demonstrated utility for lupus patients with joint, skin and renal disease. It is likely that other biologics identified more recently, such as anifrolumab, will have a part to play for those lupus patients for whom standard drugs are insufficient.⁵ These changes will not happen today, tomorrow or next year, but in the next decade I predict that the majority of lupus patients will be treated with biologic drugs and newer treatment modalities.

Learning Objectives

- Explain the need for new biologic treatments for patients with lupus, for whom standard drugs have failed
- Describe the importance of embracing new evidence-based treatments including small molecules and biologics, for the numerous disease manifestations that characterise lupus
- Discuss the role of biologic therapies in future treatment of patients with lupus

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03

DEBATE: A MINORITY OF LUPUS PATIENTS (WILL) NEED A BIOLOGIC!

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10.1136/lupus-2020-la.3

Obviously, the expected role for biologic therapy in lupus is to control disease activity and prevent damage and co-morbidities, but what is the evidence that we are not faring well in those areas?

Over the past 5 decades there has been a dramatic improvement in survival rates for patients with systemic lupus erythematosus (SLE) perhaps due to a combination of earlier diagnosis, more effective treatments, recognition of important comorbidities and their earlier diagnosis and treatment. Currently, the 20-year survival rate is 80%!^{1 2} Standardised Mortality Ratios have decreased from over 14 in the 1970s to just over two in the 2000s.³ Furthermore, the cause of the 206 deaths in our cohort due to lupus was only 19% whereas deaths from atherosclerotic disease was 21.5% and from infection 34.6% neither of which would require a biologic.⁴ In terms of disease activity, in the first decade of disease the adjusted mean Systemic Lupus Erythematosus Disease Activity Index-2K (AMS) has decreased from 7.94 in the 1970s to 5.16 in the 2000s and the percentage of time on prednisone >7.5 mg was significantly lower, all indicating much improved control of disease. This is corroborated by the fact that patients are spending a

significant portion of their disease over the first 10 years in clinical remission.

So, if patients are surviving longer with less active disease and lower steroid therapy, are they suffering more co-morbidities? The prevalence of atherosclerotic vascular events has similarly declined over the past 4 decades in our cohort from a prevalence from 11.0% to 3.8% (an incidence of 0.44 per 100 patient years) an incidence seen also in the SLICC cohort.⁵ This dramatic decrease is due to better control of lupus disease activity and also treatment of atherosclerotic risk factors.

Finally, when one looks at the randomised controlled trials with biologics in lupus, more than a third of the placebo-treated patients who were getting standard of care achieved their respective primary endpoints. The difference in outcome in those getting biologics was only in the range 10% greater, hardly a major impact.

In summary, lupus is being much better controlled, less steroid is being used, co-morbidities are less and biologics to date have had a minimal impact. A Minority of Lupus Patients Will Need a Biologic!

Learning Objectives

- Describe how lupus survival has improved dramatically in past 5 decades
- Explain how mortality in lupus is now less related to lupus and more related to co-morbidities or infection
- Demonstrate that lupus patients are currently spending more of their time in remission and on less corticosteroids
- Show that the major co-morbidity atherosclerotic vascular disease has decreased dramatically

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Plenary I: New Aspects in the Management of SLE

04

MEASURING SLE DISEASE ACTIVITY IN 2020: PERSPECTIVES FROM CLINICAL RESEARCH

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10.1136/lupus-2020-la.4

Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with heterogeneous clinical presentation and disease course. It can involve many organ systems with widely diverse clinical patterns in different patients and over time. Furthermore, there are no reliable biomarkers for monitoring the disease course. As a result, measuring SLE disease is highly challenging and there is a lack of user-friendly,

sensitive and accurate disease activity measures. This is a top barrier, both for treat-to-target management of SLE patients in clinical practice, as well as in clinical trials for new SLE treatments.^{1 2}

