Abstract S05.2 Table 1

	No SLE flare post COVID-19 n=76	SLE flare post COVID-19 n=14	Univariable OR [CI 95]
DEMOGRAPHICS			
Male sex, n (%)	4 (5.2)	2 (14.3)	2.91 [0,4-16,8]
Age during COVID-19 episode (years, median [IQR])	56.60 [43.37, 68.30]	44.20 [30.90, 54.73]	0,96 [0,93-1,00]
MEDICAL HISTORY			
Diabetes mellitus, n(%)	11 (14.4)	1 (7.1)	0,44 [0,02-2,58]
Chronic kidney disease, n(%)	15 (19,7)	2 (14.3)	0,65 [0,09-2,76]
Renal replacement therapy, n(%)	5 (6.5)	0	1,2 [NA-1,3]
Kidney transplantation, n(%)	9 (11,8)	0	1,1 [NA-1,3]
COVID EPISODE			
Patient fully vaccinated before COVID-19	11 (14.5)	3 (21.4)	1,6 [0,3-6,0]
Oxygen therapy > 6L.min-1, n(%)	30 (39,5)	1 (7.1)	0,1 [0,01-0,6]
Thrombosis, n (%)	6 (7,8)	0 (0.0)	1,1 [NA-1,4]
TREATMENTS RECEIVED FOR COVID-19			
High dose steroids, n(%)	22 (28,9)	5 (35.7)	1,3 [0,4-4,3]
Biotherapy, n(%)	6 (7,8)	0	1,3 [NA-1,4]
LUPUS CHARACTERISTICS			
Time since SLE diagnosis (years, median [IQR])	14.80 [6.80, 22.80]	6.40 [1.92, 17.53]	0,97 [0,91-1,02]
History of SLE renal flare, n (%)	38 (50,0)	6 (42.9)	0,7 [0,2-2,2]
Antiphopholipid biology, n(%)	15 (19,7)	4 (28.6)	1,5[0,4-5,4]
APLS , n(%)	9 (11,8)	2 (14.3)	1,2 [0,4-6,5]
Associated Sjögren syndrome, n(%)	13 (17.1)	4 (28.6)	1,8 [0,4-6,5]
SLE TREATMENT BEFORE COVID-19			
Steroids, n(%)	52 (68,4)	10 (71.4)	1,0 [0,3-4,0]
Hydroxychloroquine, n(%)	49 (64,4)	9 (64.3)	0,9 [0,3-3,1]
Mycophenolate mofetil, n(%)	23 (30,3)	2 (14.3)	0,4 [0,1-1,5]
Azathioprine, n(%)	5 (6.5)	1 (7.1)	1,1 [0,1-7,3]
Rituximab , n(%)	7 (9.2)	0	1,12 [NA-6,9]
Methotrexate_t0, n(%)	9 (11,8)	1 (7.1)	0,5 [0,03-3,4]

post COVID-19 SLE flare could be hypothesized. Our objectives were to assess this risk and to look for factors associated with a post-COVID-19 SLE flare.

Methods We conducted a retrospective cohort study using the Assistance Publique - Hôpitaux de Paris (AP-HP) Clinical Data Warehouse which collects all the medical data produced in the 39 AP-HP facilities in Paris area. We included every adult patient with a history of SLE (defined by a 'M32' ICD-10 diagnosis code) and an hospital stay with a first episode of COVID-19 diagnosis (defined by a 'U07.1' ICD-10 code) between March 2020 and February 2022. All the medical records were individually reviewed to retrieve demographics, SLE characteristics, COVID-19-episode characteristics, and vaccination status. We look for clinically defined SLE flares during the follow-up period. Features associated with post COVID-19 SLE flares were analysed by using univariable and multivariable logistic regression procedures.

