3 (mg/L) ^c	1.003 ^c	1.001-1.005 ^c	0.002 ^c	1.004 ^c	1.001-1.008 ^c	0.028 ^c
UTP (mg) ^c	0.997 ^c	0.995-0.999 ^c	0.005 ^c	0.9992 ^c	0.9987-0.9998 ^c	0.007 ^c
Scr (μmol/L) ^c	0.98 ^c	0.97-0.99 ^c	0.049 ^c	0.98 ^c	0.96-1.00 ^c	0.094 ^c
IS treatment for at least 6 months ^{a,c}	0.39 ^c	0.15-0.96 ^c	0.040 ^c	0.30 ^c	0.02-3.50 ^c	0.333 ^c

^a Years: disease duration at recruitment defined as time from disease onset to recruitment.^{b,c}

^c Present ever during course of disease.^d

Abbreviations: LN=lupus nephritis; NPSLE=neuropsychiatric SLE; AIHA=autoimmune hemolytic anemia;

PAH=pulmonary arterial hypertension; Scr=serum creatinine; IS: Immunosuppressant.^e

Table 2 -Determinants of disease flare by univariate and multivariate Cox regression analysis^{a,b}

Variables ^c	Univariate analysis ^d			Multivariate analysis ^d		
	HR ^e	95% CI ^e	P value ^e	HR ^e	95% CI ^e	P value ^e
Gender-Female ^c	0.80 ^c	0.38-0.71 ^c	0.568 ^c			
Age at disease onset (years) ^c	0.97 ^c	0.95-0.99 ^c	0.004 ^c	0.97 ^c	0.95-0.99 ^c	0.026 ^c
Disease duration at recruitment (years) ^{a,c}	1.01 ^c	0.98-1.05 ^c	0.504 ^c			
Organ involvements ^{a,c}						
Skin & mucous involvement ^c	1.40 ^c	0.81-2.43 ^c	0.230 ^c			
LN ^c	0.76 ^c	0.45-1.28 ^c	0.298 ^c			
NPSLE ^c	0.74 ^c	0.29-1.85 ^c	0.513 ^c			
AIHA ^c	1.10 ^c	0.64-1.87 ^c	0.735 ^c			
Thrombocytopenia ^c	0.88 ^c	0.47-1.63 ^c	0.683 ^c			
PAH ^c	1.13 ^c	0.35-3.62 ^c	0.842 ^c			
Laboratories at recruitment ^c						
Anti-dsDNA positive ^c	1.43 ^c	0.82-2.5 ^c	0.209 ^c			
C3 (mg/L) ^c	0.996 ^c	0.995-0.998 ^c	0.000 ^c	0.997 ^c	0.996-0.999 ^c	0.001 ^c
UTP (mg) ^c	0.998 ^c	0.993-1.002 ^c	0.450 ^c			
Treatments ^c						
Prednisone or equivalent dose at recruitment ^c	1.00 ^c	0.99-1.02 ^c	0.684 ^c			
IS for 6months ^{a,c}	1.21 ^c	0.57-2.58 ^c	0.614 ^c			
Percentage time of LLDAS ^{a,c}	0.10 ^c	0.04-0.25 ^c	0.000 ^c	0.18 ^c	0.07-0.48 ^c	0.001 ^c

^a Years: disease duration at recruitment defined as time from disease onset to recruitment.^{b,c}

^c Present ever during course of disease.^d

^e Using immunosuppressant for 6 during whole follow-up^e

^f Percentage time of LLDAS in whole follow-up time^e

Abbreviations: LN=lupus nephritis; NPSLE=neuropsychiatric SLE; AIHA=autoimmune hemolytic anemia;

PAH=pulmonary arterial hypertension.^e

Methods: The baseline and follow-up data of all consecutive patients in a longitudinal lupus cohort from January 2017 to December 2018 were collected prospectively. SLEDAI-2K, PGA and disease flare were assessed at each follow-up visit, and further compared to the previous routine clinical visits. Irreversible disease damage was captured using the SLICC damage index and the short form (36) health survey for health-related quality of life was completed annually.

Results: One hundred and forty-nine patients were enrolled, with the median disease duration at recruitment of 2.4 (0.9–8.2) years, and median follow-up of 15.4 (10.1-18.2) months. By the end of the study, 104 (69.8%) patients