



## Artery Research

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### **15. OPEN LABEL, RANDOMIZED, ACTIVE DRUG COMPARATIVE, PARALLEL GROUP, MULTI-CENTER, PHASE IV STUDY TO COMPARE THE EFFECT OF BENIDIPINE AND LOSARTAN ON ARTERIAL STIFFNESS AND CENTRAL BLOOD PRESSURE IN MILD TO MODERATE ESSENTIAL HYPERTENSIVE PATIENTS (BELASC)**

Sang-Hyun Ihm, Shung Chull Chae, Do Sun Lim, Kee Sik Kim, Dong Ju Choi, Jong Won Ha, Dong Soo Kim, Kye Hun Kim, Myeong Chan Cho, Hui Kyung Jeon, Sang Hong Baek

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clinical practice is unknown. This study aimed to test the value of central BP as a management tool for physicians treating patients with essential hypertension.

**Methods:** Patients with hypertension ( $n = 84$ ;  $61 \pm 8$  years) were randomized to 12 months of treatment decisions guided by usual care (UC,  $n = 39$ ) or, in addition, by central BP (CBP,  $n = 45$ ; based on age and gender-specific normal central systolic BP [SBP] values). Titration recommendations were provided to each patient's general practitioner, as well as the patient themselves. Relevant clinical information (eg left ventricular [LV] mass, blood biochemistry and symptoms) were considered when making titration recommendations in all patients. Central BP was estimated by SphygmoCor 8.0. Primary outcome measures were; 1) change in LV mass 2) use of medication and 3) quality of life. We hypothesized that there will be no significant difference in LV mass between groups (study powered for equivalence). However, it was expected that there will be significantly less use of medication and improved quality of life in the CBP group because more appropriate titration choices will be made to maintain normal central SBP.

**Results:** Baseline LV mass index (CBP,  $27.6 \pm 5.7$  v UC,  $29.7 \pm 5.9$  g/m<sup>2.7</sup>), brachial SBP (CBP,  $130 \pm 14$  v UC  $130 \pm 14$  mmHg) and central SBP (CBP,  $118 \pm 13$  v UC  $118 \pm 15$  mmHg) were similar between groups ( $P > 0.05$  for all). However, in the CBP group, 33% ( $n = 15$ ) received a recommendation to reduce medication, whilst there were 3% ( $n = 1$ ) in the UC group ( $P = 0.001$ ). Moreover, 8 CBP patients were recommended to cease antihypertensive medication but maintained normal BP, indicating that they may have been incorrectly diagnosed with hypertension and unnecessarily taking medication based on brachial BP assessments.

**Conclusion:** Therapeutic decisions based on CBP are different from those based on standard BP. Follow up data and final results ( $N = 312$ ) are expected in 2011.

#### 15.

##### OPEN LABEL, RANDOMIZED, ACTIVE DRUG COMPARATIVE, PARALLEL GROUP, MULTI-CENTER, PHASE IV STUDY TO COMPARE THE EFFECT OF BENIDIPINE AND LOSARTAN ON ARTERIAL STIFFNESS AND CENTRAL BLOOD PRESSURE IN MILD TO MODERATE ESSENTIAL HYPERTENSIVE PATIENTS (BELASCO TRIAL)

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**Objectives:** The purpose of this study was to compare the effect of benidipine (calcium channel blocker) and losartan (angiotensin receptor blocker) on arterial stiffness and central blood pressure (BP) in mild to moderate essential hypertensives.

**Methods and Results:** This 24 weeks, multi-center, open label, randomized, active drug comparative, parallel group study was designed as a noninferior study. Eligible patients ( $n = 200$ ) were randomly assigned to receive benidipine ( $n = 101$ ) or losartan ( $n = 99$ ). Radial artery applanation tonometry and pulse wave analysis were used to derive central aortic pressure, pulse wave velocity (PWV) and augmentation index (Alx). No significant differences were found in the mean changes in central BP between 2 groups [-16.66 (systolic BP)/-10.70 (diastolic BP) mmHg in the benidipine group and -18.44/-11.79 mmHg in the losartan group;  $P = NS$ ]. The mean changes in central, brachial and femoral PWV were -0.06, +0.06 and -0.51 m/sec for the benidipine group and -0.02, -0.15 and -0.06 m/s for losartan group (respectively;  $P = NS$ ). No significant differences were found in the mean changes in Alx between two groups [-5.46 in the benidipine group and -4.22 in the losartan group;  $P = NS$ ].

**Conclusion:** The reduction in central BP after 24 weeks of benidipine was non-inferior to that of losartan in mild to moderate essential hypertensives. There were no significant difference between two drugs in aspect of PWV and Alx. Both drugs had similar central BP lowering effect and affected similarly arterial stiffness.

