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## Review

### The relevance of “non-criteria” clinical manifestations of antiphospholipid syndrome: 14th International Congress on Antiphospholipid Antibodies Technical Task Force Report on Antiphospholipid Syndrome Clinical Features <sup>☆</sup>



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#### ABSTRACT

The purpose of this task force was to critically analyze nine non-criteria manifestations of APS to support their inclusion as APS classification criteria. The Task Force Members selected the non-criteria clinical manifestations according to their clinical relevance, that is, the patient-important outcome from clinician perspective. They included superficial vein thrombosis, thrombocytopenia, renal microangiopathy, heart valve disease, livedo reticularis, migraine, chorea, seizures and myelitis, which were reviewed by this International Task Force collaboration, in addition to the seronegative APS (SN-APS). GRADE system was used to evaluate the quality of evidence of medical literature of each selected item. This critical appraisal exercise aimed to support the debate regarding the clinical picture of APS. We found that the overall GRADE analysis was very low for migraine and seizures, low for superficial venous thrombosis, thrombocytopenia, chorea, longitudinal myelitis and the so-called seronegative APS and moderate for APS nephropathy, heart valve lesions and livedo reticularis. The next step can be a critical redefinition of an APS gold standard, for instance derived from the APS ACTION registry that will include not only current APS patients but also those with antiphospholipid antibodies not meeting current classification criteria.

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<sup>☆</sup> Dedication: The authors would like to dedicate this manuscript to the memory of Silvia Pierangeli.  
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## 1. Introduction

### 1.1. Panorama of APS clinical criteria and diagnosis challenges

Antiphospholipid syndrome (APS) classification process is characterized by the presence of antiphospholipid antibodies (aPL), namely anticardiolipin antibodies (aCL), anti-beta 2 glycoprotein I (anti-b2GPI), or lupus anticoagulant (LA) associated with thrombosis of arteries or veins or the microcirculation and/or well defined obstetrical manifestations. However, to date there are no accepted criteria for diagnosis of this condition, although classification criteria tend to be used for definition and for diagnostic purposes. Current classification criteria for definite APS were established in a workshop, preceding the 11th International Congress on aPL in Sydney. These criteria derived from the Sapporo preliminary classification criteria for APS [1].

Several clinical manifestations associated with aPL are not included in the revised classification criteria [1]. Since the Congress in Sydney, a significant body of basic research and clinical studies on APS has appeared, bringing new data and an opportunity to revise clinical as well as laboratory manifestations. Considering these new data, the main goal of this task force was to examine the body of evidence related to the set of clinical manifestations that are not included in the current criteria and their association with aPL.

In this context, the Antiphospholipid Antibodies Task Force on Clinical Manifestations was carried out from January to September, 2013 to examine data, the quality of evidence according to GRADE system and develop recommendations in order to carefully suggest a revision of the current classification criteria [2]. A workshop held in

Rio de Janeiro at the 14th International Antiphospholipid Congress discussed the findings [3,4]. We examined all potential clinical criteria and selected the most relevant ones, we did not discuss the obstetrical manifestations, the future trends in treatment and the catastrophic APS which were evaluated by other groups [5–7].

## 2. Objectives

The objectives of this task force were: (1) to assess the patient-important outcomes that have been considered as non-criteria APS manifestations, and (2) to assess the body of evidence of each outcome to support the recommendation to be included on APS classification criteria.

## 3. Methodology

The PICO question was formulated as: “In patients with APS (*P*), are non-criteria APS manifestations (*I*) associated with APS classification, leading to earlier and most adequate treatment intervention to improve the patient-important outcomes (*O*)?”

We aimed to define and assess the outcomes that may be related to each non-criteria manifestation. An international group of APS experts of different specialties suggested *non-criteria APS manifestations* that were considered relevant. Some of the authors presented the current evidence in their area of expertise. Finally, during the Meeting, there was a debate in order to evaluate the proposal to include each manifestation as part of updated APS classification criteria.

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