RWD9

Advanced Therapies and the Unmet Need in Systemic Lupus Erythematosus Patients: Results from a Real-World Study in the United States and Germany

Russel Burge[1], Victoria Barton[2], Emily Goddard[2], Alastair Hinds[2], James Piercy[2]

[1] Eli Lilly and Company, Indianapolis, Indiana, United States of America; [2] Adelphi Real World, Bollington, United Kingdom.

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OBJECTIVE

- We aimed to examine the unmet need and steroid use in patients with systemic lupus erythematosus (SLE) receiving advanced therapies (ATs).

CONCLUSION

- ATs appear to support steroid sparing, however, despite AT treatment, unmet needs remain with regards to polypharmacy and impact to QoL and increased fatigue among SLE patients.

ISPOR EU 2025; Glasgow, Scotland; November 9 – 12, 2025

BACKGROUND

- Systemic lupus erythematosus (SLE) is a chronic autoimmune disease with multiorgan manifestations.
- Current advanced therapies (ATs) approved for SLE target the underlying pathophysiology of the disease, with immunomodulators and corticosteroids often used alongside.[1]
- However, there remains opportunity to improve patient quality of life (QoL) and reduce corticosteroid burden with more efficacious treatments.

METHODS

- Data were drawn from the Adelphi Real World Lupus Disease Specific Programme™, a cross-sectional survey of rheumatologists and their patients with SLE (plus additional SLE patients receiving anifrolumab) in Germany and the United States (US) from July 2024 – January 2025.
- The DSP methodology has been previously published and validated.[2,3,4]
- Rheumatologists reported patient demographics and treatment details.
- Patients self-reported QoL via the Functional Assessment of Chronic Illness Therapy (FACIT) – Fatigue[5] and EuroQol Visual Analogue Scale (EQ-VAS).
- General population mean for FACIT – Fatigue 43.5 Germany, 43.6 US, lower scores indicate greater fatigue.[6,7] General population mean for EQ-VAS 71.59 Germany, 80.40 US.[8,9]
- Bivariate analysis compared AT with non-AT patients; p<0.05 indicates significance.

RESULTS

Demographics:

- Overall, 104 rheumatologists (Germany, n=35; US, n=69) reported data for 1054 patients (Germany, n=280; US, n=774), of whom 539 were AT and 515 were non-AT. Mean (standard deviation; SD) patient age was 43.1 (13.9) years, 62.9% were White and 81.8% female.

Treatment use:

- At survey, in Germany and in the US, 42.7% and 28.5% of AT patients were receiving steroids, respectively, and 61.8% and 30.5% of non-AT patients were receiving steroids, respectively (**Table 1**). In total, 38.4% of AT patients were prescribed ≥3 concurrent treatments. AT patients in Germany were more likely to have reduced rates of steroid prescription (p=0.0018) and reduced steroid dose since treatment initiation (p=0.0190) than non-AT patients. AT patients in the US were more likely to have a fluctuated and recently decreased steroid dose than non-AT patients (p=0.0038; **Figure 1**).

Patient-reported quality of life impact:

- AT patients reported QoL impact, with mean (SD) EQ-VAS scores of 64.4 (17.5) in Germany and 73.3 (18.8) in the US (**Figure 2**). Mean (SD) FACIT-Fatigue scores for AT patients across Germany and US were 32.0 (10.2) and 34.5 (12.4), respectively, (**Figure 2**).