#### 16.

##### IS IT POSSIBLE TO PREDICT CORONARY ARTERY STENOSIS BASED ON CAROTID ARTERY INTIMA MEDIA THICKNESS IN DIABETIC PATIENTS

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**Background:** Noninvasive measurement of carotid artery intima media thickness (IMT) has been widely used as a surrogate marker of coronary atherosclerosis. However, evidence for the clinical implications of increased carotid IMT in diabetic patients is not well established. The aim of this study

was to determine if coronary artery disease (CAD) can be predicted based on carotid IMT, intimal, and medial thickness.

**Methods:** A total of 569 type 2 diabetic patients (male:female = 311:258, mean age =  $63 \pm 9$  years) who underwent coronary angiography were divided into two groups. Group 1 was composed of patients with no significant CAD ( $n = 105$ , male% = 37.1%, mean age =  $61 \pm 10$  years) on angiography. Group 2 was composed of patients with significant CAD ( $n = 464$ , male% = 58.6%, mean age =  $64 \pm 9$  years). Carotid intimal, medial thickness, and IMT were compared between the two groups. Sensitivity and specificity for detecting significant CAD by carotid ultrasound were evaluated.

**Results:** There were significant differences in the right maximal IMT, mean IMT, and medial thickness for both carotid arteries. However, there were no significant differences in the left maximal IMT and intimal thickness (Table). A right IMT of 1.13 mm and a left IMT of 1.19 mm had 94% sensitivity and 80% specificity for CAD, respectively. A right medial thickness of 0.99 mm and a left medial thickness of 1.03 mm had 100% sensitivity and 86% specificity. **Conclusion:** Carotid medial thickness and IMT were useful as screening methods for detecting significant CAD in patients with diabetes.

#### 17.

##### CAROTID INTIMA-MEDIA THICKNESS IN A LARGE COHORT STUDY AND REALLY NORMAL SUBJECTS

Woo-Baek Chung, Ho-Joong Youn, Yun-Seok Choi, Hee-Jung Hwang, Jae-Beom Lee, Jong-Won Chung, Chul-Soo Park, Yong-Seog Oh, Sang-Hong Baek, Wook-Sung Chung, Ki-Bae Seung, Jae-Hyung Kim. *The Catholic University of Korea*

**Background:** Carotid intima-media thickness (IMT) has been widely used as a surrogate of early atherosclerosis. However, the characteristics of patients in cohort-based studies of carotid IMT are very heterogeneous. We evaluated the carotid intima, media, and IMT in really normal (RN) subjects who had no coronary artery disease or other coronary risk factors.

**Methods:** Among the 3041 patients (male:female = 1819:1222, mean age =  $61 \pm 11$  years) who have undergone carotid ultrasound at our institution since 2003, 124 patients (male:female = 84:40, mean age  $54 \pm 12$  years) who had no coronary artery stenosis confirmed by coronary angiography and no diabetes, hypertension, hypercholesterolemia, or renal dysfunction were enrolled in this study. The carotid intima, media, and IMT were compared between the general population group and the RN subjects.

**Results:** Right maximal, mean IMT, intimal thickness, and medial thickness were  $0.93 \pm 0.25$ ,  $0.78 \pm 0.16$ ,  $0.24 \pm 0.36$ , and  $0.51 \pm 0.15$  mm in RN subjects, respectively. The left maximal, mean IMT, intimal thickness, and medial thickness were  $0.92 \pm 0.33$ ,  $0.79 \pm 0.24$ ,  $0.23 \pm 0.03$ , and  $0.55 \pm 0.24$  mm, respectively. The maximal and mean IMT and medial thickness of both carotid arteries were significantly higher in subjects from the general population.

**Conclusion:** In a large Korean cohort for carotid IMT, the carotid medial thickness and IMT were significantly related to atherosclerotic risk factors. We must be careful in defining the normal reference values of carotid IMT due to heterogeneous characteristics in the population.

#### 18.

##### ARTERIAL STIFFNESS IN GERIATRIC MEDICINE

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**Background:** Aging exerts a number of deleterious changes in the cardiovascular system, and, in particular, on the large arteries. Previous studies have suggested that augmentation index (Aix) and aortic pulse wave velocity (aPWV) increase linearly with age, yet epidemiological data concerning arterial stiffness suggest that large artery stiffening predominantly occurs later in life. Therefore, the aim of the study was to test the hypothesis; 1) age-related changes in Aix are more prominent in younger individuals, whereas changes in aortic stiffness per se are more marked in older individuals, 2) whether these changes are similar between Caucasians and Koreans.

**Methods:** 1,188 subjects aged 17 to 87 years (mean age of 45.5 years and female 52%) were included and all were apparently healthy and free of any medication for hypertension, diabetes and dyslipidemia. Aix and aPWV were measured by pp-1000 and Gaon 21 (both Hanbyul Medtech, Korea). **Results:** Women showed significantly higher central Aix ( $15.4$  vs.  $22.5$  of men,  $p < 0.001$ ) even with lower peripheral pressure ( $117/72$  vs.  $126/78$  of men,