1403 LONELINESS AMONG INDIVIDUALS LIVING WITH INFLAMMATORY RHEUMATIC DISEASES DURING THE LATER STAGES OF THE COVID-19 PANDEMIC

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Introduction Loneliness is prevalent among patients with inflammatory rheumatic diseases (IRDs), however the COVID-19 pandemic may intensify loneliness among patients with IRDs, as they are at higher risk of severe illness. Early evidence suggests that this was indeed the case during the early stages; however, it remains largely unknown whether loneliness remains present and what factors are associated. The objective of the present study was to identify risk and protective factors associated with loneliness in individuals living with IRDs in the later stage of the COVID-19 pandemic.

Methods Data from an online cross-sectional survey study of individuals with systemic lupus erythematosus (SLE) and rheumatoid arthritis (RA) between May 2022 and February 2023. Participants were recruited from a list of patients already enrolled in a multi-site longitudinal observation study. All participants provided informed consent. Loneliness was assessed with the University of California, Los Angeles Loneliness Scale (Version 3), Short Form 3-item (UCLA- LS3-SF3). The Impact of Event Scale-Revised (IES-R) assessed post-traumatic stress symptoms (PTSS) caused by the COVID-19 pandemic. The Patient Health Questionnaire-8 (PHQ-8) measured symptoms of depression. Resilience and concerns related to COVID-19 were also assessed. Descriptive statistics and linear regressions were conducted.

Results The study population was n = 160 (SLE = 102, RA = 58), mean age 60.1 years (±13) and 21.9% (n=35) were men. Almost one third (28.1%) reported moderate to severe loneliness. (UCLA-LS3-SF3 score ≥6), with statistically significant difference between both disease groups (SLE = 36.3%; RA= 13.8%). Among participants with SLE, gender (men), psychological burden from the COVID-19 pandemic, and higher depressive symptoms were independently associated with greater loneliness, accounting for 38% of the variance (table 1). Among individuals living with RA, identifying as female and greater psychological burden from the COVID-19 pandemic were independently associated with greater loneliness, accounting for 55% of the variance.

Discussion The results suggest that special attention to men with SLE and women with RA is needed when targeting loneliness in people with IRDs. More attention to strategies to decrease depressive symptoms and the psychological burden of the pandemic in patients living with IRDs are needed in future public health crises.

Abstract 1403 Table 1 Factors associated with loneliness during the later stages of the COVID-19 pandemic in people with IRDs

	Parameter	B1	p-value	95% C.I.	
				Lower	Upper
SLE	Age	.013	.877	−.022	.025
	Gender	**−.178**	**.032**	**-2.55**	**−.199**
	Psychological Burden of pandemic	**.212**	**.035**	**.002**	**.063**
	Covid-19 concerns	.062	.514	−.025	.050
	Depression	**.333**	**.002**	**.046**	**.208**
	Resilience	−.154	.136	−.903	.125
RA	Age	.022	.855	−.029	.035
	Gender	**.229**	**.032**	**.051**	**1.12**
	Psychological Burden of pandemic	**.380**	**.014**	**.010**	**.081**
	Covid-19 concerns	.240	.114	−.010	.087
	Depression	.109	.352	−.046	.127
	Resilience	−.170	.100	−.707	.063

[1]Standardized beta coefficients. CI = confidence interval.

Clinical

1501 LONG-TERM SAFETY OF BELIMUMAB AMONG ADULT PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS (SLE): POOLED DATA FROM THREE OPEN-LABEL EXTENSION STUDIES OVER 11+ YEARS

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Background Belimumab is approved for the treatment of SLE in >75 countries.[1] Clinical trials and long-term extension (LTE) studies have demonstrated the consistent safety profile of belimumab in patients with SLE receiving standard therapy (ST).[2–4] A pooled analysis of LTE studies could provide a more robust dataset to explore the long-term safety of belimumab.

Objectives To evaluate the long-term safety of belimumab in adult patients with SLE using pooled data from three multicentre, LTE studies.

Methods This post hoc analysis pooled data from three belimumab LTE studies: LBSL02 LTE (Phase 2; GSK Study 112626),[2] BLISS-76 LTE (included US patients only; Phase 3; GSK Study 112233),[3] and BLISS-52 + BLISS-76 LTE (excluding US patients from BLISS-76; Phase 3; GSK Study 112234).[4]Patients were eligible for LTE studies if they completed treatment through Week 72 (LBSL02 and BLISS-76 trials), or Week 48 (BLISS-52 trial). LBSL02 LTE also required an improvement in physician global assessment at Week 72 or 68 versus at first belimumab dose. From the start of each LTE, all enrolled patients received open-label belimumab

10 mg/kg intravenously every 28 days plus ST, regardless of study drug allocation in the double-blind phase of the trials. Adverse events (AEs) were assessed at each infusion visit and summarised (based on observed data) any time post baseline (first belimumab dose in prior trial or LTE), and in each year.

