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Original article

MultlethNic Study of BrEast ARterial Calcium Gradation and CardioVAscular Disease: cohort recruitment and baseline characteristics

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ABSTRACT

Purpose: MultlethNic Study of BrEast ARterial Calcium Gradation and CardioVAscular Disease (MINERVA) was designed to answer the question of whether a novel continuous breast arterial calcification (BAC) mass score improves cardiovascular risk stratification among asymptomatic postmenopausal women. This article describes recruitment and baseline characteristics.

Methods: MINERVA is a multiethnic longitudinal cohort study. The phenotype data include BAC mass by densitometry applied to digital mammograms, sociodemographic factors, self-reported medical history, medications, parental history, reproductive history, smoking, alcohol consumption, physical activity, anthropometry, ankle-brachial index, blood pressure, laboratory panel, breast volumes, cognitive function, bioelectrical impedance, habitual diet, dietary supplements, sleep, psychosocial factors, and sun exposure.

Results: A total of 5145 women aged 60 to 79 years with available digital, uncompressed mammograms were recruited from the membership of Kaiser Permanente of Northern California between October 24, 2012 and February 13, 2015 and completed a baseline clinic visit or an abbreviated phone questionnaire. Of those, 4153 underwent phlebotomy and have blood biomarkers. Overall prevalence of BAC was 26%, and it varied by age and race. The mean (SD) BAC mass was 12 (23) mg and the range 0–342 mg.

Conclusions: MINERVA is the first cohort with a continuous measure of BAC. The cohort is large, ethnically diverse, and deeply phenotyped in terms of socioeconomic, behavioral, and clinical factors, and blood biomarkers.

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Background

The leading causes of death among women in the United States in 2013 were heart disease, cancer, chronic lower respiratory diseases, and stroke.¹ The current recommendations from the U.S. Preventive Services Task Force include the following: (1) biennial screening mammography for women aged 50 to 74 years; (2) the decision to start screening mammography in women between the

ages of 40 and 49 years should be individualized; and (3) current evidence is insufficient to assess the balance of benefits and harms of screening mammography in women aged 75 years or older.²

Breast arterial calcification (BAC), a type of vascular calcification appearing as a tram-track pattern that follows the contour of the vessel (see Fig. 1), has been shown to be associated with angiographically defined coronary artery disease,^{3–8} subclinical coronary artery disease,^{6,9–11} and risk of incident clinical cardiovascular disease (CVD).^{12–18} Emerging evidence indicates a correlation between BAC and coronary artery calcium,^{6,9,11,19–21} a recognized cardiovascular risk marker in women.^{22,23} However, BAC is currently considered an incidental finding and has not been endorsed as an established cardiovascular risk factor. If BAC is

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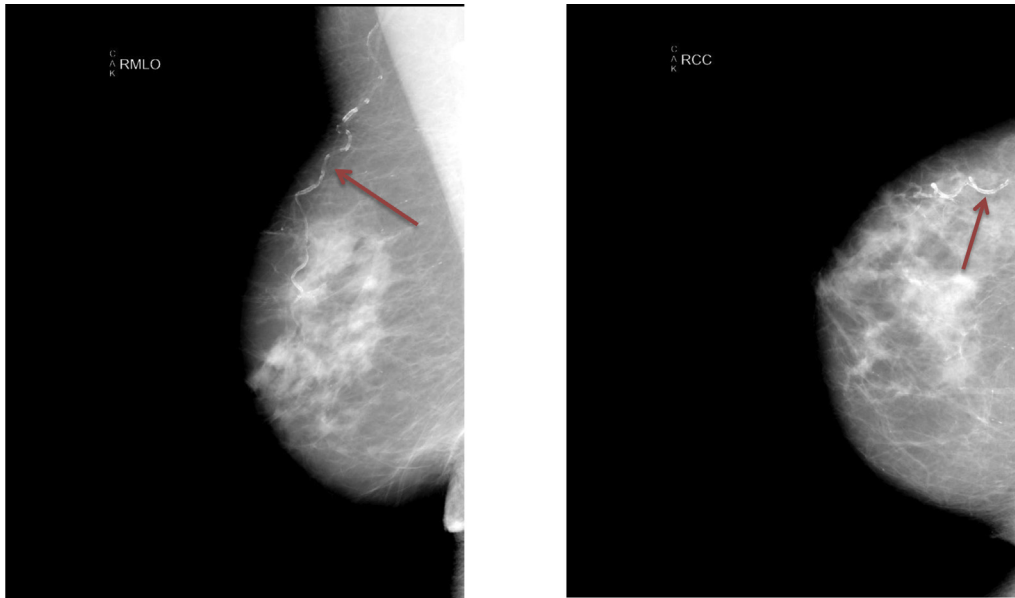


