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ORIGINAL INVESTIGATIONS

Generalizability of SPRINT Results to the U.S. Adult Population

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ABSTRACT

BACKGROUND In SPRINT (Systolic Blood Pressure Intervention Trial), a systolic blood pressure (SBP) goal of <120 mm Hg resulted in lower cardiovascular disease (CVD) risk compared with an SBP goal of <140 mm Hg.

OBJECTIVES The purpose of this study was to estimate the prevalence, number, and characteristics of U.S. adults meeting SPRINT eligibility criteria and determine the broader population to whom SPRINT could be generalized.

METHODS We conducted a cross-sectional, population-based study using data from the National Health and Nutrition Examination Survey, 2007 to 2012. The SPRINT inclusion criteria were age ≥50 years, SBP 130 to 180 mm Hg depending on the number of antihypertensive medication classes being taken, and high CVD risk (history of coronary heart disease, estimated glomerular filtration rate of 20 to 59 ml/min/1.73 m^2, 10-year CVD risk ≥15%, or age ≥75 years). Exclusion criteria were diabetes, history of stroke, >1 g in 24 h of proteinuria daily, heart failure, estimated glomerular filtration rate <20 ml/min/1.73 m^2, or receiving dialysis. Treated hypertension was defined by self-reported use of medication to lower blood pressure with ≥1 class of antihypertensive medication identified through a pill bottle review.

RESULTS Overall, 7.6% (95% confidence interval [CI]: 7.0% to 8.3%) or 16.8 million (95% CI: 15.7 to 17.8 million) U.S. adults, and 16.7% (95% CI: 15.2% to 18.3%) or 8.2 million (95% CI: 7.6 to 8.8 million) adults with treated hypertension met the SPRINT eligibility criteria. Among both the overall U.S. population and adults with treated hypertension, the percentage meeting SPRINT eligibility criteria increased with older age, was higher among males than females, and was higher among non-Hispanic whites compared with non-Hispanic blacks or Hispanics. Of U.S. adults eligible for SPRINT, 51.0% (95% CI: 47.8% to 54.1%) or 8.6 million (95% CI: 8.0 to 9.1 million) were not treated for hypertension.

CONCLUSIONS A substantial percentage of U.S. adults meet the eligibility criteria for SPRINT. (J Am Coll Cardiol 2016;67:463-72) © 2016 by the American College of Cardiology Foundation.

The SPRINT (Systolic Blood Pressure Intervention Trial) tested whether lowering systolic blood pressure (SBP) to <120 mm Hg versus <140 mm Hg results in reduced cardiovascular disease (CVD) risk (1). Between 2010 and 2013, SPRINT enrolled 9,361 adults age ≥50 years who had SBP 130 to 180 mm Hg and were at high risk for CVD. Individuals were not eligible if they had

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ABBREVIATIONS AND ACRONYMS

ACEI = angiotensin-converting enzyme inhibitors

BMI = body mass index

CHD = coronary heart disease

DBP = diastolic blood pressure

eGFR = estimated glomerular filtration rate

SBP = systolic blood pressure

diabetes, had a history of stroke, had >1 g in 24 h of proteinuria, had heart failure, were on dialysis, or had an estimated glomerular filtration rate (eGFR) <20 ml/min/1.73 m^2 (1). On September 11, 2015, the National Institutes of Health issued a press release stating that SPRINT was being stopped early due to an approximately 30% relative risk reduction in CVD events and 25% relative risk reduction in mortality among participants randomized to the SBP goal <120 mm Hg compared with the SBP goal <140 mm Hg (2).

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SPRINT enrolled a diverse population, and therefore, its results may be relevant to a large percentage of U.S. adults (1). Characterizing U.S. adults who are potentially eligible for antihypertensive treatment initiation or intensification to achieve an SBP <120 mm Hg may help the health care and scientific community understand the relevance and effect of the findings from SPRINT. We, therefore, estimated the prevalence, number, and characteristics of U.S. adults who meet the SPRINT eligibility criteria and may be candidates for an SBP goal of <120 mm Hg. As clinicians often need to generalize results beyond the population examined in a clinical trial, we also estimated the size of the broader sample of U.S. adults with SBP ≥120 mm Hg who are free of SPRINT exclusion criteria.

METHODS

STUDY POPULATION. The National Health and Nutrition Examination Survey (NHANES) is conducted by the National Center for Health Statistics. The data and information on the design and conduct of NHANES are available on the Centers for Disease Control and Prevention website (3). NHANES uses a multistage stratified probability sampling approach to identify potential participants. Multiple cycles can be pooled together to provide stable estimates in population subgroups (4). We pooled data from the 2007 to 2008, 2009 to 2010, and 2011 to 2012 NHANES cycles for the current analyses. Analyses were restricted to participants who were ≥20 years of age and completed a medical evaluation at the NHANES mobile examination center (n = 17,085). We excluded participants who did not have SBP and diastolic blood pressure (DBP) measurements taken during their NHANES medical evaluation (n = 803) or were missing self-reported information on the use of prescription antihypertensive medication (n = 22), leaving 16,260 participants in the current analyses. The National Center for Health Statistics institutional review board approved each NHANES cycle, and all participants provided written informed consent.

DATA COLLECTION. Data for each NHANES cycle were collected through participant interviews and a medical evaluation. Data collected during the interview included age; race/ethnicity; sex; smoking status; a prior diagnosis of comorbid conditions including hypertension, diabetes, heart failure, myocardial infarction, angina, coronary heart disease (CHD), and stroke; receipt of dialysis in the past 12 months; and use of antihypertensive and diabetes medication.

During the NHANES medical evaluation, height and weight were measured and used to calculate body mass index. Serum glucose, serum creatinine, and hemoglobin A1c were measured from a blood sample collected during the study visit. Diabetes mellitus was defined by a prior diagnosis, excluding during pregnancy, with concurrent use of insulin or oral hypoglycemic medication, or by a fasting glucose ≥126 mg/dl, nonfasting glucose ≥200 mg/dl, or a hemoglobin A1c ≥6.5%. eGFR was calculated using the Modification of Diet in Renal Disease equation (5). Urine albumin and creatinine were measured using random spot urine samples.

BLOOD PRESSURE MEASUREMENT. Blood pressure was measured by a trained physician using a mercury sphygmomanometer and an appropriately sized cuff. Readings were obtained after 5 min of seated rest. The mean of 3 blood pressure measurements obtained at 1-min intervals during the medical evaluation was used to define SBP and DBP.

PILL BOTTLE REVIEW. Participants were asked to bring all prescription medications taken in the past 2 weeks to the NHANES medical evaluation. Pill bottles were reviewed, and medication names were recorded and coded into medication classes based on their generic equivalents. Single-pill combinations were classified into their component classes. We coded the following antihypertensive medication classes: angiotensin-converting enzyme inhibitors (ACEIs), alpha blockers, aldosterone receptor antagonists, angiotensin receptor blockers, beta-blockers, calcium-channel blockers, central-acting agents, loop diuretic agents, potassium-sparing diuretic agents (not including spironolactone and eplerenone), thiazide diuretic agents, renin inhibitors, and direct vasodilators.

SPRINT ELIGIBILITY. Potential eligibility for SPRINT was determined using a multistep algorithm (**Figure 1**). The population was restricted based on age