**Background** Serologically active clinically quiescent (SACQ) is a clinical state of systemic lupus erythematosus (SLE) characterized by high levels of serologic markers without clinical activity. The outcome and treatment strategy after SACQ achievement remains unclear. After achieving the treatment goal, maintaining low-dose glucocorticoids has always been both a blessing and a curse. In this multi-center prospective study, we aimed to identify the risk of flares, organ damage accumulation, and the glucocorticoids discontinuation feasibility of SLE patients who achieved the clinical state as SACQ.

**Methods** This study was conducted based on data from the Chinese SLE treatment and research (CSTAR) registry. Demographic characteristics, autoantibody profiles, clinical manifestations, organ damage, and treatment profile were collected at recruitment and during follow-up. SACQ was defined as persistent serologic activity (positive anti-dsDNA antibody, and/or hypocomplementemia), and without clinical activity. Serologically quiescent clinically quiescent (SQCQ) was defined as a persistent serologic and clinical quiescent stage. Organ damage is principally assessed using the SLICC damage index (SDI).

**Results** Of 4107 SLE patients, 1889 reached the clinical quiescent stage (990 achieved SACQ, and 899 achieved SQCQ). Among SACQ patients, 364 (36.7%) underwent flares, 163 (16.5%) showed organ damage, 47 (4.7%) developed renal damage, and 21 (2.1%) died during a mean follow-up of 7.30 years. Compared with SQCQ, SACQ patients were at a higher risk of flares (HR=1.47, 95% CI 1.25–1.73, p<0.001) and renal damage accumulation (HR=2.02, 95% CI 1.23–3.33, p=0.004). Furthermore, 224 (22.6%) SACQ patients withdraw glucocorticoids and 125 (55.8%) of them did not flare. Glucocorticoids discontinuation was a favorable factor of survival (HR=0.22, 85% CI, 0.05–0.96, P=0.044). As shown in the figure, withdrawing glucocorticoids can reduce organ damage (p=0.0075), especially renal damage accumulation (p=0.045), even experience flares after discontinuation.

**Conclusions** Glucocorticoids withdrawal under tight surveillance could be considered after achieving the clinical state as SACQ to prevent the accrual of renal damage.

**REFERENCES**

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**Effect of Belimumab in Patients with Systemic Lupus Erythematosus Treated with Minimal or No Steroid**

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**Background** Belimumab is the only biologic agent approved for systemic lupus erythematosus (SLE). In cornerstone clinical trials, belimumab demonstrated SRI-4 response in patients with moderate disease activity, and real-world studies showed consistent findings. However, most previous studies have been conducted in patients with use of steroids, with mean prednisolone-equivalent dose of approximately 10 mg/day (1–3). Therefore, the effect of belimumab has been focused on the steroid sparing. Here, we aimed to identify the effect of belimumab in SLE patients treated with minimal or no steroid with mild-to-moderate activity.

**Methods** We retrospectively reviewed the electronic medical records of patients (age ≥18 years) who first received belimumab from May 2021 to June 2022 and maintained use at least 6 months. We only included patients who received prednisolone-equivalent ≤5mg or without steroid (for more than 1 year). The primary endpoint was SRI-4 response at 6 months, and secondary endpoint was improvement in serology at 6 months. Analysis Of Variance (ANOVA) with Bonferroni’s post hoc analysis were performed to compare the continuous variables.

**Results** In total, 31 patients were included, with 12 minimal steroid users and 19 non-steroid users. The mean age was 39.2 (±11.4) years, and 90.3% were female. Baseline SELENA-SLEDAI was 6.0 (4.0–9.0). The primary endpoint was seen in 32.3% (10/31). Anemia (p=0.025), C4 level (p<0.001), and SELENA-SLEDAI (p=0.016) showed significant improvement over time during treatment. Univariable analysis showed baseline SELENA-SLEDAI and arthritis were significantly associated with SRI-4 response at 6 months, and SELENA-SLEDAI only remained significant in multivariable logistic regression analysis.

**Conclusions** In our cohort study, belimumab was shown to be effective in improving SELENA-SLEDAI, anemia and low C4 in patients who did not use or did use minimal dose of steroids. Therefore, the effect of belimumab can be expected even in patients not taking steroids.

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Basel Profile of Systemic Lupus Erythematosus Patients on Treatment with Belimumab of a Spanish Multicenter Cohort

Methods Multicenter retrospective and longitudinal cohort study. Data was collected at baseline, 6, 12 months and in the last visit available. Different periods (2010–2015/2016–2021) were compared.

Results 324 patients (91% female) were enrolled. Mean (±SD) age at diagnosis: 31.8 years (±11.9); mean disease duration of 8.7 years (±9.07). At baseline, mean SLEDAI-2K score was 8.7 years (±9.07). 152 (47.5%) patients had damage with a mean duration of 8.7 years (±9.07). At baseline, mean SLEDAI-2K score was 8.7 years (±9.07). 152 (47.5%) patients had damage with a mean duration of 8.7 years (±9.07).

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Systemic Lupus Erythematosus (SLE) is a chronic, complex autoimmune disease characterized by pathogenic autoantibodies and tissue damage to multiple organ systems. Nipocalimab is a novel high affinity, fully human, aglycosylated, effectorless IgG1 monoclonal antibody that selectively blocks the neonatal Fc receptor (FcRn). Nipocalimab has demonstrated rapid and durable serum IgG and pathogenic autoantibody reductions (NCT02828046; NCT03896295). Here we describe the protocol of a Phase 2 study evaluating the efficacy and safety of nipocalimab in patients with active SLE (NCT04882878).

Methods Phase 2, multicenter, randomized, placebo-controlled, double-blind, parallel-group study enrolling adults with active, autoantibody-positive SLE with an inadequate response to one or more standard of care treatments. The study consists of a ≤6-week screening period, a 52-week double-blind treatment period, and a 6-week follow-up period (figure 1). A target of approximately 225 participants will be enrolled. Participants will be randomized in a 1:1:1 ratio to receive nipocalimab dose 1, dose 2 or placebo intravenously every 2 weeks through week 50.

Results The primary efficacy endpoint is the percentage of participants achieving an SLE Responder Index (SRI)-4 composite response at Week 24. Secondary efficacy endpoints assessed at Week 24 include the percentage of participants achieving: ≥50% reduction in Cutaneous Lupus Erythematosus Disease Area and Severity Index Activity score (CLASI), ≥50% reduction in active joints, ≥4 points improvement in SLE Disease Activity Index 2000 (SLDAI 2K), and British Isles Lupus Assessment Group Composite Lupus Assessment score (BICLA); time to first disease flare; and reduction in body weight.