activity states [remission (SLEDAI-2K=0) and lupus low disease activity state (LLDAS)], accrual of irreversible damage (SLICC damage index, SDI), number and severity of flares, and side-effects. Analyses were performed at quarterly intervals and only patients with at least 3 months of follow-up were included in the study.

Results: A total of 56 patients were included [53 women (94.6%), mean (SD) age 46.3 (12.7) years]. Evidence of serologic activity (low C3/C4 and/or high anti-ds DNA) was evident in 30 patients (53.5%). Most frequent manifestations were arthritis (82.1%), inflammatory rash (73.2%), active hair loss (57.1%), mucosal ulcers (26.8%) and leukopenia (10.7%).

Median (range) duration of follow-up was 9.1 (2.9 - 34.6) months. We observed a significant decrease in the SLEDAI-2K, physician global assessment (PGA) and daily prednisone dose over time, starting as early as 3 months after belimumab initiation (Table 1). This effect was significantly more pronounced in patients who were serologically active (SA) at baseline, even after exclusion of the serologic component of the SLEDAI [median (range) *clinical* SLEDAI-2K for SA patients: 7 (1–24) at baseline vs. 2 (0–16) at 6 months and 2 (0–16) at 12 months, $p<0.0001$ and p=0.013, respectively; for serologically inactive patients: 6 (2–23) at baseline vs. 6 (0–14) at 6 months and 5 (0–18) at 12 months, p=0.017 and p=0.024, respectively]. For patients with $\geq$12 months of follow-up (n=20), belimumab treatment resulted in a significant decrease in flare rate [median (range) total number of flares for the 12 months before and after belimumab treatment, 3 (0–7) and 0 (0–2), respectively, $p<0.0001$). 10 patients (17.8%) discontinued belimumab due to inefficacy after a median (range) 7.1 (5.5 - 20.4) months of therapy and 5 patients discontinued due to planned pregnancy. There were no drug discontinuations due to side-effects.

Table 1. Changes in disease activity and daily prednisone dose during treatment with belimumab

	Baseline (reference) n=56	3 months n=56	6 months n=47	9 months n=26	12 months n=22	18 months n=10	p value
SLEDAI, median (range)	8 (2-28)	6 (0-24)*	4 (0-20)*	4 (0-18)*	4 (0-18)*	3 (0-14)**	*p<0.001 **p=0.01
	Baseline (reference)	3 months	6 months	9 months	12 months	18 months	p value
PGA, median (range)	1.9 (1-3)	1.5 (0.3-3)*	1.5 (0.5-3)*	1.5 (0-2.2)*	1.15 (0-3)*	1 (0-2)***	*p<0.001 **p=0.18 ***p=0.01
	Baseline (reference)	3 months	6 months	9 months	12 months	18 months	p value
Pr dose, median (range)	7.5 (0-40)	7.5 (0-30)*	5 (0-25)*	5 (0-10)*	5 (0-30)**	4.3 (0-7.5)***	*p<0.001 **p=0.001 ***p=0.021
Low disease activity states, n(%)	Baseline	3 months	6 months	9 months	12 months	18 months	
LLDAS	0 (0)	10 (17.9)	15 (31.9)	10 (34.5)	5 (21.7)	4 (40)	
Remission	0 (0)	3 (5.4)	4 (7.1)	3 (5.4)	4 (7.1)	2 (3.6)	

Conclusions: In real-life clinical settings, belimumab is efficacious in controlling disease activity of SLE and permitting tapering of glucocorticoid dose. Similar to data from RCTs, this effect seems to be more pronounced in serologically active patients.

Disclosure of Interest: None declared

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AB0443 INFUSION REACTIONS TO RITUXIMAB IN SYSTEMIC LUPUS ERYTHEMATOSUS: A RETROSPECTIVE ANALYSIS

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Background: B-cell depletion with Rituximab (RTX) has been used since since 2000 in the treatment of Systemic Lupus Erythematosus (SLE). An issue with the use of RTX is the attrition rate due reactions during of following infusions. This can prevent re-treatment with RTX in patients with a good initial response to RTX and in whom other treatments had failed, this is especially important in SLE patients with limited biologic options.

Objectives: To identify the rates and patient characteristics of infusion reactions to RTX in patients with SLE.

Methods: A retrospective analysis of the SLE patient cohort receiving RTX at University College London Hospitals via examination of patient records was used to determine if there was a clinically significant reaction (from clinic letters or discharge summary) for each RTX infusion. One cycle of RTX refers to 2 infusions given 2 weeks apart. A descriptive analysis of the reaction was recorded as was the decision making surrounding the infusions.

