

Statin therapy fails to slow progression of atherosclerosis in pediatric lupus patients

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Atorvastatin therapy was found to be ineffective in reducing atherosclerosis progression in children and adolescents with systemic lupus erythematosus (SLE). Results of the Atherosclerosis Prevention in Pediatric Lupus Erythematosus (APPLE) Trial, now available in *Arthritis & Rheumatism*, a journal published by Wiley-Blackwell on behalf of the American College of Rheumatology (ACR), report that the statin therapy did trend toward positive effect of treatment and may benefit patients with more severe SLE who were not included in the trial.

The ACR reports that SLE affects 322,000 adult Americans. Exact figures for pediatric SLE cases are difficult to establish, but the best estimate is that 5,000 to 10,000 children in the U.S. have lupus (Lehman 1996). One of the long-term complications of SLE for both adult and pediatric [patients](#) is accelerated atherosclerosis—a build-up of plaque in the arterial wall which can lead to heart attack and stroke. Medical evidence reports that SLE patients are up to 8 times more likely to develop premature coronary heart disease, compared to the general population. Women with lupus are 50 times more likely to have a heart attack than healthy premenopausal women.

"The prognosis for pediatric [lupus](#) patients has significantly improved over the last few decades, however diagnosis at an earlier age subjects these patients to greater cardiovascular risk from systemic [disease activity](#) and treatment side effects over a longer time period," explains lead investigator, Dr. Laura Schanberg with the Department of Pediatrics at Duke University Medical Center in Durham, North

Carolina. Previous studies show children with SLE have more severe organ damage, and longer exposure to illness and potentially toxic treatments compared with adults.

Prevalence of atherosclerosis in pediatric SLE is unknown, but precursors of the disease such as thickening of arterial artery walls as measured by carotid intima-media thickening (CIMT), have been reported. Statins have been shown to reduce atherosclerosis progression in adults, but have not been investigated in a pediatric SLE population. The APPLE Trial assessed 36-month therapy with atorvastatin, commercially known as Lipitor®, in 221 SLE patients between 10 and 21 years of age at 21 sites in North America. Participants were randomized, with 113 receiving treatment with atorvastatin and 108 a placebo at 10 or 20 mg/day (depending on weight). Researchers determined effectiveness of therapy by progression CIMT as measured by ultrasound.

"Our results demonstrate no significant effect on progression of atherosclerosis in children and [adolescents](#) with SLE who were treated with atorvastatin use over the 3-year period," concluded Dr. Christy Sandborg from Stanford University School of Medicine in California and co-primary investigator of the Apple Trial. "Further study of subgroups of SLE patients that may benefit from [statin therapy](#) is warranted." While ineffective in reducing progression of atherosclerosis in this study population, atorvastatin was determined to be safe and well tolerated.

In a related editorial also published today in [Arthritis & Rheumatism](#), Dr. Angelo Ravelli from the 1Università degli Studi di Genova and Istituto di Ricovero e Cura a Carattere Scientifico in Italy said, "Although the APPLE Trial found atorvastatin to be ineffective in pediatric SLE patients with low to moderate disease activity, a trend toward positive effect was detected. This indicates that while statin

therapy may not be necessary in all SLE patients, preventative statin therapy may benefit those with more severe disease activity." Post-hoc subgroup analyses of the APPLE Trial are underway which may uncover those patient groups who may benefit from treatment with [atorvastatin](#).

More information: "Use of Atorvastatin in Systemic Lupus Erythematosus in Children and Adolescents." L. E. Schanberg, C. Sandborg, H. X. Barnhart, S. P. Ardoin, E. Yow, G. W. Evans, K. L. Mieszkalski, N. T. Ilowite, A. Eberhard, L. F. Imundo, Y. Kimura, E. von Scheven, E. Silverman, S. L. Bowyer, L. Punaro, N. G. Singer, D. D. Sherry, D. McCurdy, M. Klein-Gitelman, C. Wallace, R. Silver, L. Wagner-Weiner, G. C. Higgins, H. I. Brunner, L. Jung, J. B. Soep, A. M. Reed, J. Provenzale, and S. D. Thompson. *Arthritis & Rheumatism*; Published Online: Oct. 27, 2011 ([DOI: 10.1002/art.30645](#)).

Editorial: "Should Children and Adolescents with Systemic Lupus Erythematosus be Given Statin Therapy to Prevent Early Atherosclerosis?" Angelo Ravelli. *Arthritis & Rheumatism*; Published Online: Oct. 27, 2011 ([DOI: 10.1002/art.30642](#)).

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