Background: Immunosuppressive therapy increases the risk of pneumococcal infection in patients with systemic lupus erythematosus (SLE). The therapy, as well as some features of the course of the disease, can lead to a decrease in the immunogenicity of the pneumococcal vaccine in these patients.

Objectives: The aim of the study was to identify "risk factors" that negatively affect the immunogenicity of the 23-valent polysaccharide pneumococcal vaccine (PPV-23) in patients with SLE.

Methods: The study included 60 patients aged 19–68 years with a reliable diagnosis of SLE, disease duration from 9 months up to 42 years old. Nine patients had high disease activity, 12 had medium, 33 had low, and 6 had remission. Therapy: 58 patients received glucocorticoids (GC) 5–40 mg/day, 46-hydroxychloroquine, 33-cytostatics (CS), 23-biologics: 12-rituximab (RTM), 10-belimumab (BLM), 1-RTM and BLM. 1 dose (0.5 ml) of PPV-23 was administered subcutaneously. During the year, standard clinical and laboratory studies were carried out, the level of antibodies to polysaccharides of the *S. pneumoniae* cell wall in the blood serum was determined.

Results: After 1–2 months after vaccination, 78.7% of patients showed a more than twofold increase in protective antibodies, a year later – in 56.7% of patients ("responders"). The severity of the vaccine response did not depend on age: in the subgroup of patients under 50 years of age ($n = 46$), the proportion of "responders" remained 52.2%, and in patients over 50 years of age ($n = 14$) – 50%. With different duration of the disease, the vaccine response did not differ significantly: with a disease period of up to 5 years, the vaccine response was observed in 47.6%, from 5 to 10 years – in 66.7%, over 10 years – in 55.6% of patients. Patients in remission had the lowest vaccine response (33.3%), while with high SLE activity, 100% response to the vaccine was recorded ($p = 0.02$), which is probably due to the fact that remission requires long-term and active immunosuppressive therapy, and patients with high activity such therapy has just been initiated or is to be. With an average and low degree of activity, the number of "responders" was the same (50% and 51.5%, respectively). In patients receiving biologics therapy, a full-fledged vaccine response was observed less frequently than in patients without biologics (39% and 68%, respectively, $p = 0.03$), while no differences were found against the background of RTM and BLM therapy (41.6% and 40% of "responders", respectively). The effect of the duration of biologics therapy on the severity of the vaccine response was analyzed. There was a tendency for the predominance of "responders" in the group with a duration of therapy before vaccination up to 1 year, as well as in the group of initiation of biologics after vaccination, however, the differences were not statistically significant.

Conclusion: RTM and BLM have a negative effect on the immunogenicity of the PPV-23 vaccine. However, if the timing of administration is observed (initiation of biologics therapy after vaccination or vaccination against the background of biologics therapy lasting less than a year), the number of "responders" increases. Further recruitment of patients is needed to clarify and confirm the results obtained.

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DECREASED RISK OF OSTEONECROSIS OVER TIME IN PATIENTS WITH SYSTEMIC LUPUS ERYTHEMATOSUS USING JAPANESE HEALTH INSURANCE DATABASE

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Background: In patients with systemic lupus erythematosus (SLE), prevalence of osteonecrosis (ON) was 20–40%¹, and 4–10 times higher risk of ON than the general population was observed^{2,3}. Because ON can influence patients' physical activity and quality of life, it is essential for rheumatologists to manage ON appropriately. Recently, medications such as mycophenolate mofetil (MMF) and hydroxychloroquine (HCQ) were approved for SLE in Japan. Considering the changes in treatments for SLE over time, it is clinically important to investigate the risk and risk factors of ON in patients with the disease. However, to date, only evidence is found in the literature.

Objectives: To estimate incidence rate (IR) and identify risk factors of ON in patients with SLE using a Japanese health insurance database.

Methods: This retrospective longitudinal population-based study was conducted using claims data provided by Medical Data Vision Co., Ltd (Tokyo,

Japan). We defined individuals as SLE cases if they met all of the following: 1) having at least one ICD10 code (M321 or M329); 2) having at least one prescription of oral corticosteroids (CS), methylprednisolone (mPSL) pulse therapy, immunosuppressive drugs (IS) (azathioprine, mizoribine, tacrolimus, MMF, cyclophosphamide, methotrexate), biologics (belimumab, rituximab) or HCQ between January 2010 and January 2017; 3) being 16 years old or over. The start of observation was defined by the first month in which cases met all of the above criteria. Patients were followed until the earliest of date of first ON, date of loss of follow-up, or the end of follow-up (December 2017). ON was defined when patients had at least one ICD code (M87.0, M87.1, M87.2, M87.3, M87.8, M87.9, M90.5) during the observation period. Patients were excluded if they had a previous diagnosis of ON during the first 3 months of the observation period. We defined baseline characteristics using the data in the month of starting observation, and calculated incidence rate (IR) in each year, adjusted relative risk (RR [95% CI]) of ON using a Poisson regression model, and adjusted odds ratio (OR [95% CI]) of risk factors of ON after adjusting for age and sex at baseline, and medications and comorbidities during the observation period using a logistic regression model.

Results: In this study, 16,386 cases were included. The median age was 55 years and 81.3% were female. Median observation period was 33 months, and total observation period was 47,138 patient-years (PY). IR/1,000 PY of ON in each year from 2010 to 2017 was 13.2, 10.6, 11.0, 13.3, 13.1, 9.8, 8.5, and 7.3, respectively. Adjusted RR in each year from 2011 to 2017 compared to 2010 was 0.5 [0.2–1.4], 0.3 [0.1–0.9], 0.6 [0.3–1.4], 0.7 [0.3–1.6], 0.4 [0.2–0.8], 0.4 [0.2–0.8], and 0.3 [0.1–0.7], respectively. Adjusted OR was 1.22 [1.10–1.34] for younger age by decade, 1.41 [1.11–1.79] for male, 2.69 [1.52–4.76] for use of oral CS (> 0 and < 5 mg/day of prednisolone [PSL] equivalent dose versus no use), 2.21 [1.26–3.86] for oral CS (≥ 5 and < 10 mg/day versus no use), and 1.25 [1.02–1.54] for dyslipidemia.

Conclusion: Significant decrease in IR of ON after 2015 was observed in Japanese patients with SLE for the first time. Younger age, use of CS, and dyslipidemia were identified as significant risk factors of ON.

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