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Remission and low disease activity state in childhood-onset systemic lupus erythematosus: differential impact on damage accrual in a Latin American cohort (GLADEL)

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ABSTRACT

Objective To examine the impact of different disease activity states (DAS) on outcomes in a longitudinal inception childhood-onset SLE cohort.

Materials and methods Three DAS were included—remission: clinical SLE DAS (SLE Disease Activity Index (SLEDAI)=0, prednisone (≤5 mg/day) and/or immunosuppressants (IS) (maintenance dose)); lupus low DAS (LLDAS): SLEDAI ≤4 with 0 scores for major organ involvement, no increase in any SLEDAI component since the previous visit, on prednisone (≤7.5 mg/day) and/or IS (maintenance dose); and active disease otherwise. The association of these DAS with new damage (increase of at least 1 point in the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index (SDI)), severe new damage (an increase of ≥3 points in the SDI) and mortality (any cause) at any time during the follow-up was examined using Cox proportional hazards regression models.

Results The majority of the 212 patients included had active disease at baseline (84%). There was no association between LLDAS and lower risk of new damage or severe new damage (HR 0.98, 95% CI 0.43 to 2.22, p=0.955 and HR 0.40, 95% CI 0.04 to 3.62, p=0.415, respectively). Remission was associated with lower risk of new damage (HR 0.36, 95% CI 0.15 to 0.91, p=0.030), but it had no impact on mortality (HR 0.45, 95% CI 0.06 to 3.66, p=0.454).

Conclusions Attaining LLDAS and remission was lower in our cohort than in other contemporary paediatric lupus cohorts. Remission but not LLDAS was associated with lower risk of new damage over 4.3 years of follow-up. None of these DAS were associated with mortality.

WHAT IS ALREADY KNOWN ON THIS TOPIC

⇒ Lupus low disease activity state (LLDAS) and remission have been associated with lower damage accrual and decreased mortality in adults and children with SLE.

WHAT THIS STUDY ADDS

⇒ In this inception childhood-onset SLE (cSLE) cohort including patients from low- and middle-income countries, remission but not LLDAS was associated with lower risk of new damage accrual.

HOW THIS STUDY MIGHT AFFECT RESEARCH, PRACTICE OR POLICY

⇒ The results of this study underscore the need for more collaborative research efforts and implementation of strategies in Latin America to better understand and improve the long-term outcomes of cSLE.

INTRODUCTION

Lupus low disease activity state (LLDAS) and remission have been associated with improved outcomes, including lower damage accrual and decreased mortality in adults with SLE; therefore, they have been proposed as treat-to-target strategies.[1–3]

Patients with childhood-onset SLE (cSLE) exhibit higher disease activity and more severe organ involvement when compared with their adult counterpart.[4] A task force has recently proposed a definition for LLDAS status and remission in cSLE which have been validated in a small number of cSLE cohorts.[5 6] Some studies showed that LLDAS and remission were associated with better outcomes, including lower risk of severe flares and new damage in cSLE.[7 8] However, there are few studies examining the impact of

LLDAS and remission on outcomes in cSLE in low- and middle-income countries (LMICs), including those from Latin America. Our aims are to examine the association of LLDAS and remission on the development of new organ damage and mortality in an inception cSLE cohort from Latin America using data from the Latin American Group for the Study of Lupus (*Grupo Latino Americano De Estudio del Lupus* or GLADEL).

METHODS

Data source and population

GLADEL is an observational multiethnic inception cohort that was started in 1997, and it includes 34 centres from nine countries in Latin America. This cohort included 1480 patients with SLE, of whom 230 were diagnosed <18 years of age or with cSLE.[9] The diagnosis of SLE was based on clinical experience; however, more than 90% of the patients met ≥4 of the 1997 American College of Rheumatology (ACR) classification criteria for lupus at baseline, and they were enrolled in the study following a single protocol, consensus definitions as well as outcome measures. Among the patients included in the analyses, the first patient was enrolled on 1 December 1996 and the last patient on 28 December 2003. The study was performed in accordance with the Declaration of Helsinki for the conduct of research in humans and followed the local institutional review board's regulations. Further details of this cohort have been previously described.[9 10]

Variables

The main outcome variables included new damage (defined as an increase of at least 1 point in the Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index (SDI)) and severe new damage (defined as an increase of at least 3 points in the SDI) over the study period. The secondary outcome was mortality (of any cause) at any time during the follow-up. Covariates at baseline included age, sex, socioeconomic status, race/ethnicity, educational level, medical coverage, number of ACR criteria, use of corticosteroids (highest dose at baseline or prior to enrolment), antimalarial use, SDI and class III or IV with/without class V lupus nephritis. Covariates over follow-up included the proportion of disease activity states (DAS) over time as follows:

- Remission: clinical SLE Disease Activity Index (SLEDAI)=0, prednisone dose ≤5 mg/day, with or without immunosuppressant (IS) at a stable dose.
- LLDAS: SLEDAI ≤4 with no SLEDAI score for renal, central nervous system, serositis, vasculitis and constitutional components; no increase in any SLEDAI component since the previous visit; and prednisone dose ≤7.5 mg/day, with or without IS at a stable dose.
- Active disease: SLEDAI >4 and/or prednisone dose >7.5 mg/day and/or new or increased dose of IS.

