### Abstracts

**MALE SEX AND DISEASE ACTIVITY AT DIAGNOSIS ARE PREDICTORS OF SEVERE HEMOLYTIC ANEMIA IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: DATA FROM A MULTIETHNIC LATIN AMERICAN COHORT**


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**TWO-YEAR OUTCOMES BY BELIMUMAB ADDITIVE ON STANDARD OF CARE IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS: A SINGLE CENTER RETROSPECTIVE COHORT STUDY**

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**RESULTS**

The median SLEDAS at 2 years was significantly decreased from baseline in BEL+SoC (2.08 to 1.12, p<0.001) but not in SoC (2.09 to 2.03, p=0.058). Low disease activity was achieved with significant difference in BEL+SoC compared to SoC (29 (88.8%) vs 17 (51.5%), p=0.023) without difference in remission rate (72.7% vs. 51.5%, p=0.127). Median daily prednisolone (PSL) dose at 24 weeks significantly decreased in both treatment groups from baseline (BEL+SoC; 6.0 to 3.5 mg/day, p<0.001, SoC; 5.0 to 4.0 mg/day, p<0.001) without a statistical difference (p=0.112). However, absolute reduction was significant in BEL+SoC (-3.0mg) compared to SoC (-1.0mg) (p=0.004). Disease recurrence occurred in 5 (15.2%) patients in BEL+SoC and 4 (12.1%) in SoC (p=0.714). All recurrences in patients with BEL+SoC were experienced after 10 months and later during PSL tapering. Whereas those in SoC occurred from one month and later, which did not always relate to PSL tapering.

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**BACKGROUND**

Systemic lupus erythematosus (SLE) is an important cause of secondary warm-antibody autoimmune hemolytic anemia (AIHA). The prevalence of AIHA has been estimated to range from 5% to 30%, but severe AIHA is comparatively less frequent in SLE patients. The severity of AIHA has rarely been studied in SLE patients; 1–3 we thus have examined the predictors of severe AIHA using the extensive database of a large Latin American inception cohort.

**METHODS**

In patients with a recent diagnosis of SLE (≤2 years), factors associated with the occurrence of severe AIHA (hemoglobin level <7 g/dl) were examined by Cox proportional univariable and multivariable hazards regression analyses.

**RESULTS**

Of 1,349 patients, 103 (7.6%) developed AIHA over 5.4 (3.8) years. Of them, 49 (47.6%) patients were classified as having severe AIHA (Mestizo 44.9%, Caucasians 40.8%, and African-Latin American 14.3%). The median time from the first clinical SLE manifestation to the occurrence of severe AIHA was 3.7 months (IQR 1.4–15). In the univariable analyses, male sex and disease activity at diagnosis were associated with a shorter time to severe AIHA occurrence while malar rash and photosensitivity were associated with a longer time. By multivariable analysis and after adjusting for age at SLE diagnosis, gender, and ethnicity, male sex, and higher disease activity at diagnosis remained associated with a shorter time to the occurrence of severe AIHA. The results are shown in the Table below.

**CONCLUSIONS**

Severe AIHA occurred in 3.6% of our cohort and it is an early manifestation of lupus. In Latin American patients with SLE, male sex represents more than a two-fold higher risk of experiencing severe AIHA at a faster pace. A higher level of disease activity at SLE diagnosis is also an independent predictor of the occurrence of severe AIHA in a shorter time.

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**RESULTS**

The median SLEDAS at 2 years was significantly decreased from baseline in BEL+SoC (2.08 to 1.12, p<0.001) but not in SoC (2.09 to 2.03, p=0.058). Low disease activity was achieved with significant difference in BEL+SoC compared to SoC (29 (88.8%) vs 17 (51.5%), p=0.023) without difference in remission rate (72.7% vs. 51.5%, p=0.127). Median daily prednisolone (PSL) dose at 24 weeks significantly decreased in both treatment groups from baseline (BEL+SoC; 6.0 to 3.5 mg/day, p<0.001, SoC; 5.0 to 4.0 mg/day, p<0.001) without a statistical difference (p=0.112). However, absolute reduction was significant in BEL+SoC (-3.0mg) compared to SoC (-1.0mg) (p=0.004). Disease recurrence occurred in 5 (15.2%) patients in BEL+SoC and 4 (12.1%) in SoC (p=0.714). All recurrences in patients with BEL+SoC were experienced after 10 months and later during PSL tapering. Whereas those in SoC occurred from one month and later, which did not always relate to PSL tapering.
Conclusions Add-on treatment with BEL was effective to achieve low disease activity during PSL tapering which would lead to reducing GC related organ damages. However, recurrence was observed in both groups indicating the need for GC tapering strategies in an individual setting.

Methods Patients who fulfilled ≥4 ACR criteria for SLE and had a DEXA scan performed were followed longitudinally. The incidence of MACEs documented by imaging studies was evaluated. Osteoporosis/fracture at baseline was defined as a T score of <−2.5 or Z score <−2.0 at the hip/femoral neck/spine, or old fragility fractures. The effect of osteoporosis on incident MACEs was studied by Cox regression, adjusted for confounders.

