



Review

International and multidisciplinary expert recommendations for the use of biologics in systemic lupus erythematosus



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ABSTRACT

Background/purpose: Despite conventional immunosuppressants, active and steroid-dependent systemic lupus erythematosus (SLE) represents a therapeutic challenge. Only one biologic, belimumab, has been approved, but other biologics are sometimes used off-label. Given the lack of evidence-based data in some clinical situations encountered in real life, we developed expert recommendations for the use of biologics for SLE.

Methods: The recommendations were developed by a formal consensus method. This method aims to formalize the degree of agreement among experts by identifying, through iterative ratings with feedback, the points on which experts agree, disagree or are undecided. Hence, the recommendations are based on the agreed-upon points. We gathered the opinion of 59 French-speaking SLE experts from 3 clinical networks dedicated to systemic autoimmune diseases (FLEUR, IMIDIAE, FAI2R) from Algeria, Belgium, France, Italy, Morocco, Switzerland and Tunisia. Represented medical specialities were internal medicine (49%), rheumatology (34%), nephrology (7%), dermatology (5%), pediatrics (3%) and cardiology (2%). Two methodologists and 3 strictly independent SLE expert groups contributed to developing these recommendations: a steering group (SG) ($n = 9$), an evaluation group (EG) ($n = 28$) and a reading group (RG) ($n = 22$). Preliminary recommendations were drafted by the SG, then proposed to the EG. Each EG member rated the degree of agreement from 1 to 9 (1: lowest; 9: strongest) for each recommendation. After 2 rating rounds, the SG submitted a new version of the recommendations to the RG. With comments from the RG, the SG finalised the recommendations.

Results: A total of 17 final recommendations were formulated by the SG, considering all agreement scores and comments by the EG and RG members and the two methodologists. These recommendations define the subset of patients who require a biologic; the type of biologics to use (belimumab, rituximab, etc.) depending on the organ involvement and associated co-treatments; what information should be given to patients; and how to evaluate treatment efficacy and when to consider discontinuation.

Conclusion: Overall, 17 recommendations for the good use of biologics in SLE were formulated by a large panel of SLE experts to provide guidance for clinicians in daily practice. These recommendations will be regularly updated according to the results of new randomized trials and increasing real life experience.

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