VitaLES Health Initiative in Patients with Systemic Lupus Erythematosus: Protocol for an Observational Longitudinal Study on Its Clinical Utility

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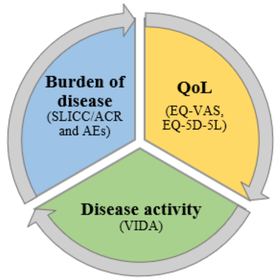
Introduction

- Systemic lupus erythematosus (SLE) is a chronic and heterogenous disease characterized by inflammation and damage across multiple organ domains, leading to reduced quality of life and premature mortality.
- Early diagnosis, periodic assessment and prompt initiation of effective treatment are essential to prevent flares and organ damage, improve prognosis and enhance quality of life.
- The VitaLES health initiative aims to establish a systematic assessment approach for SLE patients in clinical practice with three main components: disease activity, burden of disease and quality of life (**Figure 1**).

Figure 1. Score components measured in the VitaLES study



SLICC/ACR, Systemic Lupus International Collaborating Clinics/American College of Rheumatology; QoL, quality of life; AEs, adverse events; EQ-VAS, EuroQol visual analogue scale; VIDA, VitaLES Initiative Disease Activity (that includes clinical, laboratory and treatment data

Objectives

Primary objectives:

- to evaluate clinicians' perceptions of the VitaLES initiative in terms of clinical utility, influence on therapeutic decisions, disease management impact, satisfaction, and willingness to recommend it and
- to understand patients' perspectives on changes in their condition and satisfaction with follow-up care.

Secondary objectives:

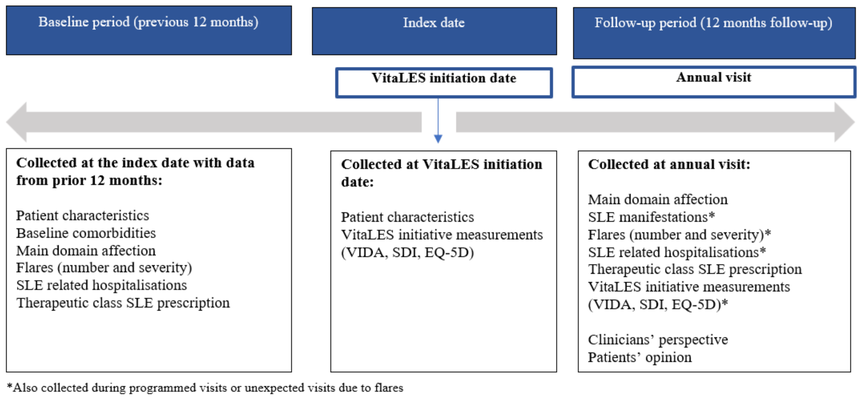
- to assess changes in VitaLES Disease Activity (VIDA) Indicators and disease control over a 12-month period,
- to evaluate clinical practices prior to the initiative, and
- to analyze correlations between quality-of-life scales and disease burden.

Methods

- Multicentre, longitudinal, observational study of a cohort of moderate to severe SLE adult patients from 19 hospitals in Spain, aiming to include at least 180 patients.
- Index date: day on which the VitaLES initiative begins for each patient.
- Data is collected retrospectively from electronic medical records over the previous 12 months and prospectively during routine follow-up visits over the next 12 months (**Figure 2**).
- VitaLES initiative data will be collected during the clinical practice considering the disease activity, through the evaluation of VIDA indicators (**Table 1**), burden of disease, assessed by SLICC/ACR Damage Index (SDI) and quality of life, measured by the EQ-5D-5L questionnaire.
- The clinicians' opinion on the utility and the patients' opinion on satisfaction with the follow-up of their disease, based on the VitaLES initiative, will be evaluated at the final visit.

Methods (continued)

Figure 2. VitaLES study design



*Also collected during programmed visits or unexpected visits due to flares

Table 1. VitaLES Initiative Disease Activity (VIDA) Assessment

	Partial evaluation					Final evaluation
Clinical data (A)						
Fever	0	1				Higher
Arthritis	0	1	2	3		
SLE skin condition	0	1	2	3		
Non-scarring alopecia	0	1	2	3		
Myositis	0	1	2	3		
Serositis	0	1	2	3		
Clinical data (B)						
Kidney disease	0	1	2	3	4	Higher
Neurological condition	0	1	2	3	4	
Lung disease	0	1	2	3	4	
Haematological condition	0	1	2	3	4	
Vasculitis	0	1	2	3	4	
Laboratory data (C)						
C3	0		1			Higher
C4	0		1			
Anti-DNA n	0		1			
Treatment (D)						
Prednisone ≤5 mg/day	0					Higher
Prednisone 5.1-7.5 mg/day		1				
Prednisone > 7.5 mg/day			2			
Stable immunosuppressant	0					
Recent immunosuppressants			2			
Biologically stable	0					
Recent biologicals			2			
Quality of life (E)	0				10	Higher
Overall assessment						(A + B + C + D)

Methods (continued)

Table 1 (continued). VitaLES Initiative Disease Activity (VIDA) Assessment

The score for the partial evaluation of the clinical data depends on:

4= Endangers the life or endangers any organ of the patient

3 = If the use of high doses of corticosteroids, immunosuppressants and biological therapy is required

2 = If the use of medium doses of corticosteroids is required

1 = If the use of non-steroidal anti-inflammatories and low doses of hydroxychloroquine is required

0= No organ altered

The sum of clinical, laboratory and treatment data will define the overall assessment, interpreted as:

- Good control: Total score of the assessment ► ≤ 2 points
- Poor control: Total assessment score of 3-4 points in the same block or ≥ 4 points in different blocks ► requires reviewing the patients and therapeutic escalation.
- Exacerbation: Increase of ≥ 2 points from the previous measurement.

Results

- The study will include comprehensive data on burden of disease, disease activity and quality of life, capturing both the physician and the patient´s perspective.
- We hypothesize that VitaLES initiative will contribute to the standardization of the clinical practice leading to a more rigorous measure of the disease in SLE patients improving the control of the disease, which will satisfy clinicians.
- Moreover, considering the inclusion of quality of life in routine clinical practice, patients will report higher involvement in their disease and consequently, higher satisfaction.
- By considering both the physician's and the patient's perspectives, increased alignment between patients' and physicians' treatment objectives and disease management expectations can be anticipated.

Conclusions

The VitaLES initiative offers an opportunity to standardize clinical practice and the measurement of SLE in moderate to severe patients in Spain by:

- **considering a holistic approach to the disease,**
- **taking into account not only the clinical aspects but also the patients' perspectives..**

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