Results Among the 4,533 SLE patients followed in AP-HP, 128 (2.8%) had an hospital stay with a COVID-19 diagnosis during the period of interest. After reviewing all the individual records, we excluded 38 patients who did not meet the inclusion criteria. Accordingly, there were 90 patients included in the analysis; 84 (93.3%) were female with a median [IQR] age of 54.6 [40.8–68.3] years. The median time between SLE diagnosis and the COVID-19 episode was 13.5 [5.6–22.8] years. Seventy-three (81.1%) patients did not receive any dose of anti-Sars-Cov2 vaccine before the COVID-19 episode and 9 (10%) died directly from COVID-19. We observed 14 (15.5%) post-COVID-19 SLE flares, 6 (42.9%) of them occurred in the same hospital stay. The median time between the beginning of the COVID-19 episode and the SLE flare was 60 [20.5–117.5] days. Six (42.9%) of these flares involved the kidneys with 3 (21.4%) class III or IV glomerulonephritis. We did not observe any significant difference in the characteristics of patient who experienced a flare compared to the others. Interestingly, there were no difference in the proportion of patients vaccinated between the two groups: 10/14 (76.9) in the flare group versus 62/74 (83.8%) in the group with no flare (p=0.83).

Conclusions Autoimmune flares seem to be frequent after COVID-19 infection among SLE population. We did not identify any risk factor associated with a risk of post-COVID-19 SLE flare.

Friday 07 October 2022 from 09:50 to 11:20

S06 nephritis

S06.1 B CELL KINETICS UPON THERAPY COMMENCEMENT FOR ACTIVE EXTRA-RENAL SYSTEMIC LUPUS ERYTHEMATOSUS IN RELATION TO DEVELOPMENT OF RENAL FLARES

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Purpose To investigate changes in B cell subsets in relation to renal flares upon initiation of standard therapy (ST) plus belimumab or placebo in patients with systemic lupus erythematosus (SLE).

Methods We analysed data from the BLISS-76, BLISS-SC and BLISS Northeast Asia trials. Circulating CD19+ B cell subsets were characterised through flow-cytometry. We investigated the associations of relative to baseline rapid (through week 8) and early (through week 24) percentage changes in circulating B cell subsets, anti-dsDNA antibodies and complement levels with the occurrence of at least one renal flare during follow-up.

Results Patients who developed renal flares showed a more prominent rapid decrease in CD19+CD20+CD138+ short-lived plasma cells (-50.4% versus -16.7%; P=0.019) and CD19+CD20-CD27bright plasmablasts (-50.0% versus -29.9%; P=0.020) compared with patients who did not flare, followed by a subsequent return to near-baseline values, while patients who did not flare showed gradual yet non-significant decreases in these cell subsets. Remarkably, more prominent rapid reductions in CD19+CD20-CD138+ long-lived plasma cells were associated with a protection against renal flares in belimumab-treated patients (-11.3% versus -29.2%; OR: 1.16; 95% CI: 1.03–1.32; P=0.019), while changes in long-lived plasma cells did not differ between patients who developed renal flares and patients who did not in the subgroup treated with ST alone. Rapid and early changes in anti-dsDNA or complement levels showed no clear association with renal flares.

Conclusions An initial decrease followed by a subsequent return in circulating short-lived plasma cells and plasmablasts upon treatment for active SLE portended renal flares, indicating a need for therapeutic adjustments in selected patients. Rapid decreases in long-lived plasma cells upon belimumab therapy commencement may signify a greater protection against renal flares.

S06.2 LONG-TERM EFFICACY AND SAFETY OF VOCLOSPORIN WITH MMF AND LOW-DOSE STEROIDS: DATA FROM THE AURORA 2 CONTINUATION STUDY