Abstract 1501 Table 1 Incidence of treatment-emergent AEs over time† (pooled safety population, N=1299)

n (%)	Any time post baseline‡ (N=1299)	Year 0–1 (N=1299)	Year 2–3 (N=1140)	Year 4–5 (N=867)	Year 6–7 (N=541)	Year 8–9 (N=175)	Year 10–11 (N=131)	Year 11+ (N=88)
AEs	1267 (97.5)	1168 (89.9)	907 (79.6)	631 (72.8)	361 (66.7)	160 (91.4)	105 (80.2)	45 (51.1)
Serious AEs	525 (40.4)	152 (11.7)	141 (12.4)	91 (10.5)	59 (10.9)	28 (16.0)	14 (10.7)	7 (8.0)
AEs resulting in study drug discontinuation	139 (10.7)	18 (1.4)	30 (2.6)	12 (1.4)	8 (1.5)	3 (1.7)	2 (1.5)	0 (0.0)
Deaths	21 (1.6)	3 (0.2)	3 (0.3)	2 (0.2)	2 (0.4)	0 (0.0)	0 (0.0)	0 (0.0)

†AEs occurred on or after first belimumab dose (in prior trial or LTE); post hoc data shown for every other year
‡Post-baseline data include follow-up visits. Data from Year 0 up to last visit in the treatment period are shown by years of study participation. Note: patients may be counted in ≥1-year intervals
AE, adverse event; LTE, long-term extension

Results In total, 1304 patients were enrolled into the three LTE studies and 1299 (99.6%) received ≥1 dose of study drug (pooled safety population). Cumulative belimumab treated patient-years was 7040.1. Overall, 604 (46.5%) patients completed their respective studies. The main reasons for withdrawal included 'withdrawal by patient' (18.3%) and 'AE' (10.6%).

In the pooled safety population, 1054 (81.1%) and 618 (47.6%) patients received steroids and immunosuppressants at baseline, respectively. Over 11+ years, 1267 (97.5%) patients had ≥1 AE (incidence generally decreased yearly; **table 1**), while 525 (40.4%) had ≥1 serious AE (SAE) and 139 (10.7%) experienced ≥1 AE resulting in study drug discontinuation (incidence of each was stable over time). By system organ class, infections and infestations were the most frequent AE, SAE, and AE resulting in study drug discontinuation. The most common AE of special interest was post-infusion systemic reactions (9.7 events per 100 patient-years). There were 21 (1.6%) deaths in total, 3 (0.2%) were considered possibly related to study drug (cardiogenic shock, lung infection pseudomonal, and pneumonia cytomegaloviral [all n=1]).

Conclusions Among a large, pooled population of patients with SLE treated with belimumab plus ST over 11+ years, the incidence of AEs generally decreased or remained stable over time. No new safety concerns were observed. This analysis was limited by use of a self- selected population that had not withdrawn from prior trials, and the open-label nature of the study.

REFERENCES

1. Levy RA, *et al*. *Lupus.* 2021;**11**:1705–1721
2. Wallace DJ, *et al*. *Arthritis Rheumatol.* 2019;**7**:1125–1134
3. Furie RA, *et al*. *Arthritis Rheumatol.* 2018;**6**:868–877
4. van Vollenhoven RF, *et al*. *Rheumatol.* 2020;**2**:281–291

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1502 LUPUS LOW DISEASE ACTIVITY STATE ATTAINMENT IN THE PHASE 3 PLACEBO-CONTROLLED TULIP LONG-TERM EXTENSION TRIAL OF ANIFROLUMAB

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Background The Lupus Low Disease Activity State (LLDAS) has been prospectively validated as protective from flares, damage accrual, and mortality and is an important treatment goal in patients with SLE. Recent analysis of pooled data from 2 phase 3 trials (TULIP-1 and TULIP-2) found that LLDAS attainment was achieved earlier, more frequently, and for a more sustained period with anifrolumab vs placebo in patients with moderate to severe SLE.

Aims and Objectives We investigated the long-term impact of anifrolumab compared with placebo on LLDAS attainment over the 1-year TULIP-1/TULIP-2 and 3-year long-term extension (LTE) study periods.

Methods TULIP-1 and TULIP-2 (NCT02446912, NCT02446899) were randomized, placebo- controlled, 52-week trials of IV anifrolumab (Q4W, 48 weeks) in patients with moderate to severe SLE despite standard therapy. Following the double-blind treatment period of the TULIP trials, patients could reconsent to participate in the 3-year, randomized, blinded, placebo-controlled LTE study (NCT02794285). Here, data were analyzed by timepoint from TULIP baseline through the end of the LTE (Week 208) for patients who were assigned and received the same study drug (anifrolumab 300 mg or placebo) during the TULIP+LTE periods. LLDAS attainment was defined as all of the following: SLEDAI-2K ≤4 without major organ activity, no new disease activity, Physician Global Assessment [0–3] ≤1, prednisone or equivalent ≤7.5 mg/day, standard immunosuppressant dosing, and no use of restricted medications (considered only during the pooled TULIP-1/TULIP-2 period but not during the LTE period).