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Meta-Analysis of Lipid-Lowering Therapy in Maintenance Dialysis Patients

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Commentary

By Professor Richard Glassock

Current practice guidelines do not recommend initiation of hypolipidemic agents (such as statins) in patients undergoing regular maintenance dialysis for ESRD. Green and colleagues have re-examined this issue by conducting a meta-analysis of lipid-lowering therapy (LLT) in 3 randomized controlled trials (AURORA, 4D and SHARP) which include 3,541 subjects treated with statins and 3,510 placebo controls, all undergoing maintenance dialysis (hemodialysis or peritoneal dialysis, mostly prevalent patients). The Odds Ratio (OR; treated vs. placebo) was 0.88 ($p = 0.04$) for a composite of major cardiovascular events, but the OR ranged from 0.88 to 1.29 (p = NS) for other outcomes, and no benefits were observed for CV deaths or all-cause mortality (OR of 0.99 and 0.97, respectively). This is not surprising since most deaths in ESRD patients are not of an atherosclerotic nature. Fatal and non-fatal coronary heart disease was not affected by treatment. The studies were heterogeneous with respect to enrollees – The SHARP study excluded those with prior CV events while the AURORA and 4D studies did not. The 4D study was carried out exclusively in diabetics. The LDL cholesterol fell substantially in all studies (ranging from 35 to 43%), independent of the statin used. The authors estimated that to prevent one major atherosclerotic event over one year of observation would require treatment of about 103 patients. Although no formal cost analysis was conducted, this would approximate to $ 20,000 per CV events avoided per year and an indeterminable cost per life saved (cost of drugs only using discounted generic prices). These costs might differ significantly once drug side effects, laboratory testing and hospitalization for CV events is included.

Whether routine treatment with statins of patients on dialysis for ESRD is worthwhile remains in doubt, in my opinion. Whether this applies to such patients with overt atherosclerotic coronary artery disease and markedly elevated C-reactive protein, regardless of the level of LDL cholesterol, remains an unanswered question, requiring further study.

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