Results 383 SLE patients were studied (age 40.5±13 years; 94% women). Osteoporosis/fractures was present in 113 patients at baseline. Over 153±41 months, 44 MACEs (acute coronary syndrome [n=19]; ischemic stroke [n=19]; peripheral vascular disease with digital gangrene [n=6]) developed in 42 patients. The incidence of MACEs was significantly higher in patients with osteoporosis/fracture than those without (1.59 vs 0.63/100 patient-years; p=0.001). The cumulative risk of MACEs by KM plot was significantly higher in the osteoporosis than non-osteoporosis groups (p=0.002). Cox regression revealed osteoporosis/fracture was an independent risk factor for MACEs after adjustment for age, sex, vascular risk factors, past MACE, APL antibodies, and the use of immunosuppressive drugs, aspirin/warfarin, statins, vitamin D and bisphosphonates (HR 2.41[1.25–4.67]; p=0.009). 62(16%) patients succumbed and osteoporosis/fracture at baseline was associated with vascular mortality (HR 11.1[1.02–120]; p=0.048) but not with all-cause mortality after adjustment for the same confounders.

Conclusions Osteoporosis increases the risk of MACEs and vascular mortality in patients with SLE, which is not accounted by traditional vascular risk factors.

Prevalence and Risk Factors of Fragility Fractures in Systemic Lupus Erythematosus (SLE): A Longitudinal Study over 12 Years

Background To study the prevalence and risk factors of fragility fractures in patients with SLE.

Methods 383 patients who fulfilled ≥4 ACR criteria for SLE and had a DEXA scan performed (baseline) were longitudinally followed for new fragility fractures. Osteoporosis/fracture was defined as a DEXA T score <−2.5 or Z score <−2.0 at the hip/femoral neck/spine or a history of old fractures. The cumulative incidence of new fractures was studied by Kaplan-Meier’s analysis and risk factors by Cox regression, adjusted for confounders.

Results 383 SLE patients were studied (age 40.5±13 years; 94% women). Patients with osteoporosis/fracture at baseline (n=113) were more likely to have childhood onset disease (<18 years), longer SLE duration and higher prevalence of hematological or neuropsychiatric manifestations than those without. Use of glucocorticoids (GCs) and MMF/AZA, BMI≥18kg/m2, premature menopause (<45 years) were also more frequent in the osteoporosis/fracture group. However, no difference in the SLEDAI scores was observed. Over 153±41 months, new symptomatic fragility fractures developed in 34(8.9%) patients (vertebral [n=19], hip [n=2], limbs (non-hip) [n=6], digital/rib [n=7]; incidence 0.69 per 100 patient-years). The cumulative risk of fragility fractures was

Effect of Osteoporosis on Major Adverse Cardiovascular Events (MACEs) in Systemic Lupus Erythematosus (SLE): A Longitudinal Study

Background To study the effect of osteoporosis on MACEs in a longitudinal cohort of patients with SLE.

Methods We reviewed the medical records of SLE patients who were diagnosed with LS endocarditis or infective endocarditis between 1990 and 2021. Poor outcomes were defined as the occurrence of stroke, transient ischemic attack, or seizure during follow-up.

Results A total of 47 patients with LS endocarditis were compared with 5 patients with infective endocarditis. Patients with LS endocarditis were less likely to have fever, chest pain, and vegetation (40.4% vs. 100%, p=0.019) and had smaller vegetation size (median, 0 mm, vs. 12 mm, p=0.008) compared with those with infective endocarditis. Of the 37 patients with LS endocarditis who were followed for more than one year, 11 patients had poor outcomes, who had a significantly higher rate of vegetation (63.6% vs. 29.2%, p=0.048) and a lower rate of vegetation and pericardial effusion (27.3% vs. 66.7%, p=0.039) than those without poor outcomes. The presence of vegetation and pericardial effusion were significantly associated with the development of poor outcomes.

Conclusions Patients with LS endocarditis had different clinical features compared with those with infective endocarditis. Neuropsychiatric outcomes occurred in approximately 30% of patients with LS endocarditis during follow-up, and the presence of vegetation and pericardial effusion were significant factors for the development of poor outcomes.

Clinical Characteristics and Outcomes of Libman-Sacks Endocarditis in Patients with Systemic Lupus Erythematosus

Background Libman-Sacks (LS) endocarditis is one of the major cardiac involvement of systemic lupus erythematosus (SLE) and can manifest with neuropsychiatric events including stroke. However, data on the clinical features of LS endocarditis in comparison with infective endocarditis are limited. Thus, we compared SLE patients with LS endocarditis and those with infective endocarditis and analyzed the long-term clinical outcomes.

Methods We reviewed the medical records of SLE patients who were diagnosed with LS endocarditis or infective endocarditis between 1990 and 2021. Poor outcomes were defined as the occurrence of stroke, transient ischemic attack, or seizure during follow-up.

Results A total of 47 patients with LS endocarditis were compared with 5 patients with infective endocarditis. Patients with LS endocarditis were less likely to have fever, chest pain, and vegetation (40.4% vs. 100%, p=0.019) and had smaller vegetation size (median, 0 mm, vs. 12 mm, p=0.008) compared with those with infective endocarditis. Of the 37 patients with LS endocarditis who were followed for more than one year, 11 patients had poor outcomes, who had a significantly higher rate of vegetation (63.6% vs. 29.2%, p=0.048) and a lower rate of pericardial effusion (27.3% vs. 66.7%, p=0.039) than those without poor outcomes. The presence of vegetation and pericardial effusion were significantly associated with the development of poor outcomes.

Conclusions Patients with LS endocarditis had different clinical features compared with those with infective endocarditis. Neuropsychiatric outcomes occurred in approximately 30% of patients with LS endocarditis during follow-up, and the presence of vegetation and pericardial effusion were significant factors for the development of poor outcomes.