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RESULTS FROM NEW STUDY SHOW THAT BLOOD PRESSURE NEAR THE HEART IS MORE PREDICTIVE OF CARDIOVASCULAR OUTCOMES THAN BLOOD PRESSURE MEASURED IN THE ARM

Benefits of atenolol-based treatment may be overestimated, while benefits of amlodipinebased treatment are underestimated

Leicester, United Kingdom, November, 13, 2005 – Results from a new study show that amlodipine-based (calcium channel blocker) treatment is much more effective at reducing blood pressure near the heart than a conventional atenolol-based (beta blocker) regimen. The results also show that the blood pressure near the heart (central aortic blood pressure) may be more predictive of cardiovascular events, such as stroke and heart attack, than using traditional blood pressure measurements in the arm.

The results were presented as a late-breaking clinical trial today at the annual meeting of the American Heart Association in Dallas.

The new study, the Conduit Artery Function Evaluation (CAFE), is a sub-study of the Anglo-Scandinavian Cardiac Outcomes Trial (ASCOT) study – the study was led from Leicester and involved 5 major University centres in the UK and Ireland.

"The results of the CAFE study may help to explain why certain types of blood pressure treatments are more effective than others," said Bryan Williams, professor of medicine in the Department of Cardiovascular Sciences at the University of Leicester in the United Kingdom and lead investigator for the study. "The CAFE study showed that there was a clear difference between amlodipine and atenolol with regard to their effects on central aortic blood pressure. This suggests that the different types of drugs we use to lower blood pressure have very different effects on the cardiovascular system and that these effects cannot always be appreciated from the simple measurement of blood pressure".

"Measuring blood pressure in the arm seems to underestimate the efficacy of drugs such as amlodipine and overestimate the efficacy of drugs such as atenolol," Professor Williams said.

"The data is clear-cut and has important implications for clinical practice as it gives a plausible explanation for the benefits of amlodipine-based blood pressure treatment compared to the traditional atenolol-based treatment."

The CAFE study demonstrates for the first time in a large clinical outcomes trial, that different blood pressure-lowering drugs have profoundly different effects on central aortic pressure and blood flow characteristics despite similar blood pressure measurements obtained through the use of an arm cuff. It has been previously assumed that blood pressure in the arm was reflective of blood pressure in other parts of the body. However, findings from the study indicate that central aortic pressure is a better and more accurate method of measuring actual blood pressure near the heart and is an independent predictor of cardiovascular and renal outcomes.

"This is a really significant advance as it demonstrates for the first time the clear benefits to patients of using this treatment. The announcement of the results as a highlight of the American Heart Association meeting in Dallas is a major achievement for Leicester and the other centres involved in the study in UK and Ireland," Professor Williams said.

About the CAFE trial

The CAFE trial is a sub-study of the ASCOT trial and involved more than 2,000 patients from ASCOT. It was designed to illustrate the differences between peripheral blood pressure and central aortic blood pressure measurements. It also evaluated the impact that these differences have on cardiac outcomes demonstrated in ASCOT.

Participants in the CAFE study were recruited from patients participating in ASCOT at five centers after stabilization of blood pressure. Central aortic pressure measurements were performed every six months to one year in these patients. The patients selected were representative of the ASCOT study population, i.e. male patients, mostly above the age of 55 and with hypertension.

Central aortic pressure was measured using the non-invasive SphygmoCor® system, which measures central aortic pressure through the use of a computer program that interprets the shape of pulse waves measured at the wrist. This information is then used to generate a pulse wave and measurements of pressure inside the large arteries in the body.

The study found that the amlodipine-based regimen reduced central aortic pressure by 4.3 millimeters of mercury (mm Hg) compared the atenolol-based regimen which may explain the differences in cardiac outcomes observed in ASCOT. The differences may be attributable to the drugs' differing effects on arterial stiffness near the heart.

About the ASCOT study

ASCOT is one of the largest studies of high blood pressure ever conducted in Europe, involving nearly 20,000 patients with high blood pressure and additional risk factors for heart disease and stroke. Patients were randomized to receive either calcium channel blocker-based (amlodipine \pm the ace inhibitor perindopril) or beta blocker-based (atenolol \pm the diuretic bendroflumethiazide-K) treatment regimens and their blood pressure was monitored using the traditional arm cuff measurements. The ASCOT study showed that patients receiving the amlodipine-based treatment did better than those getting the atenolol-based treatment on all cardiovascular endpoints, including a 24 percent reduction in cardiovascular death

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