Association Between Patient-Reported Outcomes and Disease Activity in Systemic Lupus Erythematosus Patients: A Systematic Review

Citation

Manuel Ugarte-Gil, Gloria Vasquez, Concepcion Marañon, Ana María Blassini, Bernardo Pons-Estel, Guillermo Pons-Estel, Lucila Garcia, Diana Castaño, Roberto Muñoz-Louis, Miguelina Cordero, Teresandris Polanco, Martin Rodriguez, Laurent Arnaud. Association Between Patient-Reported Outcomes and Disease Activity in Systemic Lupus Erythematosus Patients: A Systematic Review. PROSPERO 2024 CRD42024500459 Available from: https://www.crd.york.ac.uk/prospero/display_record.php?ID=CRD42024500459

Review question

To evaluate the associations between several PROs and disease activity in SLE patients with a previously validated instrument.

Searches

PubMed (1946-January 2024), Cochrane Library (1985-January 2024), EMBASE (1974-January 2024), Virtual Health Library (VHL) (1998- January 2024), and SciELO (1997- January 2024)

Types of study to be included

We will include both observational studies (case-control, cross-sectional or cohort) and clinical trials on adults with SLE reporting the association between PROs and disease activity as ascertained by the physician using a validated instrument. The article should include at least one PRO and one disease activity measurement.

Condition or domain being studied

Systemic lupus erytemathosus, which is an autoimmune inflammatory disease that affects mainly women in childbearing age.

Participants/population

SLE patients older than 18 years.

Intervention(s), exposure(s)

We will evaluate the association between patient-reported outcome measures and physician-reported disease activity, to determine which patient-reported outcome measures are associated with disease activity. Patient-reported outcome measures include not only patient-reported disease activity, but also HRQoL, fatigue, work disability, among other measures.

Comparator(s)/control

As we are looking for correlation, we do not have an exposure/control group. We would have a correlation between variables.

Context

Studies will be excluded if published only in the form of congress abstracts.

Studies in humans published in English, French and Spanish will be included. Case reports, case series, reviews and animal studies will be excluded.

Main outcome(s)

Main outcome: physician-reported disease activity

Measures of effect

In each manuscript, we expect to found correlations between disease activity and PROs.

Due to the heterogeneity of the articles to be included and the diversity of PRO and disease activity scales and the various statistical tests performed, a meta-analysis might not be feasible for most of the variables; therefore, studies will be summarized using a narrative synthesis approach.

Additional outcome(s)

None

Data extraction (selection and coding)

Two reviewers will screen independently all articles and apply the eligibility criteria to identify appropriate studies for inclusion; the reviewers will then independently extract data using a predetermined form. Information will be collected on the study characteristics (study design, country, sample size), the number of participants, gender, age, PROs (health-related quality of life, fatigue, etc) and disease activity as assessed by the patient and by the physician using a validated instrument.

Risk of bias (quality) assessment

The quality of the studies identified will be assessed using the Newcastle-Ottawa Scale (NOS) for case-control and cohort studies; this scale has been specifically developed to assess the quality of observational studies (10). The scoring system covers three major domains: selection of cases and controls (maximum 3 points), comparability of selected groups (maximum 2 points) and ascertainment of either the exposure or outcome of interest (maximum 3 points): the resulting score may range between 0 to 8, a higher score representing a better methodological quality. While there is no validated cutoff value to discern between studies of good or poor quality, studies with a score of ≥ 7 will be arbitrarily defined as being of high quality.

Strategy for data synthesis

Due to the heterogeneity of the articles to be included and the diversity of PRO and disease activity scales and the various statistical tests performed, a meta-analysis might not be feasible for most of the variables; therefore, studies will be summarized using a narrative synthesis approach.

Analysis of subgroups or subsets

We would analyze each PRO independently, so, the subgroups will be made based on the PRO used, and not on a specific characteristic of the population.

Contact details for further information

Manuel Ugarte-Gil

mugarte@cientifica.edu.pe

Organisational affiliation of the review

Universidad Científica del Sur

https://www.cientifica.edu.pe

Review team members and their organisational affiliations

Dr Manuel Ugarte-Gil. Universidad Científica del Sur

Professor Gloria Vasquez. Universidad de Antioquía

Dr Concepcion Marañon. Government Centre for Genomics and Oncological Research (GENYO)

Dr Ana María Blassini. Universidad Central de Venezuela

Professor Bernardo Pons-Estel. Centro Regional de Enfermedades Autoinmunes y Reumáticas (GO-CREAR),

Dr Guillermo Pons-Estel. Centro Regional de Enfermedades Autoinmunes y Reumáticas (GO-CREAR),

Dr Lucila Garcia. HIGA General San Martin

Dr Diana Castaño. Universidad de Antioquia

Dr Roberto Muñoz-Louis. Hospital Docente

Miguelina Cordero. Hospital Docente

Teresandris Polanco. Hospital Docente

Dr Martin Rodriguez. Universidad Central de Venezuela

Professor Laurent Arnaud. University Hospitals of Strasbourg and French National Reference Center for Rare Autoimmune Diseases (RESO)

Type and method of review

Narrative synthesis, Systematic review

Anticipated or actual start date

01 March 2024

Anticipated completion date

30 September 2024

Funding sources/sponsors

None

Conflicts of interest

None known

Language

English

Country

Argentina, Colombia, Dominican Republic, France, Peru, Venezuela

Stage of review

Review Ongoing

Subject index terms status

Subject indexing assigned by CRD

Subject index terms

MeSH headings have not been applied to this record

Date of registration in PROSPERO

08 February 2024

Date of first submission

28 January 2024

Stage of review at time of this submission

The review has not started

Stage	Started	Completed
Preliminary searches	No	No
Piloting of the study selection process	No	No
Formal screening of search results against eligibility criteria	No	No
Data extraction	No	No
Risk of bias (quality) assessment	No	No
Data analysis	No	No

The record owner confirms that the information they have supplied for this submission is accurate and complete and they understand that deliberate provision of inaccurate information or omission of data may be construed as scientific misconduct.

The record owner confirms that they will update the status of the review when it is completed and will add publication

details in due course.

Versions

08 February 2024

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