The Physician's Global Assessment (PGA) is a pragmatic disease activity measure, using a 100 mm visual analogue scale (VAS) for physicians to quantify the patient's overall disease activity in a 0–3 range. The PGA is sensitive to change, but it requires an experienced physician to use it reliably and consistently in the follow-up of individual patients; furthermore, it has a high interobserver variability. Despite these pitfalls, the PGA is widely applied, including in the composite responder indexes used as primary outcome measure in SLE clinical trials (i.e. SLE Responder Index [SRI] and BILAG-Based Composite Lupus Assessment [BICLA]), the proposed definitions for clinical remission (e.g. DORIS), and low disease activity states (i.e. LLDAS).¹

The SLE Disease Activity Index (SLEDAI), with 24 items, is an extensively used disease activity measure, both in clinical practice and in clinical trials, where it is the driver of clinical response in the SRI. However, SLEDAI presents low sensitivity to change in disease activity – 14.9–47.4% for improvement and 26.2–59.1% for worsening.^{3 4} As a result, usefulness of SLEDAI for guiding treatment decisions in clinical practice is limited. Furthermore, its use for defining responders with the SRI leads to low efficiency of clinical trials.¹

The BILAG is an organ-based instrument that classifies disease activity separately in nine organ-systems and includes 97 items. Due to its high complexity it is not widely used in clinical practice. It is a component of SRI and BICLA. However, it consolidates all features within an organ-system into a single score and thresholds defined for category change impede interpretation. In SRI it is applied only to guarantee specificity of clinical response that is defined by a 4-point decrease in the SLEDAI. The usefulness of BILAG in SRI is unclear, as SLEDAI shows a specificity for change over 90% and in clinical trials few patients improving in SLEDAI presented deterioration in BILAG.^{1 3 4}

The SLE Disease Activity Score (SLE-DAS) is a recently validated 17-item composite index with continuous measurement properties. As compared to SLEDAI-2K, the SLE-DAS presented higher accuracy in measuring SLE disease activity and better sensitivity-to-change, as well as higher predictive value for damage accrual.⁵ Advantages of SLE-DAS include its continuous nature and the inclusion of important disease activity features absent from SLEDAI. Ongoing research suggests that SLE-DAS can accurately define clinical remission, low disease and active disease categories, with a more practical definition compared to other instruments.

Learning Objectives

- Identify unmet needs for measuring SLE disease activity in clinical practice and clinical trials
- Understand the strengths and pitfalls of instruments to measure SLE disease activity
- Apply at each clinical context the most appropriate instrument for measuring disease activity

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05

LIFESTYLE FOR LUPUS PATIENTS: EXERCISE, DIET, AND WELL-BEING: PERSPECTIVES FROM CLINICAL PRACTICE

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10.1136/lupus-2020-la.5

As systemic lupus erythematosus (SLE) is a chronic condition with a significant impact on physical and mental health, all potential interventions to improve quality of life are relevant for SLE patients.

Among the possible non-pharmacological interventions, exercise and diet have a pivotal role.^{1 2} For SLE patients aerobic exercise programs are safe and effective on improving aerobic and functional capacity, in addition to tolerance to exercise. Physical activity enhances cardiovascular well-being in SLE patients by reducing their body weight and waist circumference, while improving their maximum oxygen consumption, endothelial function and insulin sensitivity. Moreover, several studies also suggest a reduction in fatigue and a beneficial effect of exercise on depression, anxiety, pain, poor-quality sleep and, more generally, on health-related quality of life (HRQoL).

Diet can have a role in reducing modifiable cardiovascular risk factors; a benefit on SLE activity and HRQoL is also reported. The most robust evidence is available for polyunsaturated fatty acids enriched diets; however, we cannot draw definitive conclusions on whether there is any kind of diet that is better than another for SLE patients. Patients with SLE who smoke have an increased risk of disease flare, particularly skin manifestations, a poorer HRQoL and a reduced response to antimalarial drugs. The more intense and the longer tobacco consumption is the higher the risk of poor control of disease activity. Therefore, these facts can provide additional motivation for patients to stop smoking.

Alongside clinical advantages, evidence-based activities promoting healthy lifestyles could contribute both to patient empowerment in disease self-management and to the sustainability of public health services.

Learning Objectives

- Describe the link between lifestyles, disease activity and long-term outcomes in SLE
- Discuss the current state of studies on non-pharmacological interventions in SLE

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