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Therapeutic Guidelines for Latin American Lupus Patients

Methodology

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BACKGROUND

Modern medicine is in a continuous state of flux given the relentless development of new evidence; thus, it is quite difficult for clinicians to remain abreast of all advances as they happen. Trustworthy clinical practice guidelines (CPGs) rigorously developed following a transparent methodology (http://www.gradeworkinggroup.org/) and including the best available evidence represent one of the best solutions to overcome these problems.[1,2]

Systemic lupus erythematosus is a complex multisystemic autoimmune disease. Limited epidemiological data on lupus are available in Latin America. In 1 study conducted in Argentina, the estimated prevalence of systemic lupus erythematosus was of 47 to 98 cases per 100,000 inhabitants.[3] Because of the impact that ethnicity and poverty have on its presentation, activity, severity, and mortality,[4] it is essential to develop guidelines for these patients.

OBJECTIVE

The aim was to describe the methodology used by GLADEL (Grupo Latino Americano De Estudio del Lupus) and PANLAR (Pan American League of Associations of Rheumatology) to develop guidelines for Latin American lupus patients.

METHODS

Guideline Process

Two main groups were involved: the GLADEL/PANLAR group, which coordinated the logistics and selected the guideline panel, and the Consulting Core Methods Group (Hospital Alemán, Buenos Aires, Argentina), which conducted the methodological work.

Selection of Guidelines Panel and Chapter Distribution

GLADEL/PANLAR established a working structure for the development of these guidelines. A careful selection of potential coordinators and participants was based on strict criteria including clinical experience, publications' record, and willingness to participate. Each coordinator had a balanced team with rheumatologists from different Latin American countries representing GLADEL/

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on behalf of the Grupo Latino Americano De Estudio del Lupus (GLADEL) and Pan American League of Associations for Rheumatology (PANLAR).

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The authors declare no conflict of interest.

M.H.C., E.R.S., E.S.D.O.B., G.S.A., and A.I. have contributed equally to this work; they should all be considered first authors.

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PANLAR centers. The 13 topics selected for the review of the evidence were musculoskeletal, cutaneous, renal, cardiovascular, pulmonary, hematological, neuropsychiatric, ophthalmic, gastrointestinal, lupus and pregnancy, pediatric lupus, antiphospholipid syndrome, and comorbidities. Finally, an external committee consisting of 3 international reviewers and another one of patients were established. In all, 93 individuals were involved in the process.

Conflict of Interest

All participants completed a conflict of interest form (forms available on the online version of this article).

Question Development

The panel members framed up to 5 questions for each topic in the PICO (patients, interventions, comparison and outcome) format.[5] All questions were included in a document that was circulated to all members and discussed during the first face-to-face guideline panel meeting, held April 11, 2016 in Panama City, Panama. During that meeting, the panel generated the final questions to be addressed in the CPG, prioritized the subpopulations, and selected the outcomes to consider when making recommendations.

Evidence Retrieval

The Core Methods Group used several methods to retrieve evidence to address the guidelines questions. For evidence on benefits and harms, randomized controlled trials and observational studies (in cases where evidence provided by randomized controlled trial was scarce) were used. For evidence on patient values and preferences, qualitative studies were used. Special emphasis was placed in studies conducted in Latin America. The methods group used a rapid staggered search strategy. In the first stage, the search "lupus" or "lupic" was directed at identifying CPG and systematic reviews using PubMed, Epistemonikos, Trip database, and Google Scholar without time restrictions. Studies so identified were retrieved. In the second stage, the Epistemonikos matrices of evidence tool[6] were used to identify additional systematic reviews that could have been missed in stage 1. In the third stage, the search was directed to (1) identifying primary studies not included in systematic reviews or guidelines and (2) identifying additional publications that could be relevant to decision making (i.e., qualitative research on patients' values and preferences); it was performed in PubMed and Google Scholar, and time restrictions were placed based on the previous results. In the fourth stage, the search was directed at identifying additional studies that could have been missed in the previous stages, specifically for clinical scenarios and comparisons in which the evidence identified in the previous stages was scarce. For this purpose, more specific tailored search strategies using terms included in the PICO questions were developed. The searches were performed in PubMed and Google Scholar. Specific databases (such as SCIELO) covering Latin American publications in Spanish or Portuguese were not searched directly but rather via Epistemonikos and Google Search, which would have identified any relevant work from the region.

Evidence Synthesis and Quality Grading

Details of eligible studies and systematic reviews were abstracted and synthesized quantitatively (whenever possible) or narratively. Based on them, the Methods group prepared tables summarizing the available evidence supporting each recommendation using the GRADE (Grading of Recommendations Assessment, Development and Evaluation) approach.[7,8] The quality of the evidence (certainty in the effect estimates) was rated as high, moderate, low, or very low,[9] taking into consideration factors that may downgrade risk of bias,[10] indirectness,[11] inconsistency,[12] imprecision,[13] and publication bias[14] or upgrade the quality of the evidence.[15]

From Evidence to Recommendations

Recommendations in response to all the proposed questions were constructed in a second face-to-face guideline panel meeting held November 11, 2016, in Washington, DC. For all guidelines' questions, evidence to decision frameworks was developed following the GRADE approach.[16,17] Information extracted about benefits and harms, patient values and preferences, resources, acceptability, and feasibility was summarized in each decision framework during that meeting. In formulating the recommendations, the panel considered the balance between the desirable and undesirable consequences of an intervention, the certainty of the evidence, the variability in patient values and preferences, acceptability, feasibility, and resource use issues. The panel had an option to grade recommendations as strong for or against the intervention when moderate or high certainty detected in attributing desirable effects was much greater than undesirable effects or vice versa, or as conditional (weak) for or against the intervention when desirable and undesirable effects were balanced or low or very low certainty when no attribution could be made.[16,17] Additional considerations around research, implementation, and monitoring were also discussed. The Core Methods Group recorded the panel's discussions and decisions, ultimately creating a final unabridged guideline report for approval (Fig.).

CONCLUSIONS

We followed a transparent and structured process that will provide readers in addition to practical guidance the information needed to understand how these recommendations were developed.

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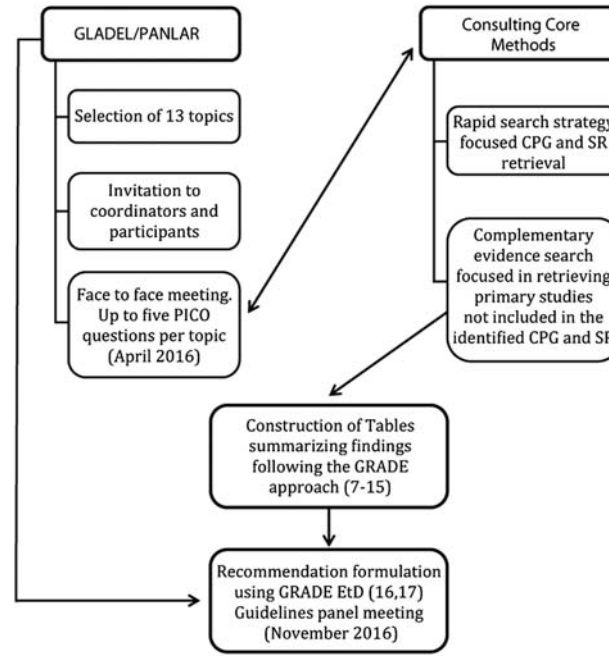

FIGURE. Methodology diagram. EtD indicates evidence to decision; SR, systematic reviews.

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APPENDIX A

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