Results: Records from 151 RTX-treated patients were reviewed with 13 excluded due to missing data. 138 remaining patients (130 females and 8 males, mean age (1st infusion) =33 years; range: 16–73) received a total of 478 individual RTX infusions (between 1–9 cycles). Prior to 2007, standard of care was to receive Cyclophosphamide (CYC) with each cycle. The total rate of infusion reactions was 5.85% (23 patients had 28 reactions). Of these 4 (50%) were males, 19 females (14.6%; *p*=0.009, Chi square). Average number of cycles in those without, compared to with a reaction was 1.61 vs 1.64. With 1st dose, 7 patients (25%) had reactions, 19 with 2nd (67.9%). 3 patients were retreated (1 twice); 2/3 had further reactions and the 3rd two further cycles without issues. Most were not retreated. Reactions ranged from mild to severe (Table 1). A total of 24 RTX reactions were categorized into: Immediate- unlikely immune mediated 4; likely cytokine release 7; IgE mediated 5; and bone pain reactions 2. Delayed-early (24–48hours) 1; and late (>48hours) 5; by a Clinical Allergist. 4 reactions were excluded from this analysis; 1 death as likely CYC induced (but occurred within 24 hours of RTX) and 3 due to lack of data.

Table 1. Severity of Infusion Reactions

Severity of reaction	Number of patients	% of total infusion reactions	Retreated?
Death	1	3.6%	N
Severe	3	10.7%	Y – 1 (had further reaction)
Moderate	7	25.0%	Y – 1 (2 further cycles)
Mild	8	28.6%	Y – 1 (2 further cycles)
Delayed	5	17.9%	Y – 1 (1 further cycle)
Unclassified	4	14.3%	N

Mild (infusion resumed/completed), Moderate (had to cease infusion reaction), Severe (hospital admission), Delayed/serum sickness.

Conclusions: The number of previous cycles was similar in patients who reacted versus those who did not. Patients were most likely to experience a clinically significant reaction with the second infusion. Males had higher incidence of reactions. Most (19%) were immediate and the majority (79%) of immediate and delayed reactions occurred during 1st (10) and 2nd (9) cycles. The total rate of infusion reactions in this cohort was lower than previously reported however this is likely contributed to by the limitations of a retrospective review. However 64% of reactions (11/17) in this cohort were significant, necessitating cessation of infusion or hospital admission.

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AB0444 EFFECT OF RITUXIMAB ON A SALIVARY GLAND ULTRASOUND SCORE IN PRIMARY SJÖGREN'S SYNDROME: RESULTS OF THE TRACTISS MULTICENTRE RANDOMISED TRIAL SUB-STUDY

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Background: B lymphocytes are important in the pathogenesis of primary Sjögren's syndrome (PSS), but two phase III trials (TEARS and TRACTISS) of the B cell depleting agent rituximab (RTX) failed to show an effect on their primary endpoints in PSS. Whilst RTX may lack efficacy in a non-stratified PSS population, other possible explanations for these negative results include the choice and timing of primary outcome. In a small single-site salivary gland ultrasound (SGUS) substudy in TEARS, more subjects in the RTX arm demonstrated improvement in parotid gland echostructure. Importantly, SGUS is an operator-dependent technique.

Objectives: To compare the effects of RTX versus placebo on SGUS in PSS, in a multicentre, multiobserver substudy of TRACTISS.

Methods: Subjects consenting to SGUS were randomised to 1000mg RTX or placebo given at weeks 0, 2, 24 and 26, and scanned at baseline and weeks 16 and 48. Sonographers completed a 0–11 total ultrasound score (TUS) comprising domains of echogenicity, homogeneity, glandular definition, glands involved, and size of hypoechoic foci. Baseline-adjusted values of TUS were analysed over time, modelling change from baseline at each time point. For each TUS domain we fitted a repeated measures logistic regression model to model the odds of a response in the RTX arm (defined as a 1 point improvement) as a function of the baseline score, age category, disease duration and time point.

Results: 66 patients (49.6% of the total study population) consented to SGUS, and 52 (39.1%; n=26 RTX and n=26 placebo) completed the baseline and at least one follow-up visit. Estimated baseline-adjusted TUS at week 16 was 6.2 (95% CI 5.4–7.0) for placebo and 5.0 (95% CI 4.4–5.6) for RTX, and at week 48, 6.1 (95% CI 5.5–6.6) and 4.8 (95% CI 4.2–5.4) respectively. Estimated between group differences (RTX-placebo) in baseline adjusted TUS were -1.2 (95% CI -2.1 to -0.3; p=0.0099) and -1.2 (95% CI -2.0 to –0.5; p=0.0023) at weeks 16 and 48. Glandular definition was the only domain to show statistically significant improvement with an OR of 6.8 (95% CI 1.1–43.0; p=0.043) at week 16 and 10.3 (95% CI 1.0–105.9; p=0.050) at week 48. Improvement of $\geq$1 point in TUS was associated with improvement in oral dryness VAS at week 16 (diff=15.9; CI 1.5 to 30.3; p=0.030) but not week 48 in the RTX arm.