Results: BAFF levels (mean, SD; pg/mL) were higher in patients receiving methotrexate (1835, 1617; n=212; *P*=0.001), azathioprine (1901, 1472; n=364; *P*<0.001) or mycophenolate mofetil/sodium (1994, 1544; n=175; *P*<0.001) and no immunosuppressive treatment other than the one investigated compared with patients receiving no immunosuppressive treatment (1593, 1929; n=860); AMA were allowed in both groups, in all comparisons. In contrast, patients on AMA displayed lower BAFF levels (1654, 1318; n=1085) compared with patients who did not use AMA (1942, 2408; n=580; *P*=0.002). In linear regression, AMA use showed a consistent and independent association with lower BAFF levels in all models, whereas use of each one of methotrexate, azathioprine and mycophenolic acid was associated with higher BAFF levels. All models were adjusted for the use of immunosuppressive agents other than the one investigated.

Conclusion: Our data imply differential effects of antimalarial agents and other immunosuppressive treatments on BAFF levels; AMA diminished while methotrexate, azathioprine and mycophenolic acid increased BAFF levels. It is worth noting that methotrexate and mycophenolic acid are not approved for the treatment of SLE. Considering the importance of BAFF in B cell homeostasis and SLE pathogenesis, exploration of the biological significance of the differential effects of different immunosuppressive agents on BAFF levels is anticipated.

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FRI0199

EFFECTIVENESS AND SAFETY OF BELIMUMAB IN PATIENTSWITH ACTIVE SYSTEMIC LUPUS ERYTHEMATOSUS: RESULTS FROM A LARGE, NATIONWIDE, MULTICENTRIC STUDY

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Background: Belimumab is the unique biologic therapy available for patients with SLE.

Objectives: To investigate effectiveness and safety of belimumab in SLE patients in clinical practice.

Methods: 458 active SLE patients (ACR criteria) from 24 Italian Centers, mean±SD age 43.5±11.3 years; mean±SD disease duration 12.3±8.7 years, were treated with belimumab (10 mg/kg day 0, 14, 28 and then every 28 days), as add-on therapy.

SLEDAI-2K, anti-dsDNA, C3, C4, prednisone daily dose, DAS-28, 24H proteinuria, CLASI, PGA, Fatigue (VAS 0-10) were recorded at baseline and every 6 months. Flares were defined according to SFI. Response was evaluated according to SRI-4. Statistics were performed by pairs T-test, chi-square test and multiple logistic regression (SPSS, version 22.0).

Results: Mean±SD follow-up was 21.2±15.3 months (range 3-60). Most common features treated with belimumab were articular in 67%, mucocutaneous in 55%, and renal in 17% of cases. Improvement of clinical and serological variables, including daily prednisone dosage, was observed (Table). SRI-4 is summarized in the Figure.

At the end of follow-up 293 patients (66%) were still on belimumab. Most common cause of discontinuation were inadequate response (36%), AEs (31%), and pregnancy (8%).

Mean number of flare during belimumab treatment compared with the corresponding period before belimumab initiation decreased (p<0.001). SLEDAI-2K $\geq$10 was an independent predictor of response by logistic regression at month 12 and 24 (p=0.003 and p=0.025).

9,998 infusions were analyzed. 784 AEs were observed in 330 patients, SAEs were 43 in 36 patients. No severe infusion reactions were observed; 16 patients had infective SAEs, and 22 non infective SAEs.

Conclusion: We confirmed the effectiveness, the steroid sparing effect and good safety profile of belimumab in our cohort.

