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## **STATINS DON'T APPEAR TO BENEFIT PATIENTS UNDERGOING HEMODIALYSIS**

*Drug has Expected Effect on Cholesterol Levels and Inflammatory Markers,  
but Fails to Prevent or Treat Heart Disease*

**Orlando, FL** – It appears that statin therapy is not effective in preventing or treating heart disease among patients with end-stage renal disease (ESRD) on hemodialysis, a routine treatment with a machine that acts like a kidney to clean the blood of fluid and waste products, according to new data presented today at the American College of Cardiology's 58<sup>th</sup> Annual Scientific Session. ACC.09 is the premier cardiovascular medical meeting, bringing together cardiologists and cardiovascular specialists to further breakthroughs in cardiovascular medicine.

In the AURORA trial – a large-scale, international, double-blind, placebo-controlled study – patients aged 50-80 years with ESRD who had been receiving dialysis for at least three months (mean duration 3.5 years) were enrolled in 280 centers in 25 countries. A total of 2,776 patients were randomized to receive rosuvastatin (10 mg daily) or a placebo in order to determine whether initiating a statin during maintenance dialysis influenced cardiovascular-related events or death. Dialysis patients who were already taking statins were not included in the present trial.

“While statins lowered LDL cholesterol by 43 percent – roughly the same magnitude as expected in the general population--and caused a small reduction in inflammation, this did not translate into prevention of cardiovascular death or morbidity,” said Bengt Fellstrom, M.D., University Hospital, Uppsala, Sweden. “This is surprising because, even though cholesterol is not a traditional cardiovascular risk factor among patients with end-stage renal disease, we thought the lipid lowering and other vascular effects offered by statins would have a beneficial impact. A contributing factor could be that 30 to 40 percent of hemodialysis patients were already on statin treatment, and thus not eligible for participation in the study.”

Cardiovascular diseases are very common in patients with renal insufficiency and, in particular, rates of cardiovascular morbidity and mortality are substantially higher among dialysis patients than in those without renal disease.

“It’s critical that we find an effective way of preventing or treating cardiovascular disease in patients with ESRD, and since statins have been proven across so many studies to be effective in the general population, it made sense to conduct a larger study in this population,” Fellstrom said.

Another smaller study (the 4D trial) was conducted among dialysis patients with diabetes, which also found no benefit when using atorvastatin.

The authors believe statins may not be useful in hemodialysis patients because the vascular disease that these patients suffer from is very different from what is seen in the general population. Specifically, patients with ESRD have severe calcifications both in the heart and the vascular tree, which may not be treatable with statins. And while LDL cholesterol is not a risk factor for CV complications in patients with renal insufficiency, they have chemically and structurally modified blood lipids, which are aggressive to the vascular wall.

Baseline measures of body mass index, hemoglobin, blood pressure, total cholesterol, LDL-cholesterol, HDL-cholesterol and triglycerides confirm that the AURORA study population is representative of patients with ESRD on long-term, maintenance dialysis (median time for follow up was 3.2 years). Patients returned to the 280 study centers three times a week for dialysis sessions during follow up. During the course of the study, 1,296 patients died and of these, half died from cardiovascular causes. No patients were lost to follow up in the study. The primary endpoint, which was not met, was time to CV death, non-fatal heart attack or non-fatal stroke.

“Our data show that starting statin treatment in maintenance dialysis patients does not seem to benefit patients by preventing CV events,” Fellstrom said. “But we don’t know if the same results would hold true in younger patients with ESRD, or if it makes a difference if patients are already on statin therapy before or at the time they enter into dialysis. This should be an area of future investigation.”

The trial was sponsored by AstraZeneca. An independent steering committee had full control over the study, which was also supervised by an independent Data Safety and Monitoring Board. A separate and independent Critical Events Committee adjudicated all endpoints.

Complete study findings are being published simultaneously in the New England Journal of Medicine.

*Dr. Fellstrom will present the study, “Effect of Rosuvastatin versus Placebo on Cardiovascular Outcomes in Patients with End-Stage Renal Disease on Hemodialysis: Results of the AURORA Study,” on Monday, March 30 at 2:00 p.m. ET in Hall WF1.*

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The American College of Cardiology ([www.acc.org](http://www.acc.org)) works to influence health care policy and represents the majority of board certified cardiovascular care specialists through education, research, promotion, and the development and application of standards and guidelines. ACC.09 is the largest cardiovascular meeting, bringing together cardiologists and cardiovascular specialists to share the newest discoveries in treatment and prevention, while helping the ACC achieve its mission to address and improve issues in cardiovascular medicine.