Background: APS is an autoimmune disease characterized by persistent antiphospholipid antibodies (aPLs) positivity, leading to thrombotic events or pregnancy morbidity. High-risk aPLs profiles included positive lupus anticoagulant (LA) and multiple aPLs positivity. Association was also found between aPLs and a variety of manifestations beyond thrombosis, referred to “non-criteria manifestations” (i.e., thrombocytopenia, hemolytic anemia, heart valve disease and aPL-related nephropathy), of which the role in APS risk stratification is poorly understood. The manifestation spectrum of APS is wide, ranging from asymptomatic aPLs positivity to life-threatening catastrophic APS, and patients other than confirmed APS also need proper management. Therefore, a risk stratification integrating demographic data, aPL-related manifestations, aPLs profiles, coexisting cardiovascular risk factors and SLE is needed for management guidance and prognosis assessment.

Objectives: Using cluster analysis, to identify phenotypes among aPL-positive patients and assess the prognosis of each phenotype.

Methods: This is a single-center, prospective cohort study of aPL-positive patients who presented to Peking Union Medical College Hospital from 2004 to 2020. Demographic characteristics, aPL-related manifestations, cardiovascular risk factors, antibodies profile and follow-up data were recorded. The primary end point was defined as a combination of newly onset arterial thrombosis (AT) or deep venous thrombosis (DVT), major bleeding events, non-criteria manifestations and all-cause death. Hierarchical cluster analysis with the Euclidean distance and the Ward method was applied to identify clusters of patients and variables separately. Multiple comparison and Kaplan-Meier survival analysis were performed among clusters.

Results: For four clusters among 383 patients (70.2% female; mean age 37.7 years) were identified (Figure 1A). Cluster 1 (n=138): female patients with SLE, non-criteria manifestations, triple aPLs positivity, high AT rate and moderate DVT rate. Cluster 2 (n=112): male patients with obesity, smoking history, hypertension, hyperhomocysteinemia, triple aPLs positivity and the highest rate of AT and DVT. Cluster 3 (n=83): female patients with the highest pregnancy morbidity rate and the lowest thrombosis rate. Cluster 4 (n=50): 62% male patients with isolated LA positivity, high AT rate and moderate DVT rate. Four clusters of variables were also identified (Figure 1A). From Kaplan-Meier survival analysis, 1-, 5- and 10-year event-free survival rates were 92.6%, 79.8% and 66.8%, respectively. Cluster 3 showed lowest incidence of primary endpoint (Figure 1B), while Cluster 1 and 2 showed higher newly-onset AT risk compared with other clusters (P=0.028 for 2 vs 3 and P=0.049 for 2 vs 4).

Figure 1.

Conclusion: We identified 4 clinical phenotypes of aPL-positive patients. APS secondary to SLE was always aggregated with non-criteria manifestations. Clinicians should be alert to the possibility of SLE in aPL-positive patients with coexisting non-criteria manifestations, for whom immunosuppressive therapy besides anticoagulation may be necessary. Cluster 4 represented patients with isolated LA positivity and shared similar prognosis with secondary APS and male patients, which confirmed that LA represented a high-risk antibody spectrum. Additionally, cardiovascular risk factors (i.e., male, smoking history and obesity) played an important role in thrombosis events, and led to poor prognosis. Therefore, more attention should be paid to male patients, and the screening and management of cardiovascular risk factors should not be ignored.

Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.1133

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Disclosure of Interests: None declared.

DOI: 10.1136/annrheumdis-2021-eular.1223