Development of a Conceptual Model to Understand Disease Burden in Patients with Systemic Lupus Erythematosus and Long-Term Organ Damage

POS0739

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Introduction

- SLE is a chronic, multisystem, autoimmune disease resulting in increased morbidity and mortality, and reduced HRQoL[1,2,3]
- Patients with SLE are at risk of developing irreversible OD caused by disease activity and cumulative medication toxicities[1,4]
- The overall disease burden and impact of OD in patients with SLE is not well documented

Objective

- To develop a conceptual model to describe the burden experienced by patients with OD associated with SLE

Methods

- This qualitative study (209754) was carried out in three distinct phases:

1. Targeted literature review

- Identified articles (n=71), using PubMed and the Lupus Science and Medicine database, that described conceptual models of SLE, disease and economic impact of SLE-associated OD, and treatment benefits
- Findings from the targeted literature review were used to inform development of the draft conceptual model, and KOL and patient interview guides

2. Interviews with KOLs experienced in working with patients with SLE-associated OD

- 60-minute, semi-structured telephone interviews to assess clarity, language, comprehensibility, and potential use of the conceptual model
- Interview data were coded and analysed; the conceptual model was updated following evaluation of KOL feedback using a consensus-based approach by the study team. KOL feedback also informed development of patient interview materials

3. Interviews with patients diagnosed with SLE and OD

- Key inclusion criteria: able to provide written informed consent; ≥18 years of age; living in the US and fluent in written/spoken US-English; damage in ≥1 organ system as defined by the SDI; confirmed diagnosis of SLE-associated OD and organ involvement
- 60–75-minute, semi-structured telephone interviews to gather symptoms, impacts, treatment experiences, and HRQoL factors associated with OD
- Interview data were coded and analysed; results were used to finalise the conceptual model
- All study materials were reviewed and approved by the New England Independent Review Board *(NEIRB number 120190518)*

Results

Targeted literature review

- Indicated that the conceptual model should: **(1)** include overall impacts of SLE and disease/economic impacts of OD; **(2)** show relationship between SLE/OD and different treatments; **(3)** incorporate overall treatment goals, clinical outcomes and treatment targets

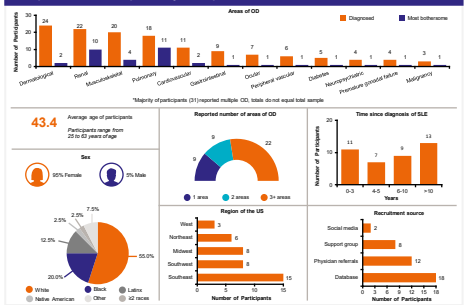
KOL interviews (5 clinicians and 1 patient advocacy leader)

- The preliminary conceptual model broadly captured KOLs' experience of working with patients with SLE-associated OD
- KOLs emphasised that the model needed to be updated to convey that impacts of OD are more severe than SLE without OD, and likely to be permanent

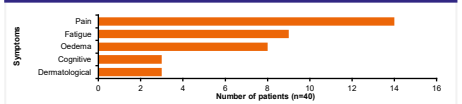
Patient interviews (40 patients)

- Almost all patients (39/40) reported emotional impacts of OD; these included anxiety, depression, frustration and worrying about the future
- All patients reported impacts of OD on their social life/ability to socialise; 30/40 patients described how it has placed a strain on their relationships
- Typically characterised as "brain fog", 27/40 patients reported cognitive impairments (slower cognitive processing, forgetfulness, confusion, aphasia) that became more pronounced after their OD diagnosis
- Impacts of SLE-associated OD were more severe, debilitating and life threatening than those of SLE prior to OD onset
- Most patients (39/40) reported aspects of their lives that were more severely affected since their OD diagnosis; 18/40 identified the risk of sustaining damage in additional organ systems as a more severe impact

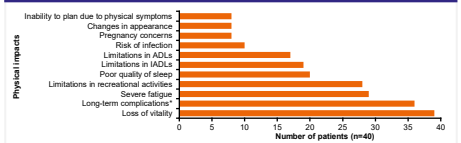
Multiple areas of OD reported by 31/40 patients



