SDC

***INCLUSION/EXCLUSION CRITERIA***

Men and women were eligible for study inclusion if they were > 18 yr of age and not pregnant or breastfeeding. Individuals with CVD risk factors and with known CAD were enrolled. Exclusion criteria included: use of long-acting nitrates or insulin, diagnosis of non-ischemic cardiomyopathy, known systemic inflammatory disease such as rheumatoid arthritis, infection in the preceding week or temperature > 38°C, upper or lower arm vascular pathology such as the presence of fistula or AV shunt, and participation in any other ongoing device or clinical trial. Participants were also excluded if they were unwilling or unable before each study visit to: 1) fast for 6 hr prior, 2) discontinue tobacco use 12 hr prior (assessed at visit 1 via a CO breath analyzer) 3) withhold all over-the-counter medications and supplements the morning of a visit, 4) refrain from exercise for 24 hr, or 5) refrain from the use of the following medications 7 d prior: vaso-active agents such as decongestants (e.g. pseudoephedrine), recreational drugs (e.g. marijuana, cocaine, amphetamines), or phosphodiesterase-5 inhibitors used in erectile dysfunction (e.g. sildenafil, vardenafil, tadalafil).

Adherence to instructions regarding food/drink intake, medications and exercise were reviewed at each visit.

***MEASURING THE FLOW-MEDIATED COMPLIANCE RESPONSE SCORE***

The Cordex SmartCuff™ (Figure 1) uses the platform of segmental plethysmography and oscillometry through a novel proprietary algorithm to quantify repeated instantaneous measurements of arterial compliance taken at a baseline condition and following a 5-min suprasystolic reactive hyperemia condition, using a standard blood pressure (BP) cuff. The deviceprovides arterial compliance measurements over the entire transmural pressure range where the artery diameter spans from complete collapse to fully open. Using fundamentals of segmental plethysmography and oscillometry the BP cuff is converted into a calibrated volume sensor providing accurate arterial compliance values (in cm2/mmHg) in response to the cumulative shear stimulus29. The area between the two curves (Figure 1) in the positive arterial transmural pressure range is calculated and is displayed as a metric referred to as the Flow-mediated Compliance Response score (FCR). The intra-subject, intra-day, test-retest coefficient of variability between FCR values has previously been reported to be 15.3% (, 95% CI, 10.8 - 19.3)26. The SmartCuff also measures systolic, diastolic and mean arterial BP in addition to heart rate and oxygen saturation, using a pulse oximeter. It can be used in place of existing automated BP cuffs as it meets the ISO 81060 standard for the accuracy against both invasive and non-invasive BP measurements. The size of the BP cuff used for BP and the FCR score is matched to the individual’s arm diameter, using the same guidelines as for clinical BP testing.

To obtain the FCR measurement, participants were placed in a quiet, temperature-controlled room on a comfortable exam table with the upper torso slightly elevated. The left arm was extended and comfortably immobilized at heart level. The device’s BP cuff was placed on the arm and the oximeter finger sensor was placed on a finger of the ipsilateral hand. Baseline measurements were obtained by pressing the start button which automatically inflated the cuff to a suprasystolic pressure. This suprasystolic pressure was identified through dissipation of the pulse signal at the SpO2 finger sensor. Once the suprasystolic pressure was reached, the cuff pressure was automatically reduced at approximately 2-3 mmHg/sec. Data on arterial compliance was acquired at a rate of 200 data points/sec across the pressure range from suprasystolic cuff pressure to 20 mmHg cuff pressure. For post-occlusion hyperemia measurements, once the cuff reached 20 mmHg, it automatically inflated again to a suprasystolic pressure which was held for 5 min. Then, the cuff pressure was automatically reduced at approximately 2-3 mmHg/sec. Data acquisition, related to arterial compliance again occurred during the cuff pressure descent to 20 mmHg. The data obtained during the cuff pressure descent of both the baseline and hyperemia tests yielded the FCR. All participants tolerated the 5 min suprasystolic cuff pressure hold well and without complication.

***STATISTICAL ANALYSIS***

Descriptive statistics were used to calculate univariate summary statistics for each variable of interest. The associations of the FCR and measures of obesity, exercise capacity, and physical activity were assessed using bivariate regression models for continuous or categorical responses. Multivariate regression models included variables that showed an association with FCR in the bivariate analyses.