Fig. 1. Example of severe BAC (BAC mass = 62 mg). BAC = breast arterial calcification. The red arrows point to a severely calcified breast artery.

incorporated in CVD risk assessment, mammography could then have the potential to address three of the four top causes of death among women in the United States.

The Multiethnic study of brEaSt aRterial calcium gradation and cardioVAscular disease (MINERVA) has three specific aims. The first aim is to establish a large multiethnic cohort of women between the ages of 60 and 79 years with adequate representation of Caucasian, African-American, Asian, and Hispanic ethnicity. Power calculations were performed indicating that a sample size of 5200 would have 80% statistical power (with a two-sided $\alpha = 0.05$) to detect hazard ratios of a composite CVD outcome (coronary heart disease [CHD], stroke, heart failure, and peripheral vascular disease) in tertiles two and three of BAC mass of at least 1.2 and 1.3, respectively.

A new, but rigorously validated densitometry method was used to estimate a continuous BAC mass (in mg) score using raw (uncompressed) digital mammograms. The second aim is to evaluate the associations of BAC mass with age, race/ethnicity, family history of CVD, traditional and novel CVD risk factors, renal function, reproductive health factors, psychosocial factors, selected mineral metabolism factors, breast size, and sleep-related factors. The third aim is to elucidate the role of BAC mass in the prediction of CHD, cerebrovascular disease (transient ischemic attack, hemorrhagic stroke, and ischemic stroke), heart failure, peripheral vascular disease, and total CVD and to determine whether adding BAC mass to prediction model based on traditional risk factors improves reclassification of risk for total CVD and its components. This report marks the completion of our first specific aim and provides a description of all the measurements made among MINERVA cohort participants at the baseline examination.

Methods

Cohort description and recruitment

Because the densitometry method to estimate calcium mass required raw, uncompressed digital images, and the existing Kaiser Permanente of Northern California (KPNC) workflow for screening mammography includes compression of images before archiving,

we had to implement a prospective recruitment strategy and real-time transmission of images in Digital imaging and communications in medicine file format from the Kaiser Permanente (KP) facilities to the picture archiving and communication system at Kaiser Permanente Division of Research (KP-DOR) and then secure Health Insurance Portability and Accountability Act of 1996 compliant transmission of the images to the University of California Irvine for BAC evaluation.

The eligible participants were female active members of KPNC between the ages of 60 and 79 years when they attended regular mammography screening at one of nine KPNC facilities (Oakland, Richmond, Pleasanton, Antioch, Walnut Creek, San Francisco, Santa Clara, Campbell, and Mountain View). Mammography done for diagnostic purposes was not included. Women entered the pool of potentially eligible for the study after the raw images were successfully captured and the recruitment period spanned between October 24, 2012 and February 13, 2015. The following six exclusion criteria were applied using available electronic health records (EHRs): (1) age less than 60 or greater than 79 years at the time of mammographic screening; (2) being in the KP-DOR “no-contact file” that contains deceased members and those who had stated in the past that they did not want to participate in research studies; (3) history of myocardial infarction, coronary revascularization, stroke, heart failure, or peripheral vascular disease; (4) history of breast cancer, mastectomy, or breast implants; (5) diagnosed dementia, chronic dialysis, or renal transplant, and (6) no assigned primary care provider. The cumulative numbers and demographic characteristics of the eligible cohort are summarized in [Supplemental Figure 1](#). A total of 201,830 women underwent screening mammography at the nine KP facilities during the recruitment period. Of those, 46,112 met electronic eligibility criteria and formed the basis of recruitment. Starting in October 2012, we arranged for all digital uncompressed mammograms from the nine Kaiser facilities to be sent to the picture archiving and communication system at the KP-DOR. The volume of mammograms was about 7500/mo. The KP-DOR analyst ran a monthly electronic screening algorithm to determine eligible women (applying the exclusion criteria listed above), and about 1700 women were eligible each month. We then generated sequential,

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