Data on Physician Global Assessment (PGA) and weight-adjusted prednisone dose were not available to be included in the operational definitions of remission and LLDAS. Antimalarials were allowed in all groups.

Table 1 Sociodemographic features at baseline

Characteristics (n=212)	
Gender, female, n (%)	189 (89.2)
Age at baseline in years, median (IQR)	15 (13–17)
Ethnicity*, n (%)	
White	86 (41.0)
Mestizo	90 (42.8)
African Latin American	30 (14.3)
Other	4 (1.9)
Educational level in years, median (IQR)	9.0 (7–11)
Socioeconomic status*, n (%)	
Upper/upper middle	15 (7.1)
Middle	54 (25.7)
Lower middle/lower	141 (67.2)
Full medical coverage**, n (%)	115 (54.8)

*Frequency missing n=2.

Statistical analyses

Demographic data, clinical and laboratory features were described using parametric and non-parametric statistics, as appropriate. The association of LLDAS/remission as time-dependent variables and outcomes was assessed using Cox proportional regression models. Active disease was used as the reference level and adjustment for covariates was performed. Sensitivity analyses were conducted using different follow-up time in percentages remaining in LLDAS and remission (30% vs 50% vs ≥70%) as well as time remaining in LLDAS as a continuous variable (eg, time in months in the DAS). Intervals between visits were defined as the period between two SLEDAI scores or between one SLEDAI and the end of follow-up. Only patients with at least two intervals were included with a minimal interval duration of at least 12 months. Statistical analyses were performed using SAS V.9.4.

RESULTS

Tables 1 and 2 depict the baseline sociodemographic and disease features. A total of 230 patients with cSLE were identified. Of these, only 212 were included since they had at least two visit intervals. Among the included patients, 189 (89.2%) were female. Mestizo was the most frequent racial/ethnic group (42.8%), followed by white patients (41.0%). The interval between visits varied from 0.1 months to 74.8 months (IQR=6.4), with an average of 10.6 months (SD=11.3) and median of 6.7 months. The length of follow-up of the cohort was from 0 years to 7 years, with an average of 3.9 years (SD=2.0). Most individuals had active disease at baseline (84%). Over the follow-up, new damage occurred in 100 (47.2%) of the patients and severe new damage in 33 (15.6%) (table 2). The cohort's

Table 2 Clinical and disease features at baseline

Characteristics (n=212)	
Number of ACR 97 criteria, n (%)	
2	3 (1.4)
3	15 (7.1)
4	42 (19.9)
5	44 (20.8)
6	54 (25.5)
7	35 (16.5)
8	12 (5.7)
9	6 (2.8)
10	1 (0.5)
Prednisone dose in mg*, n (%)	
1–20	38 (17.9)
20–60	82 (38.7)
≥60	63 (29.7)
Hydroxychloroquine use, n (%)	
No	134 (63.2)
Yes	78 (36.8)
Lupus nephritis†, n (%)	
No	112 (52.8)
Yes	100 (47.2)
SLE Disease Activity Index, median (IQR)	6 (2–10)
SDI, median (IQR)	0.0 (0.0–1.0)
Disease duration in years, median (IQR)	0.0 (0.0–0.8)

*Maximum dose after diagnosis.
†Class III or IV with/without class V lupus nephritis.
ACR, American College of Rheumatology; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index.

overall mortality rate was 8% (n=17). New damage, severe new damage and mortality were not significantly impacted by socioeconomic status (p=0.195, p=0.565, p=0.808), insurance coverage (p=0.804, p=0.380, p=0.351) and educational level (p=0.552, p=0.700, p=0.403) at baseline, respectively. Only 'other' ethnic group was associated with severe new damage (HR 9.69, 95% CI 1.99 to 47.25, p=0.005), but there was no association between ethnicity and either new damage or mortality.

Table 3 Best and last states over follow-up*

Status	Best, n (%)	Last, n (%)
Remission	47 (22.2)	32 (15.1)
LLDAS	26 (12.3)	1 (0.5)
Active disease	139 (65.5)	179 (84.4)

*Best state refers to the proportion of patients who achieved that state over their follow-up. Last state refers to the proportion of patients with that disease activity state at the end of follow-up.
LLDAS, lupus low disease activity state.