RESULTS

Table 1: Patient demographics and clinical characteristics at survey

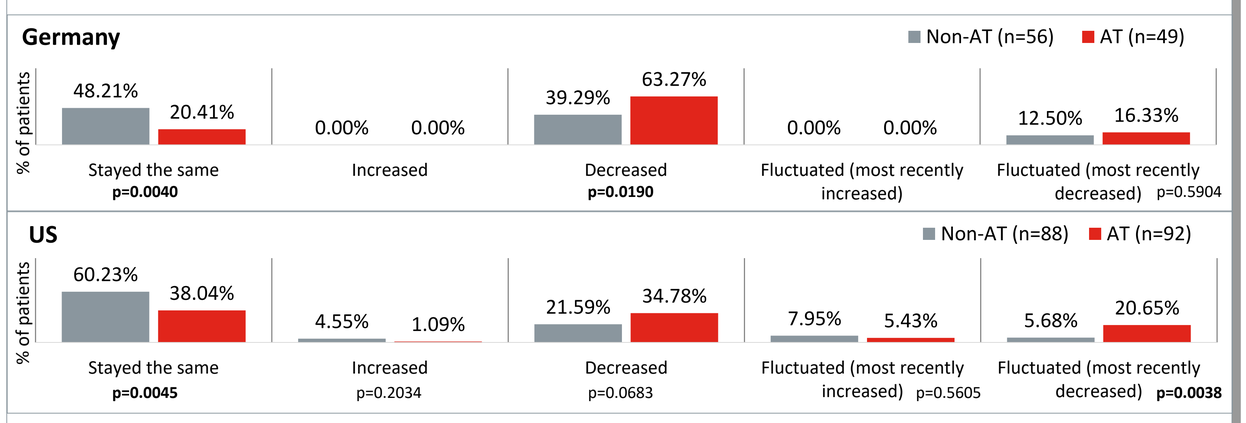
	Germany			US		
	Non-AT n=144	AT n=136	p-value	Non-AT n=371	AT n=403	p-value
Age, years, mean (SD)	38.37 (11.65)	41.45 (11.34)	**0.0259** (TT)	44.45 (15.52)	44.04 (13.52)	0.6944 (TT)
Sex, n (%)						
Male	24 (16.67)	35 (25.74)	0.0783 (FE)	56 (15.09)	77 (19.11)	0.1529 (FE)
Female	120 (83.33)	101 (74.26)		315 (84.91)	326 (80.89)	
BMI, kg/m², n (%)						
Underweight	2 (1.39)	1 (0.74)		8 (2.16)	4 (0.99)	
Normal	95 (65.97)	68 (50.00)	**0.0049** (MW)	181 (48.79)	166 (41.19)	**0.0029** (MW)
Overweight	41 (28.47)	58 (42.65)		132 (35.58)	150 (37.22)	
Obese	6 (4.17)	9 (6.62)		50 (13.48)	83 (20.60)	
Race, White, n (%)	135 (93.75)	123 (90.44)	0.376 (FE)	191 (51.48)	214 (53.10)	0.6661 (FE)
Disease duration, years, mean (SD)	2.78 (3.76)	5.63 (6.09)	**<0.0001** (TT)	5.28 (7.71)	5.43 (6.40)	0.7829 (TT)
Current treatment by class, n (%)						
Antimalarials	102 (70.83)	54 (39.71)	**<0.0001** (FE)	276 (74.39)	251 (62.28)	**0.0004** (FE)
Immunosuppressants	68 (47.22)	37 (27.21)	**0.0006** (FE)	180 (48.52)	139 (34.49)	**<0.0001** (FE)
ACE inhibitors/ARBs	26 (18.06)	26 (19.12)	0.8783 (FE)	23 (6.20)	26 (6.45)	1 (FE)
Biologics	0 (0.00)	132 (97.06)	**<0.0001 (FE)**	0 (0.00)	396 (98.26)	**<0.0001 (FE)**
Belimumab	-	*45 (33.09)*		-	*141 (34.99)*	
Rituximab	-	*11 (8.09)*		-	*12 (2.98)*	
Anifrolumab	-	*76 (55.88)*		-	*242 (60.05)*	
Other Biologic	-	-		-	*1 (0.25)*	
JAK inhibitors	0 (0.00)	8 (5.88)	**0.0028** (FE)	0 (0.00)	9 (2.23)	**0.004** (FE)
Steroids	89 (61.81)	58 (42.65)	**0.0018** (FE)	113 (30.46)	115 (28.54)	0.5811 (FE)
Other therapies	12 (8.33)	4 (2.94)	0.0704 (FE)	13 (3.50)	5 (1.24)	0.0537 (FE)
Not currently receiving treatment for SLE	3 (2.08)	0 (0.00)	0.2479 (FE)	13 (3.50)	0 (0.00)	**<0.0001** (FE)
Patient has never received treatment for SLE	0 (0.00)	0 (0.00)	.	11 (2.96)	0 (0.00)	**0.0003** (FE)

Advanced therapies include biologics, belimumab (Benlysta), rituximab, anifrolumab (Saphnelo), other biologics or JAK inhibitors.

Abbreviations: ACE inhibitors: Angiotensin-converting enzyme inhibitors; ARBs: Angiotensin receptor blockers; AT: Advanced Therapy; BMI: Body Mass Index; JAK inhibitors: Janus Kinase inhibitors; SD: Standard Deviation; SLE: Systemic Lupus Erythematosus; US: United States; SD.