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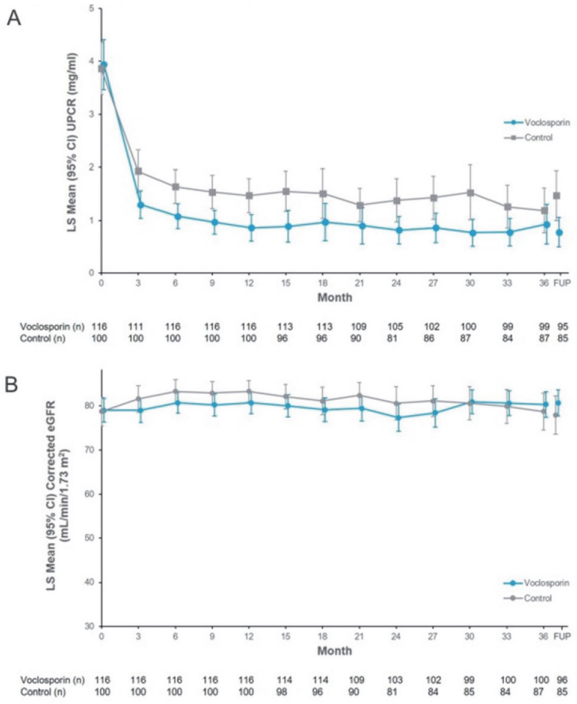
Purpose Voclosporin is a novel calcineurin inhibitor approved in the United States in January 2021 for the treatment of adult patients with active lupus nephritis in combination with background immunosuppressive therapy. The Phase 3 AURORA 1 study showed that adding voclosporin to mycophenolate mofetil (MMF) and low-dose steroids led to significantly greater reductions in proteinuria at 52 weeks. Given the potentially serious safety concerns associated with the long-term use of oral steroids, we evaluated the safety and efficacy of treatment with voclosporin in patients maintained on low-dose steroids for an additional 24 months in the AURORA 2 continuation study.

Methods Key inclusion criteria for the parent AURORA 1 study included biopsy-proven active lupus nephritis (Class III, IV, or V ± III/IV), proteinuria ≥1.5 mg/mg (≥2 mg/mg for Class V) and estimated glomerular filtration rate (eGFR) >45 mL/min/1.73 m2. Patients who completed AURORA 1 were eligible to enroll in AURORA 2 on the same blinded treatment of voclosporin or placebo in combination with MMF (target dose 2 g/day) and low-dose oral steroids. Per-protocol steroid use in AURORA 1 required a rapid taper from a starting dose of 20–25 mg/day to a target of ≤2.5 mg/day by Week 16. The final dose of steroids in AURORA 1 was the initial starting dose in AURORA 2; the dose could then be adjusted further at the discretion of the study investigator. AURORA 2 was not designed nor powered to address the impact of voclosporin on oral steroid dose.

Results In total, 116 patients in the voclosporin arm and 100 patients in the control arm enrolled in AURORA 2. The efficacy observed in patients treated with voclosporin in AURORA 1 was maintained throughout AURORA 2 as indicated by the greater Least Square (LS) mean reductions in UPCR from baseline in the voclosporin arm vs. control arm at all time points (Figure 1A). The overall exposure to oral



Analysis of AURORA 2 patients includes data from pre-treatment baseline of AURORA 1, 12 months in AURORA 1, and up to 25 months of follow-up in AURORA 2 (including 4-week post-treatment visit). CI, confidence interval; eGFR, estimated glomerular filtration rate; FUP, follow-up visit (occurred 4 weeks post-discontinuation of study drug); LS Mean, least squares mean; UPCR, urine protein creatinine ratio.

Abstract S06.2 Figure 1 A) UPCR and B) eGFR over time

Abstract S06.2 Table 1 Oral steroid use

	Voclosporin	Control
AURORA 2 Baseline (Month 12[a]) n (%)	n=116	n=100
>2.5 mg/day	14 (12.1)	15 (15.0)
≤2.5 mg/day	102 (87.9)	85 (85.0)
Month 24, n (%)	n=111	n=88
>2.5 mg/day	22 (19.8)	14 (15.9)
≤2.5 mg/day	89 (80.2)	74 (84.1)
Month 36, n (%)	n=101	n=85
>2.5 mg/day	24 (23.8)	19 (22.4)
≤2.5 mg/day	77 (76.2)	66 (77.6)

[a]Analysis of AURORA 2 patients includes 12-month data from AURORA 1 (AURORA 2 baseline) and 24 months of follow-up in AURORA 2. Values are number (percentage) calculated out of number of patients in study at time point.