

# Study sheds light on pregnancy complications and overturns common belief

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"Many doctors may be unnecessarily treating some pregnant women who have antiphospholipid antibodies (aPLs) with anticoagulants, such as expensive heparin injections, which can cause bleeding and bone loss, explained Dr. Jane Salmon, the paper's senior author. Credit: Hospital for Special Surgery

A study led by Hospital for Special Surgery researchers has demonstrated that women who have a specific type of antibody that interferes with blood vessel function are at risk for adverse pregnancy outcomes and that other antibodies in the same family thought to cause pregnancy complications do not put women at risk.

The researchers say that many doctors may be unnecessarily treating some [pregnant women](#) who have antiphospholipid [antibodies](#) (aPLs) with anticoagulants, such as expensive [heparin](#) injections, which can cause bleeding and [bone loss](#). The multicenter study appears in the July 2012 issue of the journal [Arthritis & Rheumatism](#).

"This paper identifies people who are at risk for pregnancy loss and, more importantly, those who are not at risk and who therefore do not need to be treated," said Michael Lockshin, M.D., director, Barbara Volcker Center for Women and Rheumatic Disease, and co-director, Mary Kirkland Center for Lupus Research at Hospital for Special Surgery (HSS), New York City, and lead author of the study.

Antiphospholipid antibodies interfere with phospholipids, a type of fat found in all living cells and cell membranes, including blood cells and the lining of [blood vessels](#). Patients with these antibodies are at risk for blood clots, stroke, and [pregnancy complications](#), but some patients with these antibodies can be completely healthy. "Phospholipids are highly exposed in the placenta, and as a result antiphospholipid antibodies concentrate there," said Jane Salmon, M.D., the study's senior author and Collette Kean Research Chair and co-director, Mary Kirkland Center for Lupus Research at HSS. "When antibodies are deposited in a person's tissues, inflammation is initiated leading to organ damage." And this is a mechanism for pregnancy complications.

Women who have recurrent pregnancy loss are commonly tested for the presence of aPLs, and up to 15% are positive. Most patients who test positive are treated with anticoagulants. Currently, there are no standards regarding which aPLs [doctors](#) test for to assess risk (there are three main ones) and interlaboratory consistency of results is poor.

The new study is the first clinical research publication of the PROMISSE study, an ongoing multicenter, prospective clinical trial

comparing the pregnancies of women with aPL, lupus, both aPL and lupus, and healthy controls. Between 20% and 35% of patients with lupus and aPL have pregnancy complications and the study is attempting to identify which patients are at risk.

"The identification of biomarkers that identify patients at high risk will allow us to select a subset of patients who we can consider in an interventional trial," said Dr. Salmon, the principal investigator of PROMISSE. This PROMISSE study, which involves over 700 patients from nine centers in North America, is funded by the National Institute of Arthritis, Musculoskeletal and Skin Diseases of the National Institutes of Health. A strength of PROMISSE is that all aPL tests were sent to core laboratories, eliminating interlaboratory variability.

The current analysis focused on 144 patients who had aPLs, of whom 28 had adverse [pregnancy outcomes](#). A control group, 159 healthy pregnant women, was tested parallel to the group with aPLs. Controls were selected among women with no known illness, no prior fetal loss, no more than one miscarriage and at least one successful pregnancy.

The study examined the association between adverse pregnancy outcome and the presence of three different aPLs: lupus anticoagulant [LAC], anticardiolipin antibody [aCL] and antibody to  $\beta 2$  glycoprotein I. An adverse pregnancy outcome was defined as otherwise unexplained fetal death after 12 weeks, neonatal death prior to discharge that was associated with complications of prematurity, preterm delivery prior to 34 weeks because of gestational hypertension, preeclampsia or placental insufficiency, and birthing a child that was small for its gestational age.

The researchers found that LAC was the strongest predictor of an adverse pregnancy outcome; 39% of patients with LAC had an adverse outcome compared to 3% who did not have LAC (P

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