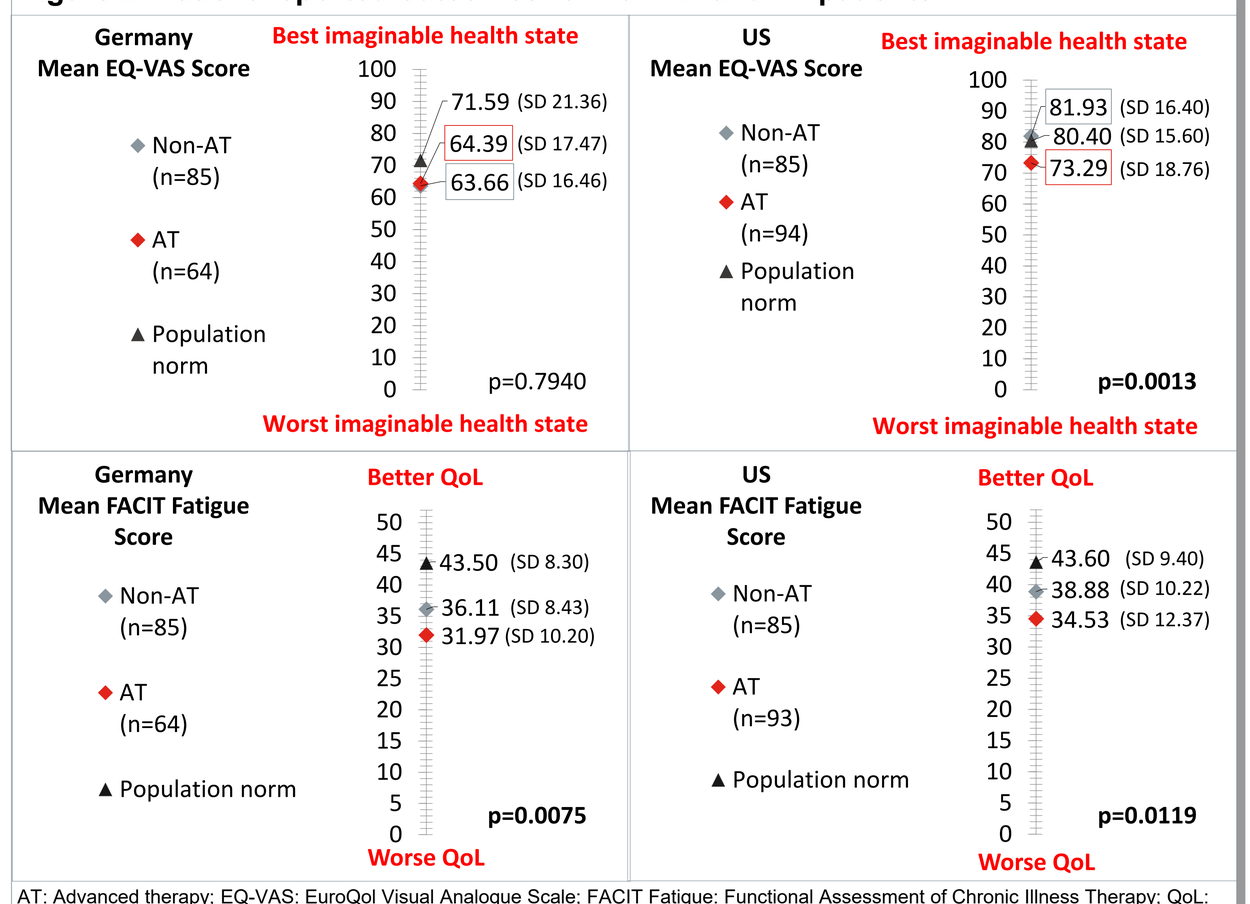
Statistical tests: TT: t-test; FE: Fisher's Exact test; MW: Mann-Whitney U test. Statistical significance p<0.05.

Figure 1: Physician-reported steroid dose change since initiation of current therapy



AT: Advanced therapy; US: United States; Advanced therapies include biologics, belimumab, rituximab, anifrolumab, other biologics or JAK inhibitors. Statistical significance determined through Fisher's exact test; p<0.05.

Figure 2: Patient-reported outcomes for non-AT and AT patients



AT: Advanced therapy; EQ-VAS: EuroQol Visual Analogue Scale; FACIT Fatigue: Functional Assessment of Chronic Illness Therapy; QoL: Quality of Life; SD: Standard deviation; US: United States. Advanced therapies include biologics, belimumab, rituximab, anifrolumab, other biologics or JAK inhibitors. Statistical significance determined through t-test; p<0.05.

Acknowledgments:
Eli Lilly and Company did not influence the original survey through either contribution to the design of questionnaires or data collection. The analysis described here used data from the Adelphi Real World Lupus DSP. The DSP is a wholly owned Adelphi Real World product. Eli Lilly and Company are one of multiple subscribers to the DSP. Publication of survey results was not contingent on the subscriber's approval or censorship of the publication.

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