LSO-068 ASSOCIATION BETWEEN ORGAN-SPECIFIC SAFETY OF ESTROGENS IN LUPUS ERYTHEMATOSUS NATIONAL ASSESSMENT-SYSTEMIC LUPUS ERYTHEMATOSUS (SLE) DISEASE ACTIVITY INDEX (SELENA-SLEDAI) RESPONSE TO BELIMUMAB AND SF-36V2 AND FACIT-FATIGUE SCORES IN PATIENTS WITH SLE

[1]Regina Rendas-Baum, [2]Wen-Hung Chen*, [3]Seth Anderson, [4]Christine Henning, [3]Anne Hammer, [1]Mark Kosinski. *[1]Consulting Science, QualityMetric, USA; [2]Value Evidence and Outcomes, GSK, UK; [3]Immunology Biostatistics, GSK, USA; [4]Global Medical Affairs, GSK, USA*

10.1136/lupus-2023-KCR.109

Background Limited data exist on quality of life (QoL) improvement in patients with SLE who were organ-specific responders per SELENA-SLEDAI. Here we explore the association between organ-specific SELENA-SLEDAI treatment response and 36-item Short Form Survey version 2 (SF-36v2) components and Functional Assessment of Chronic Illness Therapy-Fatigue (FACIT-Fatigue) scores in adults with SLE.

Methods This post hoc analysis (GSK Study 217382) used data from four belimumab trials (BLISS-52, NCT00424476; BLISS-76, NCT00410384; BLISS-SC, NCT01484496; EMBRACE, NCT01632241). Differences in mean changes in SF-36v2 and FACIT-Fatigue scores were compared with published group-level minimum important difference (MID; as defined in table 1) between responders (score decrease in those with baseline organ involvement) versus non-responders for each SELENA-SLEDAI organ domain. Mean score changes and change >MID were also compared between the treatment groups (belimumab [1 and 10 mg/kg intravenous and 200 mg subcutaneous] vs placebo) across SELENA-SLEDAI organ responders.

Results At baseline, BLISS-52, BLISS-76, BLISS-SC, and EMBRACE included 864, 818, 834, and 496 patients, respectively. As indicated in table 1, SELENA-SLEDAI central nervous system responders had better (defined as ≥group level MID) SF-36v2 Physical Functioning, Vitality, Mental Health, Mental Component Summary, and FACIT-Fatigue score changes than non-responders. Vascular responders had better SF-36v2 Bodily Pain, General Health Perceptions, Social Functioning, and Physical Component Summary score changes than non-responders. Hematologic responders had better SF-36v2 General Health Perceptions, Vitality, and FACIT-Fatigue score changes than non-responders. Cardiovascular and Respiratory responders had better FACIT-Fatigue score changes than non-responders. Across SELENA-SLEDAI organ systems, patients who were responders and treated with belimumab had a meaningfully better score change than placebo-treated patients on various SF-36v2 domains and/or the FACIT-Fatigue.

Abstract LSO-068 Table 1 Summary of differences between SELENA-SLEDAI organ system responders* and non-responders in mean QoL score change (baseline to Week 52).* Responder defined as a patient with decrease from baseline in SELENA-SLEDAI score at a post-baseline visit. †BLISS-52, NCT00424476; BLISS-76, NCT00410384. ‡BLISS-52, NCT00424476; BLISS-76, NCT00410384; BLISS-SC, NCT01484496; EMBRACE, NCT01632241. Note: Differences in mean score changes ≥MID are indicated in bold; statistically significant (p<0.05) differences between organ responders and non-responders are in grey. R, responder; NR, non-responder

