

CLASSIFICATION CRITERIA FOR ANTIPHOSPHOLIPID SYNDROME: ACR/EULAR 2023 VERSUS SYDNEY 2006 - A MONOCENTRIC AND RETROSPECTIVE STUDY.

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Background and Aims:

Antiphospholipid syndrome (APS) is a systemic autoimmune disorder characterized by thrombotic events and/or obstetric complications in individuals with the characteristic detection of specific antiphospholipid autoantibodies. The classification criteria of APS were reformulated in 2023 by the European Alliance of Associations for Rheumatology (EULAR) together with the American College of Rheumatology (ACR) to replace the previous Sydney classification criteria. The new ACR/EULAR criteria have been specifically designed to increase the capacity to identify more homogeneous subgroups of APS patients and, thereby, to facilitate the interpretation of clinical studies on APS. However, the diagnosis of APS remains a clinical challenge, and there is still ongoing discussion regarding the applicability of these classification criteria in clinical practice. Notably, previous studies have shown that the Sydney classification criteria have also been used as diagnostic criteria.

The aim of this study was to evaluate the impact of ACR/EULAR 2023 classification criteria in a monocentric cohort of patients with a previous APS diagnosis who were followed in our Institute, Medicina Generale B, at Verona University Hospital, Verona, Italy.

Methods:

In this observational and retrospective study, the clinical records of 61 subjects with diagnosis of APS according to the Sydney 2006 criteria were evaluated by applying the ACR/EULAR 2023 criteria. As regards laboratory domains of anticardiolipin and anti- β 2-glycoprotein I antibodies, since these antibodies were evaluated in our population exclusively by CLIA methods, threshold values for diagnosing APS were

deducted from a previous work investigating the harmonization in defining low, moderate, and high thresholds of positivity by different assays, including ELISA and CLIA [1].

Results:

The results showed that only 16 (26.2%) out of 61 patients with previous diagnosis of APS according to the Sydney 2006 criteria were also classified as APS by the ACR/EULAR 2023 criteria. Such divergence was more pronounced in the obstetric forms of APS, where only 1 (6.3%) out of 16 patients was confirmed. On the other hand, among patients with thrombotic forms of APS 15 (33.3%) out of 45 diagnosis were confirmed. The lack of laboratory domains, which were defined as above [1], was more prevalent than the lack of clinical domains in both thrombotic and obstetric forms of APS (55.6% vs. 22.2% and 87.5% vs. 62.5%, respectively).

Conclusions:

The results of this retrospective study support the concept of how the new ACR/EULAR 2023 classification criteria may have a substantial impact on the definition of APS and the prevalence of such diagnosis. The potential diagnostic and therapeutic implications of these results need to be addressed in further longitudinal and prospective studies.

1 : Vandavelde A, Gris JC, Moore GW, Musiał J, Zuily S, Wahl D, Devreese KMJ. Toward harmonized interpretation of anti-cardiolipin and anti- β 2-glycoprotein I antibody detection for diagnosis of antiphospholipid syndrome using defined level intervals and likelihood ratios: communication from the ISTH SSC Subcommittee on Lupus Anticoagulant/Antiphospholipid Antibodies. *J Thromb Haemost.* 2024 Aug;22(8):2345-2362. doi: 10.1016/j.jth.2024.04.016.

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