

## Statins have potential to treat an autoimmune clotting disorder called antiphospholipid syndrome

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New research suggests that statins, traditionally used for cholesterol lowering, could be used in the management of individuals who are at risk for developing clotting because they have autoimmune antiphospholipid antibodies (aPL). The research will be presented in two presentations at the annual meeting of the American College of Rheumatology/Association of Rheumatology Health Professionals (ACR/ARHP). The meeting will be held Nov. 9-14, in Washington D.C.

"What we have shown is that inflammatory and thrombotic proteins are elevated in aPL-positive <u>patients</u> and that statins can decrease these proteins," said Doruk Erkan, MD, an associate attending rheumatologist and clinician researcher at Hospital for <u>Special Surgery</u> in New York City, who was one of the two main investigators in the study together with Silvia Pierangeli, Ph.D., at University of Texas Medical Branch, Galveston, Texas. The researchers note that statins would not be useful in treating individuals who are at risk for <u>pregnancy loss</u> because of aPLs—statins are contraindicated during pregnancy.

For years, researchers have known that aPLs can trigger the production of proteins that can cause <u>inflammation</u> and increase the risk of formation of clots. While some aPL-positive individuals develop <u>blood</u> <u>clots</u>, strokes, and <u>pregnancy complications</u>, others are perfectly healthy. Individuals who are aPL-positive and have either <u>venous thrombosis</u>, arterial <u>thrombosis</u>, or fetal loss are classified as having antiphospholipid



syndrome (APS).

The new research was a collaborative effort between investigators at Hospital for Special Surgery and the University of Texas Medical Branch, Galveston, Texas. Investigators enrolled 41 patients who were aPL-positive, some of whom were healthy and some who had APS. They tested their blood for 12 inflammatory and thrombotic (clot forming) proteins, and then compared the results to data from 30 healthy patients who were aPL negative. These controls were matched for sex and age. Nine of the 12 proteins were elevated in aPL-positive patients compared to healthy controls.

The researchers then set out to test whether a statin called fluvastatin could reduce the proteins that were elevated in the individuals with aPLs. "Statins do more than just lowering cholesterol. They also have anti-inflammatory effects," said Dr. Pierangeli. The 41 aPL-positive patients were given 40 mg of fluvastatin daily for three months and then were instructed to stop taking the drug. Investigators collected blood samples and measured the levels of the inflammatory and thrombotic proteins at baseline and monthly thereafter for six months.

Of the 24 patients who completed the study, the researchers found that fluvastatin significantly decreased the levels of eight of the 12 proteins, all of which had been elevated in aPL-positive individuals compared with controls. The investigators also found that when patients stopped taking the fluvastatin, the levels of six proteins rebounded to high levels.

"Following Dr. Pierangeli's mouse experiments in which statins decreased inflammatory proteins induced by aPL, this is the first prospective study analyzing these proteins in aPL-positive patients before and after treatment with fluvastatin," said Dr. Erkan. "Launching a randomized trial to determine the effect of statins on clinical outcomes is the logical next step."



"An Open-Label Prospective Pilot Mechanistic Study of Fluvastatin in Persistently Antiphospholipid Antibody-Positive Patients" will be presented on Nov. 13 at 3 p.m. ET. Other authors involved in the study are JoAnn Vega from Hospital of Special Surgery; and Rohan Willis, M.D., Vijaya Murthy, M.D., Gurjot Basra, M.D., Emilio Gonzalez, M.D., Ana Laura Carrera Marin, and Patricia Ruiz Limon from the University of Texas Medical Branch, Galveston, Texas.

"Pro-inflammatory and Pro-thrombotic Markers in Persistently Antiphospholipid Antibody-Positive Patients With/Without Systemic Lupus Erythematosus" will be presented on Nov. 13 at 2:45 p.m., ET.

## Provided by Hospital for Special Surgery

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