SF-36v2†	Cardiovascular and respiratory (R, n=54; NR, n=19)	Central nervous system (R, n=21; NR, n=14)	Hematologic (R, n=69; NR, n=53)	Immunologic (R, n=252; NR, n=813)	Mucocutaneous (R, n=674; NR, n=418)	Musculoskeletal (R, n=586; NR, n=284)	Renal (R, n=119; NR, n=70)	Vascular (R, n=61; NR, n=22)
Physical Functioning (MID=3)	−1.6 (p=0.438)	**4.1 (p=0.173)**	0.6 (p=0.710)	0.4 (p=0.527)	1.7 (p=0.002)	1.7 (p=0.011)	−0.6 (p=0.661)	2.6 (p=0.190)
Role Limitations due to Physical Health (MID=3)	1.0 (p=0.691)	1.5 (p=0.750)	2.2 (p=0.213)	0.1 (p=0.940)	0.9 (p=0.115)	1.2 (p=0.080)	1.3 (p=0.397)	0.7 (p=0.765)
Bodily Pain (MID=3)	1.8 (p=0.502)	−1.2 (p=0.751)	2.9 (p=0.141)	0.3 (p=0.661)	1.8 (p=0.005)	2.8 (p<0.001)	−2.0 (p=0.250)	**4.6 (p=0.070)**
General Health Perceptions (MID=2)	−1.2 (p=0.554)	−1.7 (p=0.622)	**3.2 (p=0.041)**	0.8 (p=0.197)	1.7 (p<0.001)	1.9 (p=0.001)	1.0 (p=0.446)	**5.2 (p=0.021)**
Vitality (MID=2)	1.1 (p=0.720)	**3.3 (p=0.388)**	**2.7 (p=0.183)**	−0.1 (p=0.875)	1.3 (p=0.037)	0.6 (p=0.394)	0.9 (p=0.501)	1.5 (p=0.548)
Social Functioning (MID=3)	−1.6 (p=0.596)	2.2 (p=0.637)	−0.5 (p=0.836)	−0.0 (p=0.995)	1.8 (p=0.011)	1.5 (p=0.065)	−0.2 (p=0.882)	**3.0 (p=0.233)**
Role Limitations due to Emotional Problems (MID=4)	1.9 (p=0.533)	−1.5 (p=0.742)	3.2 (p=0.134)	1.1 (p=0.218)	2.1 (p=0.005)	*2.5 (p=0.004)*	2.3 (p=0.169)	0.0 (p=0.999)
Mental Health (MID=3)	0.9 (p=0.756)	**6.1 (p=0.169)**	2.0 (p=0.295)	−0.2 (p=0.776)	1.9 (p=0.002)	2.1 (p=0.006)	2.7 (p=0.051)	2.3 (p=0.361)
Physical Component Summary (MID=2)	0.3 (p=0.894)	−0.2 (p=0.932)	1.9 (p=0.222)	0.5 (p=0.425)	1.2 (p=0.019)	1.5 (p=0.010)	−1.5 (p=0.254)	**3.4 (p=0.069)**
Mental Component Summary (MID=3)	1.0 (p=0.755)	**3.9 (p=0.374)**	2.4 (p=0.203)	0.2 (p=0.791)	2.0 (p=0.003)	1.8 (p=0.018)	**3.0 (p=0.024)**	1.5 (p=0.541)
	Cardiovascular and respiratory (R, n=114; NR, n=94)	**Central nervous system (R, n=27; NR, n=29)**	**Hematologic (R, n=124 NR, n=170)**	**Immunologic (R, n=468; NR, n=1813)**	**Mucocutaneous (R, n=1360; NR, n=1197)**	**Musculoskeletal (R, n=1148; NR, n=987)**	**Renal (R, n=186; NR, n=234)**	**Vascular (R, n=108; NR, n=98)**
FACIT-Fatigue‡ (MID=3)	**5.5 (p=0.001)**	**4.5 (p=0.118)**	**3.8 (p=0.005)**	1.1 (p=0.042)	2.9 (p<0.001)	2.7 (p<0.001)	2.5 (p=0.012)	2.9 (p=0.040)

Conclusions Being an organ responder is associated with QoL benefits experienced by patients with SLE that were more often observed among belimumab-treated patients. Statistical significance was interpreted with caution owing to small sample sizes.

Funding GSK

LSO-069 SATISFACTION AND EFFECTIVENESS OF SWITCHING FROM INTRAVENOUS TO SUBCUTANEOUS BELIMUMAB TREATMENT IN DAILY CLINICAL PRACTICE

[1]Beatriz Frade-Sosa*, [2]Tarek Carlos Salman-Monte, [3]Javier Narváez, [4]Irene Peralta, [5]Sebastian Sandoval, [6]Berta Magallares, [7]Sergi Heredia, [1]Nuria Sapena, [4]Anne Riveros-Frutos, [4]Alex Olivé, [6]Hector Corominas, [5]Josefina Cortés-Hernández, [1]Jose A Gómez-Puerta.
[1]Rheumatology, Hospital Clinic of Barcelona. Barcelona, Spain; [2]Rheumatology, Hospital del Mar/Parc de Salut Mar-IMIM. Barcelona, Spain; [3]Rheumatology, Hospital de Bellvitge, L'Hospitalet de Llobregat, Spain; [4]Rheumatology, Hospital Universitario Germans Trias i Pujol, Badalona, Spain; [5]Rheumatology, Hospital Vall d'Hebron, Barcelona, Spain; [6]Rhematology, Hospital Santa Creu i Sant Pau, Barcelona, Spain; [7]Rheumatology, Hospital de Sant Joan Despí Moisès Broggi, Sant Joan Despí, Spain

