

Causes, Development and Management of Cutaneous Lupus Erythematosus

Carlos Linn*

Department of Clinical Medicine, University of Oxford, Oxford, United Kingdom

DESCRIPTION

Cutaneous Lupus Erythematosus (CLE) is a deforming skin disease that has a significant impact on Quality of Life (QoL). CLE can occur on its own or as a complication of SLE. While some treatments for CLE are helpful, many individuals remain resistant or cannot tolerate existing medications, necessitating the development of novel, safe, and effective treatments. Unfortunately, no drugs for CLE have been licensed in nearly 50 years. The dearth of validated CLE outcome metrics, as well as a concentration on SLE for novel medication development, have been important contributors to this. For years, the lupus scientific community has worked to reach a consensus on how to measure lupus disease severity outcomes, and a valid, reliable, and clinically relevant disease severity measure for CLE trials currently exists—the Cutaneous Lupus Erythematosus Disease Area and Severity Index (CLASI), which has been implemented in the most recent lupus trials.

On the other hand, Clinical and outcome research in CLE, remains difficult. First, in CLE trials, other indices of CLE disease seriousness were applied, resulting in significant variation in outcome reporting. Furthermore, various features of CLE other than clinician-reported disease severity may be valuable to investigators and patients, and have been included in trials in varying degrees, thus obscuring interpretation of data and comparing efficacy across CLE research. More broadly, without clear standards on which outcomes are essential and appropriate to monitor, clinical trial design and regulatory clearance of new treatments are problematic.

This has already slowed and continues to stymie product development. As a result, there is a requirement for agreement on the relevant outcomes and matching tools to use in CLE clinical research. These same concerns have been identified and addressed in other disease states through the introduction of Core Outcome Sets (COS), which are a minimum set of

outcomes that must be measured and reported in all clinical trials for a given condition. They include the outcomes (core domain set) as well as the instruments used to measure those outcomes or domains.

COS development would ideally involve extensive systematic literature reviews, solicitation of input from patients and other relevant stakeholders, and finally time, resource, and labor-intensive consensus exercises, as recommended by the COMET (Core Outcome Measures in Effectiveness Trials) Initiative.

These formal consensus attempts are vital and valuable, but they can take years to accomplish. There are already upcoming clinical trials and new therapeutics in the pipeline that would benefit greatly from additional guidance in trial design, outcome and measurement instrument selection, and such efforts cannot be postponed until formal consensus exercises can take place. Continuing without agreement or consensus, on the contrary, perpetuates the concerns and obstacles of CLE clinical research and may impede the discovery and approval of vitally needed new medicines for patients.

To improve CLE management, novel and effective treatments are required. However, the creation of potential pharmacological trials has been hampered by the sluggish adoption of established ways to evaluating CLE and a lack of agreement on the best outcome metrics to use. Works have been started on COS for CLE RCTs and LOS based on a multistage evaluation of CLE and SLE studies, in addition, expert input from the steering committee, to initially standardize outcomes and outcome metrics in CLE clinical research.

In conclusion, the core outcomes measured and measuring tools utilized in CLE clinical studies vary greatly, and many of the current measurement instruments have not been well-validated in patients with CLE. Importantly, the construction and implementation of a CLE COS will allow for enhanced CLE clinical study design and trial data synthesis.

Correspondence to: Carlos Linn, Department of Clinical Medicine, University of Oxford, Oxford, United Kingdom, E-mail: linnccarlos@gmail.uk

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