There was no association between LLDAS and lower risk of new damage or severe new damage (HR 0.98, 95% CI 0.43 to 2.22, p=0.955 and HR 0.40, 95% CI 0.04 to 3.62, p=0.415, respectively). Remission was associated with lower risk of damage (HR 0.36, 95% CI 0.15 to 0.91, p=0.030), but it did not have any impact on the risk of mortality (HR 0.45, 95% CI 0.06 to 3.66, p=0.454). Data available to estimate the association between LLDAS and mortality and between remission and severe new damage were insufficient (tables 3 and 4). Sensitivity analyses using alternative exposure thresholds for LLDAS and remission yielded consistent results (data not shown).

DISCUSSION

In our study, we found remission but not LLDAS to be associated with a lower risk of new damage accrual over 4.3 years of follow-up. However, none of these DAS had an impact on severe new damage or mortality in patients with cSLE from the GLADEL cohort. To our knowledge, this is the first study examining the impact of different DAS on outcomes in a multiethnic and multicentric paediatric lupus cohort from Latin America.

In a longitudinal validation cohort from the Netherlands which included 50 patients with cSLE, there was also no association between attaining LLDAS and lower damage accrual.[11] However, in a larger paediatric lupus cohort from the UK (n=430), an association between lower DAS and a lower risk of damage accrual was found, although the adjusted mean SLEDAI-2K score was used to assess disease activity instead of the consensus-based definition of LLDAS.[6] Moreover, a study from the same cSLE UK cohort found an association between LLDAS and remission with a lower risk of damage when the adult definitions of DAS were used.[7] There are limited data on the association of DAS and damage in cSLE in LMICs. A medical records review study including 272 patients with cSLE from two tertiary centres from China found that the proportion of organ damage of those who never attained LLDAS was higher when compared with those who achieved LLDAS.[12]

There are several factors inherent to our cohort that may have affected our results. First, the proportion of patients achieving LLDAS during the study period was very low (27%) when compared with other cohorts regardless of LMIC status, with LLDAS achieved in >50% of these patients.[13] Also, almost 50% of our patients had only three intervals between visits over their follow-up, this may have not accurately captured changes in disease activity over time leading to bias. Additionally, data collection in our cohort started prior to 2000, and cSLE outcomes have significantly improved over the last 20 years, which could have contributed to our cohort's lower rate of LLDAS. Despite differences in the timing of the inception of our cohort compared with other contemporary cSLE cohorts, we did observe a higher proportion of patients experiencing severe new damage (SDI ≥3) over follow-up among those with active disease at baseline

Table 4 Impact of disease activity states on mortality, new damage and severe new damage

	Remission (on/off therapy)		LLDAS	
	HR (95% CI)	P value	HR (95% CI)	P value
Mortality				
Unadjusted	0.42 (0.06 to 3.12)	0.391	*	*
Adjusted†	0.45 (0.06 to 3.66)	0.454	*	*
New damage‡				
Unadjusted	0.34 (0.14 to 0.83)	0.019	1.14 (0.55 to 2.37)	0.725
Adjusted†	**0.36 (0.15 to 0.91)**	**0.030**	0.98 (0.43 to 2.22)	0.955
Severe new damage§				
Unadjusted	*	*	0.53 (0.07 to 3.89)	0.528
Adjusted†	*	*	0.40 (0.04 to 3.62)	0.415

*Not enough data available to obtain the estimates.
†Adjusted by age at baseline, gender, ethnicity, socioeconomic status, years of education, medical coverage and first SDI.
‡One-point increment in the SDI.
§Three-point increment in the SDI.
LLDAS, lupus low disease activity state; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology (SLICC/ACR) Damage Index.

(85.7%) compared with those with LLDAS at baseline (14.3%). Second, a variable duration of the interval between visits may have also biased our results.

We acknowledge other limitations of our study. We were not able to include the PGA in the definition of both LLDAS and remission since this variable was not collected. Likewise, since data on patients' weight were not available, we were not able to calculate the prednisone dose per kilogram. The International Treat to Target Task Force proposed a ceiling prednisone dosage at 0.15 mg/kg/day, maximum of 7.5 mg, aiming for whichever dose was lowest.[5]

In summary, in this multiethnic and multicentric inception cSLE cohort from Latin America, remission but not LLDAS was associated with decreased risk of damage over follow-up; however, neither remission nor LLDAS was associated with a lower mortality. To our knowledge, this is the first study examining treat-to-target outcomes in a paediatric lupus cohort from Latin America. Controlling disease activity in SLE is associated with improved long-term outcomes including lower risk of damage accrual and ultimately mortality. LLDAS may still represent a relevant therapeutic target in cSLE; however, in this Latin American cohort, remission appeared to be the DAS most consistently associated with reduced damage accrual. More research efforts, including the inception of a contemporary multiethnic and multicentric cSLE cohort, are needed in Latin American countries and worldwide to better understand and improve the long-term outcomes of these vulnerable patient populations.

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