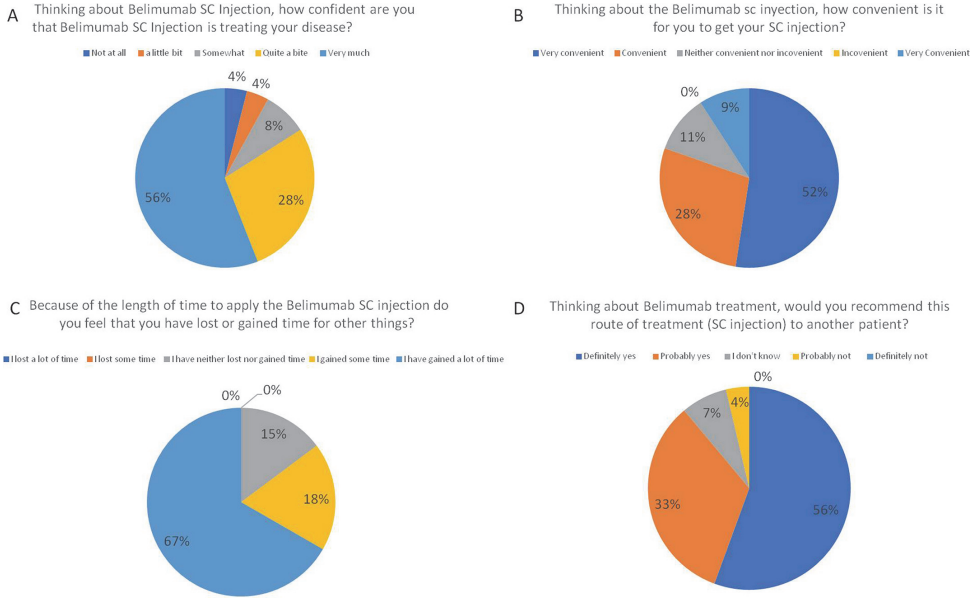
10.1136/lupus-2023-KCR.110

Background In 2017, Belimumab (BEL) was approved in subcutaneous (SC) version.[1] The effectiveness after switching from intravenous (IV) to SC and patient satisfaction in daily clinical practice has not been studied. During the pandemic, patient follow-up and treatment were significantly affected, including the administration of IV biologic therapies. In some patients, a change from IV to SC, including BEL therapy, was required.[2] Our aim was to evaluate in daily clinical practice satisfaction to BEL SC therapy in patients previously treated IV BEL. We hypothesized that SC BEL in SLE patients previously treated with IV BEL was similar in effectiveness and conferred higher satisfaction.

Methods Observational, multicenter study, conducted in 7 reference centres in Catalonia (Spain). Inclusion criteria: Stable SLE patients (EULAR/ACR 2019) on treatment with BEL SC and previous use of BEL IV (at least 3 months of treatment with BEL IV before switching).

Abstract LSO-069 Table 1 Demographic and disease characteristic

DEMOGRAPHIC	
Age at inclusion (years), n (%)	45,9 (12,5)
Female, n (%)	23 (85,2)
Ethnicity, n (%)	
Caucasian	22 (81,5)
Mestizo	4 (14,8)
Maghrebi	1 (3,7)
Current smoker, n (%)	10 (37)
DISEASE CHARACTERISTIC	
Age at diagnosis (years), mean (sd)	28,8 (13,4)
SLICC at the time of inclusion, mean (sd)	0,67 (0,88)
Cumulative manifestations, n (%)	
Fever	10 (37)
Skin manifestation	
Malar rash	17 (63)
Discoid lupus	4 (14,8)
Lupus tumidus	1 (3,7)
Acute cutaneous lupus	11 (40,7)
Ulcers	17 (63,0)
Alopecia	6 (22,2)
Articular	
Arthralgias	27 (100)
Arthritis	26 (96,3)
Renal	
Proteinuria	3 (11,1)
Serositis	
Pericarditis	4 (14,8)
Pleuritis	11 (40,7)
Neurological	
Myelitis	1 (3,7)
Acute confusional state	1 (3,7)
Hematological	
Leukopenia	18 (66,7)
Lymphopenia	15 (55,6)
Thrombocytopenia	2 (7,4)
INMUNOLOGICAL	
ANA	27 (100)
Anti-dsDNA	25 (92,6)
Anti-Sm	10 (37)
Lupus anticoagulant	5 (18,5)
aCL	4 (14,8)
Anti-B2GP1	4 (14,8)
Low C3	21 (77,8)
Low C4	20 (74,1)
CHARACTERISTICS AT THE MOMENT OF LAST BELIMUMAB IV ADMINISTRATION	
Disease duration at the moment of initiation of BEL IV (months), mean (Sd)	153,4 (114,6)
SLEDAI, mean (sd)	2,96 (2,4)
Glucocorticoid treatment, n (%)	19 (70,4)
Prednisone equivalent mg/d, mean (sd)	4,8 (6,3)
Clinical remission, n (%)	19 (70,4)
Serological remission, n (%)	10 (37)
Complete remission, n (%)	8 (29,6)
Mean time from treatment with BEL IV before switch to SC (months), mean (sd)	26,35 (21,3)
LAST VISIT WITH BELIMUMAB SC	
Time since change (months), mean (sd)	30,9 (7,8)
SLEDAI, mean (sd)	1,82 (2,02)
Glucocorticoid treatment, n (%)	17 (63)
Prednisone equivalent mg/d, mean (sd)	3,57 (2,34)
Clinical remission BEL SC, n (%)	20 (74,1)
Serological remission BEL SC, n (%)	14 (51,9)
Complete remission BEL SC, n (%)	12 (44,4)



Abstract LSO-069 Figure 1 RASQ-SC modified for belimumab