Absolute and relative changes in carotid intima-media thickness and atherosclerotic plaques during long-term antihypertensive treatment: further results of the European Lacidipine Study on Atherosclerosis (ELSA).

BACKGROUND: In ELSA, a randomized, double-blind trial in 2334 hypertensives, 4-year antihypertensive treatment with lacidipine slowed down progression of carotid atherosclerosis significantly more than atenolol treatment. To avoid bias, the primary outcome was measured blindly at study-end on a randomized sequence of scans, but measurements were limited to the four far walls of common carotids and bifurcations (CBMmax) and to one of each couple of duplicate scans recorded yearly. OBJECTIVES AND METHODS: Secondary outcomes included measurements made on all duplicate scans of both near and far walls, not only of common carotids and bifurcations, but also of internal carotids (12 walls). These measurements were made blindly during the 4-year study, shortly after recording. To avoid possible readers’ drift or bias, 250 duplicate baseline scans were re-read at yearly intervals (longitudinal on-line quality control) and a correction factor calculated. RESULTS: Measurements during the 4-year study showed a trend toward decreased values, with the lacidipine effect significantly greater than the atenolol one. A trend toward lower values was also observed in the longitudinal quality control of baseline scans. After applying a correction factor calculated
from this longitudinal control, all measurements no longer decreased with time, but significantly increased, with progression being significantly smaller in lacidipine than in atenolol patients. Corrected values were quite similar to those calculated on measurements carried out at study-end. CONCLUSION: The relative benefit of lacidipine over atenolol could be measured precisely by reading scans either during the study or at study-end. However, absolute treatment-related changes (progression versus regression) cannot safely be judged by readings made during along-term study, unless a longitudinal quality control of readings is performed.