

Developing new classification criteria for improving antiphospholipid syndrome research

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An international team of more than 80 collaborators led by Hospital for Special Surgery (HSS) investigators is developing new classification criteria for clinical research of antiphospholipid syndrome (APS), a life-threatening autoimmune clotting disorder.

In their paper, published online ahead of print on November 30, 2020, in *Arthritis Care & Research*, the investigators reported on the first two of four phases of criteria development. Phase I and II involved generating 261 candidate criteria for defining APS and reducing the list to 27 finalist criteria, grouped into six specific categories: laboratory tests, macrovascular, microvascular, obstetric, cardiac and hematologic. The ultimate goal is to develop a threshold-based scoring system that will allow researchers worldwide to determine which patients most likely have APS and should be included in research studies.

APS is an autoimmune disorder in which the

immune system produces antibodies against specific normal proteins in the blood, causing clots in blood vessels, low platelet counts, heart valve abnormalities and pregnancy complications. It is the leading cause of stroke in young people, causing one in three strokes in people under the age of 50, one in five recurrent miscarriages and up to 20 percent of all deep vein thromboses. The [disease](#) is often found in patients with other autoimmune conditions, especially lupus.

The current APS Sapporo Classification System was published in 1999, validated in 2000, and revised in 2006. "The previous [classification](#) system was based on the available evidence at the time," says lead author Medha Barbhuiya, MD, MPH, rheumatologist at the Barbara Volcker Center for Women and Rheumatic Diseases at HSS and assistant professor of medicine and population health sciences at Weill Cornell Medicine. "In the last decade, researchers have identified additional features of APS that deserve inclusion. We also now have more rigorous methods for developing and validating disease classification criteria."

The international initiative is jointly funded by the American College of Rheumatology (ACR) and the European League Against Rheumatism (EULAR), in recognition of the need for improving the method of classifying patients for APS research to be used worldwide. Doruk Erkan, MD, MPH, rheumatologist at the Barbara Volcker Center for Women and Rheumatic Diseases at HSS and associate professor of medicine at Weill Cornell Medicine, is the senior author and co-principal investigator together with Stephane Zuily, MD, MPH, Ph.D., a vascular medicine specialist and professor of medicine at the Université de Lorraine, Nancy, France.

Emphasizing the difference between classification

versus diagnosis criteria for APS, Dr. Erkan says, "Classification criteria are intended to be used in a research setting whereas [diagnostic criteria](#) are used in a [clinical setting](#) for the purpose of managing diseases; the two sets of criteria may have overlapping elements, but they have separate goals. The goal of classification criteria is to ensure that patients with common characteristics, thought to be specific for a certain disease, are included in appropriate research studies. In contrast, the goal of diagnostic criteria is to identify, as accurately as possible, whether patients have that particular disease."

The next phase of the new APS classification criteria methodology involves defining, refining, and weighting the candidate criteria and assigning a threshold score for identifying APS using real-world cases and a computer-based decision tool. Following the final validation phase of the project, researchers plan to report their results in 2021. Dr. Barbhaiya is also supported by a separate but related grant, the 2018 Rheumatology Research Foundation Investigator Award, to investigate risk factors for APS using the data collected during new classification criteria development.

"We are excited to be developing validated classification criteria for APS as previously done for other rheumatologic diseases, such as lupus and rheumatoid arthritis," says Dr. Erkan, who is also co-chair of the AntiPhospholipid Syndrome Alliance for Clinical Trials and International Networking (APS ACTION). "A threshold score for identifying patients with the disease will go a long way to advancing APS research, with the ultimate goal of high-quality research to improve APS prevention and treatment options for patients."

More information: Medha Barbhaiya et al, Development of New International Antiphospholipid Syndrome Classification Criteria Phase I/II Report: Generation and Reduction of Candidate Criteria, *Arthritis Care & Research* (2020). [DOI: 10.1002/acr.24520](#)

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