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Prevention of coronary and stroke events with atorvastatin in hypertensive patients who have average or lower-than-average cholesterol concentrations, in the Anglo-Scandinavian Cardiac Outcomes Trial--Lipid Lowering Arm (ASCOT-LLA): a multicentre randomised controlled trial.

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Abstract

BACKGROUND:

The lowering of cholesterol concentrations in individuals at high risk of cardiovascular disease improves outcome. No study, however, has assessed benefits of cholesterol lowering in the primary prevention of coronary heart disease (CHD) in hypertensive patients who are not conventionally deemed dyslipidaemic.

METHODS:

Of 19342 hypertensive patients (aged 40-79 years with at least three other cardiovascular risk factors) randomised to one of two antihypertensive regimens in the Anglo-Scandinavian Cardiac Outcomes Trial, 10305 with non-fasting total cholesterol concentrations 6.5 mmol/L or less were randomly assigned additional atorvastatin 10 mg or placebo. These patients formed the lipid-lowering arm of the study. We planned follow-up for an average of 5 years, the primary endpoint being non-fatal myocardial infarction and fatal CHD. Data were analysed by intention to treat.

FINDINGS:

Treatment was stopped after a median follow-up of 3.3 years. By that time, 100 primary events had occurred in the atorvastatin group compared with 154 events in the placebo group (hazard ratio 0.64 [95% CI 0.50-0.83], $p=0.0005$). This benefit emerged in the first year of follow-up. There was no significant heterogeneity among prespecified subgroups. Fatal and non-fatal stroke (89 atorvastatin vs 121 placebo, 0.73 [0.56-0.96], $p=0.024$), total cardiovascular events (389 vs 486, 0.79 [0.69-0.90], $p=0.0005$), and total coronary events (178 vs 247, 0.71 [0.59-0.86], $p=0.0005$) were also significantly lowered. There were 185 deaths in the atorvastatin group and 212 in the placebo group (0.87 [0.71-1.06], $p=0.16$). Atorvastatin lowered total serum cholesterol by about 1.3 mmol/L compared with placebo at 12 months, and by 1.1 mmol/L after 3 years of follow-up.

INTERPRETATION:

The reductions in major cardiovascular events with atorvastatin are large, given the short follow-up time. These findings may have implications for future lipid-lowering guidelines.