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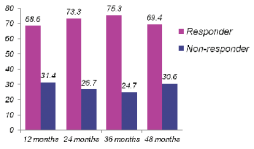
Table. Variation of clinical and serologic disease activity variables in patients with active lupus treated with belimumab

	N° pts*	Baseline	6 months	12 months	18 months	24 months	30 months	36 months	48 months	p
SLEDAI-2K	458	8.1±3.4	4.9±3.3	3.8±2.7	3.8±3.2	3.5±2.8	2.6±2.8	2.8±2.4	2.7±2.1	<0.0001
Prednisone dosage (mg/day)	458	10.5±8.1	6.7±4.6	5.3±4.7	4.5±4.8	3.8±3.7	3.5±2.9	3.4±4.3	3.4±4.5	<0.0001
DAS-28	309	3.4±1.7	2.5±1.5	2.2±1.4	1.9±1.4	1.7±1.3	1.6±1.5	1.5±1.4	1.4±1.4	<0.0001
CLASI-a	254	3.3±4.7	1.9±3.3	1.1±2.2	0.8±2.1	0.6±1.8	0.6±1.4	0. 6±1.4	0.2±0.7	<0.0001
PGA (0-3)	356	1.8±0.6	1.2±0.7	0.8±0.6	0.8±0.7	0.8±0.6	0.7±0.6	0. 7±0.6	0.7±0.6	<0.0001
Fatigue (VAS 0-10)	197	5.2±3.0	4.3±2.8	3.3±2.6	2.8±2.7	2.8±2.6	2.5±2.9	2.3±2.7	2.4±2.9	<0.0001
Anti-dsDNA (ELISA, KUI/L)	131	230±354	144±217	118±179	107±164	99.2±162	71.5±104	74.4±145	23.0±56.2	<0.006
C3 (mg/dl)	458	50.1±38.8	57.9±41.0	61.2±41.8	59.9±43.1	62.1±41.8	59.2±43.2	64.9±42.6	73.3±45.5	<0.001
C4 (mg/dl)	458	7.7±7.7	10.1±8.5	11.2±9.3	11.2±9.1	11.9±9.3	11.0±9.3	13.8±10.1	13.6±9.7	<0.006
24-h proteinuria (g/die)	77	1.4±1.1	0.8±0.9	0.6±0.6	0.6±0.7	0.6±0.6	0.7±0.8	0.4±0.5	0.6±0.6	0.012

*Number of patients at baseline. p calculated using univariate analysis
SLEDAI-2K: Systemic Lupus Erythematosus Disease Activity Index-2000; CLASI-a: Cutaneous Lupus erythematosus Area and Severity Index-activity; DAS-28: disease activity score-28 joints; anti-dsDNA: anti-double stranded DNA ELISA: Enzyme-Liked ImmunoSorbent Assay; pts: patients; CLIA: chemiluminescent immunoassay

