Patient-Reported Outcomes in Systemic Lupus Erythematosus

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KEYWORDS

- Systemic lupus erythematosus (SLE, lupus) • Quality of life (QoL)
- Patient-reported outcomes (PROs)

KEY POINTS

- Successful management of complex conditions such as systemic lupus erythematosus (SLE) and comorbid conditions benefit significantly from patient-reported outcomes (PRO) instruments.
- Measuring health-related quality of life provides SLE patients with an opportunity to participate in their treatment and to facilitate better communication with the multidisciplinary team involved in care.
- Health outcomes research has produced a number of well-validated instruments that can be used across diseases; some have been specifically developed for SLE.
- The use of a generic or SLE-specific PRO depends on specific needs, including population monitoring, treatment decision making, clinical trials research, and for evaluating and comparing the effect of therapies.

INTRODUCTION

Systemic lupus erythematosus (SLE) is a chronic inflammatory autoimmune disorder with variable multi-system involvement. The survival of patients with SLE has significantly improved but like many chronic diseases, there is currently no cure, and morbidity and mortality remain high.[1] Treatment of more severe cases of SLE often involves a balance between managing the manifestations of the disease and minimizing the treatment-related side effects. The disease has a significant impact on many aspects of patients' lives and their overall well-being, or health-related quality of life

All authors have no conflicts of interest and have nothing to disclose.
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Rheum Dis Clin N Am 42 (2016) 253–263
http://dx.doi.org/10.1016/j.rdc.2016.01.001 **rheumatic.theclinics.com**
0889-857X/16/$ – see front matter

(HRQOL) because SLE affects a relatively younger age group and improved survival has translated into longer disease duration.[1–3] Therefore, patients with SLE must cope with a significant disease burden imposed by the numerous symptoms of the disease itself and its treatment, including fatigue, pain, sleep disturbance, renal and skin problems, and neurologic/psychiatric conditions (eg, anxiety, depression, headaches, motor/sensory deficits, seizures, cognitive impairment, neuropathy).[4–10] Increasing attention to comorbidities of patients with SLE, which themselves add to the burden of the disease, has a substantial impact on patient outcomes and HRQOL.[4,11]

Successful management of complex conditions such as SLE and comorbid conditions can benefit significantly from patient-reported outcomes (PRO) instruments that validly and precisely measure the relevant aspects of health status (eg, symptoms) and HRQOL. Physicians focus on disease activity and damage as their primary therapeutic goal[12]; however, there is a mixed literature with regard to the relationship between disease activity or organ damage and changes in HRQOL in patients with SLE.[13–20] Discordant perspectives between patient and provider when assessing disease burden and activity can result in treatment nonadherence, treatment interruptions, and misunderstandings in communication between patients and providers.[21–23] PROs can have a critical role in clinical trials and clinical care assessments because PROs provide relevant yet complementary information to disease activity and damage indices when it comes to prioritizing treatment decisions, managing symptoms, formulating interventions, providing a complete approach to the management of the disease, and possibly justifying the considerable costs of new therapies. HRQOL measures have been recommended for inclusion in core datasets for observational studies and clinical trials by Outcome Measures in Rheumatoid Arthritis Clinical Trials (OMERACT).[24,25] Further, measuring HRQOL and other aspects of health status (eg, symptoms, functioning) with PROs provides patients with an opportunity to participate more fully in their treatment and ultimately facilitate better communication with the multidisciplinary team of health professionals involved in their care.[13] We review both generic and SLE-specific PRO instruments and their use in patients with SLE herein.

GENERIC PATIENT-REPORTED OUTCOME INSTRUMENTS

Generic PRO tools have been used to assess HRQOL in SLE patients, including the Medical Outcomes Study Short Form 36 (SF-36)[26,27] and EuroQoL-5 Dimensions (EQ-5D).[28,29] Although these tools allow HRQOL comparisons between SLE patients and other patients with rheumatic and nonrheumatic diseases, some limitations in assessing SLE-specific outcomes exist.

The SF-36 is among the most widely used generic PRO tool in SLE studies. The 36-item questionnaire evaluates 8 separate HRQOL domains (physical functioning, general health, mental health, vitality, role physical, role emotional, bodily pain, and social functioning) and includes 2 summary scores (the physical component score and the mental component score).[26] Two versions of the SF-36 are available to evaluate health status in 1- or 4-week intervals. The questionnaire is scored from 0 (worse health) to 100 (better health). The SF-36 was originally validated in an SLE sample from the UK and found to have favorable psychometric properties including good internal consistency, criterion validity compared with the Medical Outcomes Study Short Form 20+ (SF20+), good discriminant validity compared with a British control population, and construct validity in comparisons with the British Isles Lupus Activity Group score,[27] but an inverse association with disease