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FLARES IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS

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10.1136/lupus-2017-000215.460

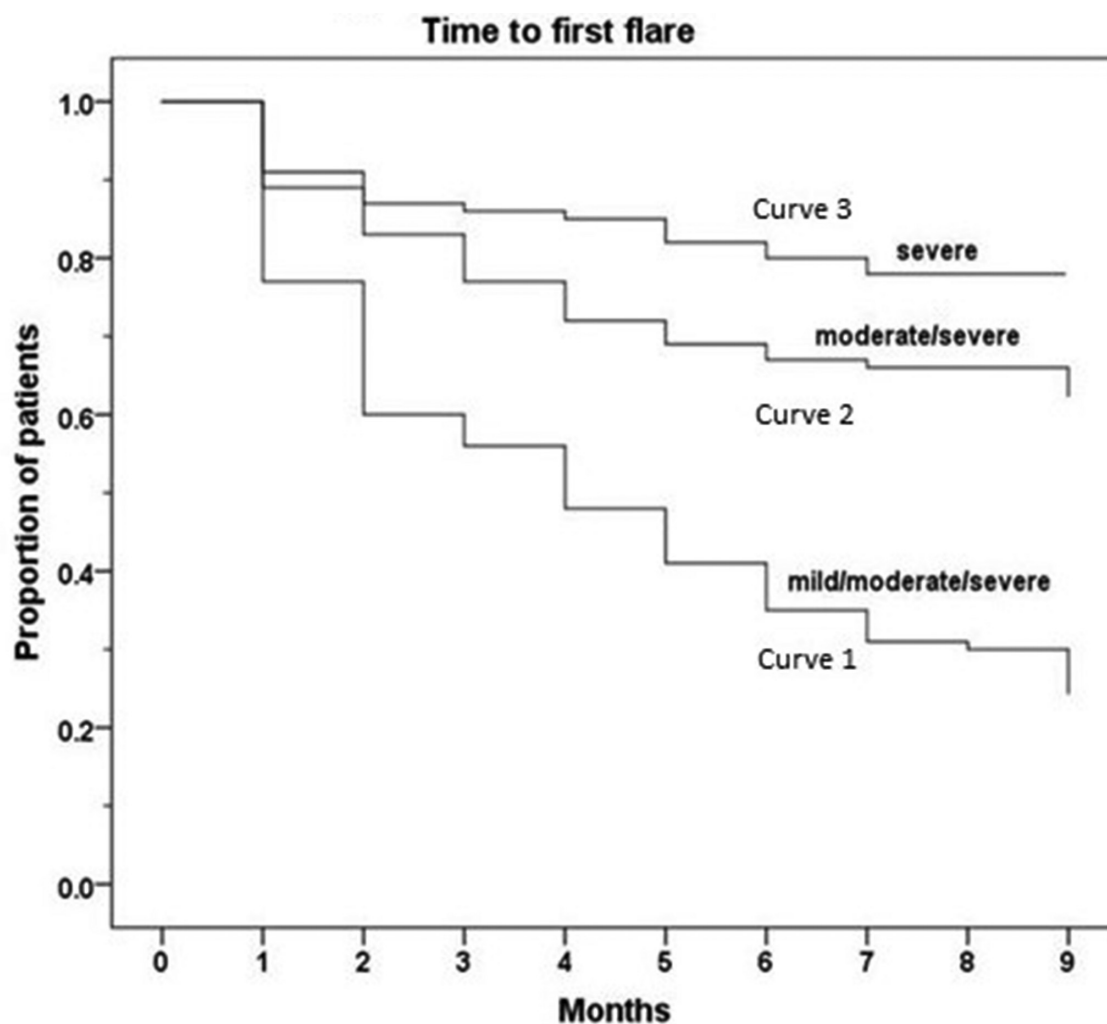
Background and aims Systemic lupus erythematosus (SLE) is characterised by relapses and remissions. This study describes the frequency, type and time to flare in a cohort of SLE patients.