Figure. SRI-4 after belimumab in 446 SLE patients



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FRI0200

REVIEW OF HYDROXYCHLOROQUINE USE AND DEVELOPMENT OF A REGIONAL STRATEGY TO MINIMISE RETINAL TOXICITY

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Background: Guidelines from the Royal College of Opthalmologists in February 2018 were developed for retinal screening for patients on hydroxychloroquine, as recent evidence suggests the risk of retinal toxicity is higher than previously reported. The prevalence of retinal toxicity in long term use appears to be 7.5% and depending on dose and duration of therapy can increase to 20-50% after 20 years of therapy. Risk is increased for patients taking more than 5mg per kg per day of hydroxychloroquine, patients on Tamoxifen and those with renal impairment. The guidelines recommend the use of a standardised referral proforma to help identify patients who are high risk.
Objectives: 1. Audit of Hydroxychloroquine use and retinal screening in the Belfast Health and Social Care Trust (BHSCT)
2. Develop a regional referral proforma and screening service for retinal toxicity
Methods: Patients who were treated with hydroxychloroquine, under the care of a consultant rheumatologist were identified on the database. A proforma was used to aid data collection and patients' electronic records were reviewed. We audited the use of hydroxychloroquine and retinal screening against current Royal College of Ophthalmology (RCO) guidelines. We designed a standardised referral proforma and regional screening strategy in conjunction with ophthalmology colleagues.
Results: There were 151 patients identified on hydroxychloroquine on the database. 40 of these patients had stopped hydroxychloroquine, 2 of which had retinal toxicity. Therefore the rate of retinal toxicity in this sample was 1.3% (2/151).
There were 111 patients who remained on hydroxychloroquine treatment with a female: male ratio of 9:1. Age range was from 22 to 84, with a mean age of 55. There were 44% of patients on hydroxychloroquine for rheumatoid arthritis, 25% had systemic lupus erythematosus, 8% had Sjogrens syndrome, 6% had pallindromic rheumatoid arthritis and 13% had other connective tissue diseases. The majority (79%) of patients were on 200mg hydroxychloroquine daily and 19% were on 400mg daily. 6% of patients had an eGFR<60. No patients were on tamoxifen. 73% of patients were on hydroxychloroquine treatment for over 5 years. Retinal screening was overdue in 64% of patients.
Conclusion: In this sample, only 1.3% of patients had evidence of retinal toxicity, although 64% of patients were overdue retinal screening. We developed a referral proforma and a regional screening strategy in line with RCO guidelines. In order to meet the RCO guidelines, we recognise the need for substantial investment in regional ophthalmology services.

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FRI0201

REAL WORLD MEDICATION USE IN INCIDENT SYSTEMIC LUPUS ERYTHEMATOSUS AND LUPUS NEPHRITIS PATIENTS

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Background: Systemic lupus erythematosus (SLE) is an autoimmune disease that causes inflammation in connective tissues and can involve multiple organs systems. Lupus nephritis (LN) is an inflammatory kidney disease caused by SLE. There is a gap in the literature regarding the standard of care in SLE and LN patients.
Objectives: This study generated real world medication use among SLE and LN patients.
Methods: This retrospective study used data from two large administrative databases in the US: Truven Health MarketScan® and Optum® databases to identify adult patients (≥18 years of age) with ≥2 medical claims on different dates for SLE or LN diagnoses from 01JAN2013-31DEC2015. SLE was identified using the International Classification of Diseases, 9th and 10th Revision, Clinical Modification [ICD-9-CM] codes (710.0) OR ICD-10-CM (M32.10-M32.19, 32.8, 32.9). LN was captured as a subset of SLE using [ICD-9-CM: 710.0 AND (581.81 or 582.81 or 583.81); OR (ICD-10-CM:M32.14)]. The first SLE or LN diagnosis was designated as the index date. Patients were required to have continuous health plan enrollment for 1 year pre-index date (baseline period) and 1 year post-index date (follow-up period) and no prior SLE/LN diagnosis claims or belimumab medical/prescription claim during the baseline period to ensure incident patients were captured. The Truven Health MarketScan® and Optum® databases were pooled together and duplicates were identified and retained in MarketScan® only. Patient demographics and clinical characteristics during the baseline period were assessed. SLE treatment used during the follow-up period was evaluated and the proportion of patients that used SLE medications and average number of medical/prescription claims (#Rx) for each medication were provided.
Results: A total of 31,345 patients were identified including 30,086 SLE and 1,259 LN patients. Key results are shown in Table 1. The mean age was 52.7 years for SLE and 48.3 years for LN patients. Over 80% of the patients were female, with a mean Charlson Comorbidity Index (CCI) score of 1.1 and 1.8 for SLE and LN patients respectively. The most common comorbidities at baseline were hypertension and infections. Corticosteroids (SLE= 58.3%, #Rx=4.5; LN=66.2%, #Rx=6.5) and hydroxychloroquine (SLE=43.4%, #Rx=5.8; LN=40.7% #Rx=6.2) were the most commonly used SLE medications during 1-year follow up period. Approximately 2% of patients used biologics including belimumab (SLE=1.1%, #Rx=8.8; LN=1.4%, #Rx=8.3) and rituximab (SLE=0.9%, #Rx=4.2; LN=2.1%, #Rx=4.0).