steroids during the study was similar for both treatment arms; over three years of treatment, the majority of patients were on steroid doses ≤2.5 mg/day (Table 1). There were no new or unexpected safety signals detected in patients who continued on voclosporin treatment compared to control-treated patients with similar rates of serious adverse events in the voclosporin (18.1%) and control arms (23.0%). There were no deaths in the voclosporin arm during AURORA 2; four deaths were reported in the control arm (pulmonary embolism [n=1], coronavirus infection [n=3]). Mean eGFR remained stable throughout the study (Figure 1B).

Conclusions Voclosporin was safe and well-tolerated over three years of treatment with a similar safety profile to control and no unexpected safety signals detected. Further, the significant reductions in proteinuria initially achieved in AURORA 1 were maintained in AURORA 2 even in the absence of traditional high-dose steroids. These data provide evidence of a long-term treatment benefit of voclosporin in patients with lupus nephritis and also support the use of lower doses of steroids in the treatment of this disease.

S06.3 EVALUATION OF PREDICTIVE FACTORS OF WORSE PROGNOSIS IN LUPUS NEPHRITIS: FOCUS ON NEW PATHOGENETIC PATHWAYS

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10.1136/lupus-2022-elm2022.15

Purpose Cytokine dysregulation plays an important role in the pathogenesis of lupus nephritis (LN). IL-17/IL-23 axis seems to have an important influence in the development of LN. The aim of this study is to evaluate the strongest prognostic factors in a cohort of patient with LN focusing on of the impact of IL-17/IL 23 axis as emerging pathogenetic pathway on renal outcome.[1,2]

Methods 91 patients with active LN (76 females and 15 males; mean age at study entry± SD, 44.1 ± 12.1, mean follow-up in months ± SD, 78.5 ± 50.1) at disease onset or at disease flare were enrolled. Laboratory, immunological and disease activity data were collected at baseline and at 6(T6),12 (T12),24(T24) months and at the last follow-up(FU). 84 renal biopsies were evaluated according to ISN/RPS classification, assessing the activity and chronicity indices and the active interstitial infiltrate using the BANFF score system. Baseline IL-17 and IL-23 serum levels were assessed by ELISA in 37 patients.

Results among the 84 renal biopsies evaluated 77% belonged to class III and IV according to ISN/RPS; 41,8% of patients had a renal active interstitial infiltrate (>5%). Regardless any significative difference in the IL -17 serum levels between patients with worse versus favourable nephritis course, patients with higher IL-17 serum levels at the baseline showed higher levels of renal interstitial infiltrate and a worse renal outcome overall. Finally, at univariate and multivariate analysis for each renal outcome considered, active interstitial infiltrate (>5%) at renal biopsy and the presence of at least one antiphospholipid antibodies positivity (APL+) were associated with worse renal outcomes. In particular active inflammatory interstitial infiltrate was associated to worse renal outcome in terms of not reaching early remission in both univariate analysis (p<0,01) and multivariate analysis (OR 0.12 (0.04–0.37)), while it was associated to chronic damage (p= 0,01), no persistent remission (p= 0,02), persistent proteinuria (p <0,01), and renal flare (p<0,001) in the univariate analysis. APL+ was associated to worse renal outcome in terms of early remission in both univariate analysis (p= 0,03) and multivariate analysis (OR 0.36(0.11–1.37)) as well as to chronic renal damage in univariate analysis (p= 0,04) and multivariate analysis (OR 0.77 (0.39–15.16)), while it was associated to persistent remission (p= 0,01) and persistent proteinuria (p= 0,01) in the univariate analysis. Higher IL-23 serum level was associated with persistent proteinuria (p<0,01) and chronic renal damage (p=0.05).

Conclusion interstitial inflammatory infiltrate and APL+ represent in our study the strongest predictors of worse renal outcome. A higher IL-23 serum level was found to be a negative prognostic factor suggesting a possible role of IL-17/IL 23 axis as a biomarker of a more aggressive renal disease.

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1. Chen DY, *et al. Lupus* 2012.
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Thursday 06 October 2022 from 08:00 to 10:00

S09 SLE EPIDEMIOLOGY AND STUDIES OF SUBGROUPS

S09.1 INCIDENCE AND PREVALENCE OF SYSTEMIC LUPUS ERYTHEMATOSUS IN A LARGE POPULATION-BASED STUDY IN NORTHEASTERN ITALY, BETWEEN 2012 AND 2020

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10.1136/lupus-2022-elm2022.16

Objectives Incidence and prevalence of SLE widely vary across different countries, being influenced by study design, population demographics, and ethnicity. Four studies evaluated the epidemiology of SLE in Italy: they covered a short period of time (4 year at most), two of them were published more than fifteen years ago, and they all involved a small number of participants (112,365, 346,000, 71,204, and 25,885 individuals as the general population screened, respectively).[1–4] We aimed at estimating the incidence and prevalence of SLE in northeastern Italy over the period 2012–2020.

Methods A retrospective population-based study was conducted in Veneto Region using the Population Registry, an administrative health database where all residents are recorded (about 4.9 million people). The population registry was linked with healthcare co-payments exemptions, hospital discharge records, and mortality records. SLE was defined by any hospital diagnosis of SLE (ICD-9-CM 710.0) or a healthcare copayment exemption for SLE (national registry code 028). Standardized incidence and prevalence were estimated per 100,000 people in the period 2012–2020, stratified by age, gender, and year.