Methods SLE patients with one or more “A” or “B” BILAG2004 systems meeting flare criteria (items that were “new” or “worse”) and requiring an increase in immunosuppressive therapy were recruited from nine UK centres and assessed at baseline and monthly for nine months. Flares were defined as: severe (“A” flare/s irrespective of number of “B” flares), moderate (2 or more “B” flares without any “A” flares and mild (one “B” flare).

Results Of the 100 patients, 94% were female, 61% white Caucasians, mean age (SD) was 40.7 years (12.7) and mean

Abstract 460 Table 1 Type and frequency of Flares.

| Types of Flares (using BILAG-2004 index) over nine months per patient (n=100) | Number of patients (n) |
|---|------------------------|
| Severe (Any As irrespective of Bs) | |
| Any severe flare | 22 |
| Only one severe flare | 15 |
| Multiple severe flares | 7 |
| Severe flares only (without moderate/mild flares) | 7 |
| Severe and Moderate Flares only | 0 |
| Severe and moderate and mild flares | 3 |
| Severe and Mild Flares only | 12 |
| Moderate (Two or more Bs without any A) | |
| Any moderate Flare | 19 |
| Only one moderate Flare | 12 |
| Multiple moderate Flare | 7 |
| Moderate Flares only (without severe/mild flares) | 2 |
| Moderate and Severe Flares only | 0 |
| Moderate and Severe and mild flares | 3 |
| Moderate and Mild flares only | 14 |
| Mild (one B) | |
| Any mild flare | 67 |
| Only one Mild flare | 36 |
| Multiple Mild flares | 31 |
| Mild Flares only (without severe/moderate flares) | 38 |
| Mild and Severe Flares only | 12 |
| Mild and Severe and Moderate | 3 |
| Mild and moderate Flares only | 14 |
| No Flares (no A or B scores) | |
| Patients with no A or B scores | 24 |



Abstract 460 Figure 1

disease duration (SD) 9.3 years (8.1). A total of 195 flares occurred in 76 patients over 781 monthly assessments, giving a flare rate of 0.25/month. There were 37 severe flares (22 patients), 32 moderate flares (19 patients) and 126 mild flares (67 patients) [Table 1]. The median time to any “A” or “B” flare was 4 months (95% CI 2.7 to 5.3 months). Figure 1 shows the time to the first mild/moderate/severe flare (Curve 1), moderate/severe flare (Curve 2) and severe flare (Curve 3). Table 2 shows that severe and moderate flares tend to be in the system/s affected at baseline whereas mild flares are more likely to affect any system.

Conclusions This real world cohort will share similarities with populations recruited to clinical studies so these results may inform future trial design.

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ASSESSING THE CONTENT VALIDITY OF THE SF-36, THE SKINDEX-29+3 PATIENT REPORTED OUTCOMES (PRO) INSTRUMENTS, AND PAIN, FATIGUE IN PATIENTS WITH CUTANEOUS LUPUS ERYTHEMATOSUS (CLE)

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10.1136/lupus-2017-000215.461

Background and aims Patients with CLE may experience symptoms, which can negatively impact their quality of life. The objectives of this study were as follows: 1) to investigate patient experiences associated with CLE, 2) to investigate the impact of living with CLE on patients’ lives, 3) to evaluate the content validity of the 36-item Short Form Health Survey (SF-36) and the Skindex-29+3 PRO instruments in the CLE population, and 4) to evaluate the appropriateness of a shorter recall period of 1 week instead of 4 weeks for the Skindex-29+3.

Methods This cross-sectional qualitative study utilised a combined concept elicitation (CE) and cognitive interview (CI) method. Study participants were recruited across three US clinical sites and interviewed one-on-one during a 90 min in-person interview. Interviews followed a semi-structured interview guide that elicited patient experiences with CLE and its impact on patients’ lives, followed by CI that assessed patients’ understanding and interpretation of each instrument.

Results Patients found these instruments to be readily understandable, interpreting items correctly and with minimal difficulty. Patients reported a one-week recall period for the Skindex-29+3 to be meaningful and easy to use, although many stated that their symptoms and experiences were felt over a longer period of time.