Three-quarters of patients with SLE reported symptoms as more severe since OD diagnosis



All patients described extreme daily physical impairment and reduced activity participation due to their OD



*e.g. unstable blood pressure, extreme pain, poor mobility, inflammation, dialysis, infection

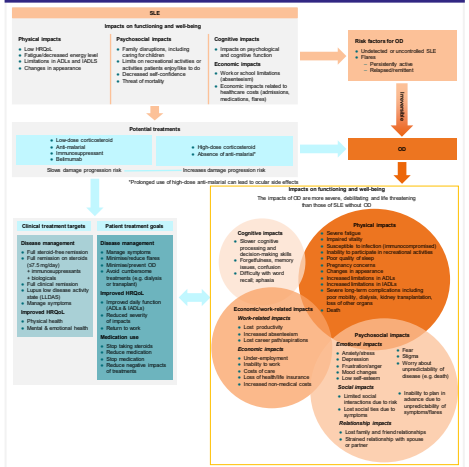
Patients' exemplary quotes of symptoms and impacts of OD

> "Fatigue is, is terrible...There are days when you wake up, you're okay, you're, you know, you're doing your thing and then, it just kind of hits you like a… ton of bricks. And, you're like, that's it. I'm done. I'm gonna go lay down, and nobody bother me. And that's just, kind of, how it goes. And you never know when this ton of bricks is gonna hit you."
>
> *Female, OD: dermatological, gastrointestinal, musculoskeletal, peripheral vascular, pulmonary*

> "It wasn't that much of an issue before the organs were involved, um, but I say that looking back, I mean at the time I felt terrible, but now that I… once I developed the organ damage I look back, I'm like oh I wish I could go back to then."
>
> *Female, OD: dermatological, musculoskeletal*

> "I did manage to keep working, you know, up until about 2010 and I just couldn't do it anymore. I just couldn't… And, you know, fortunately I managed to get my disability, a lot of people aren't able to do it and you know, it's… it's difficult but um, I got it and then that was a huge lifestyle change again for me… I'm in uh public housing so… there's no way that I could be able to live on my own, you know, out in the real world because it's too expensive… I don't know what I would do. You know, I get a whole whopping $16 in food stamps… that at times can be an issue because you know, you only have so much money to spend and then it's gone so… um… you know, it can be an issue sometimes."
>
> *Female, OD: gastrointestinal, peripheral vascular, pulmonary*

The final version of the conceptual model, reflecting learnings from both KOL and patient interviews



Conclusions

- Data from the literature, KOL and patient interviews were incorporated and refined into a comprehensive conceptual model that fully represents the patient experience of OD
- The findings of this study indicate that the patient burden of OD surpasses that of SLE without OD. This highlights a need to slow OD progression and ease physical impacts of OD
- The conceptual model will help researchers, clinicians and patients to better understand the impact of SLE-related OD progression and can be used to inform models and tools for evaluating treatment efficacy. This may lead to improved monitoring of management and treatment outcomes for patients

Abbreviations

ADL, activities of daily living; HRQoL, health-related quality of life; IADL, instrumental activities of daily living; KOLs, key opinion leaders; LLDAS, lupus low disease activity state; OD, organ damage; SDI, Systemic Lupus International Collaborating Clinics/American College of Rheumatology Damage Index; SLE, systemic lupus erythematosus; US, United States

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Disclosures

LB, AF and **CU** are consultants for GlaxoSmithKline (GSK). **WHC, RAL** and **DC** are employees of GSK and hold stocks and shares in the company.

Acknowledgements

This study was funded by GlaxoSmithKline (GSK Study 209754).

Medical writing support for poster development was provided by Casmira Brazaitis, PhD, of Fishawack Indicia Ltd, UK, part of Fishawack Health, and was funded by GSK.

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Poster presented at the EULAR 2021 E-Congress | 2–5 June 2021 | Online