Socioeconomic Status and Hypertension among Immigrants of West African Origin

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A. Study Purpose and Rationale

The Socioeconomic Status and Prevalence of Hypertension among Immigrants of West African Origin Study will be a cross-sectional study conducted in New York City. The overall goal of this study is to investigate the role of environmental exposures, particularly socioeconomic status (SES), in causing hypertension amongst persons of West African descent.

Mortality for African Americans exceeds that of whites in the United States, and much of this excess mortality can be attributed to a relatively higher prevalence of hypertension (1). Attempts to attribute the higher prevalence of hypertension in blacks compared to whites to physiologic or genetic differences have not explained the difference (2). Domestic epidemiologic studies have demonstrated a regional difference in hypertension incidence in African Americans within the US (3), and international studies of populations of African origin have shown a gradient of blood pressure between rural Africans at the low end of the blood pressure spectrum, and urban African Americans with the highest blood pressures (4, 5). Both of these findings suggest that environmental exposures are the key causative factors. Additional indirect evidence for the importance of environment are that body mass index (BMI) and urine sodium excretion are also directly related to blood pressure in West African populations in a graded manner (6). Another interesting distinction between black populations from West African and from the US is that while socioeconomic status correlates negatively with blood pressure in African Americans, SES correlates positively with BP in black West Africans(6). This difference is thought to be explained by a higher level of industrialization in the United States.

Studies of immigrant groups offer an opportunity to witness the "natural experiment" of the effect of a new environment on immigrants. Observational studies of persons of Japanese origin compared those who immigrated to the US with those who remained in Japan. These studies showed that exposure to environmental factors in the US put immigrants at a higher risk for cardiovascular disease risk factors and outcomes (7, 8). At the same time, the level of risk was intermediate between that of the country of origin and the country of arrival, which may indicate the importance of exposures early in life toward cardiovascular disease risk. Studies of Africans who moved from a rural to an urban environment within their native country demonstrated a rapid and significant increase in blood pressure (9).

Though hypertension prevalence in native West African populations has been compared to that found in African American populations, there have been no studies to date of hypertension in West African immigrants in the US. The rationale of the proposed study is to measure the effect of socioeconomic status on blood pressure in West African immigrants living for a decade or more in an urban environment in the United States, and to identify biological and lifestyle factors that protect against the development of high blood pressure in this population. Identification of protective measures (e.g. low salt diet, native diet, or physical activity) may advance our ability to prevent and treat hypertension not only in persons of West African descent, but also in other racial groups.

The primary hypothesis of this study is that measures of increased socio-economic status (i.e., occupation, income, and years of education) will be directly related to blood pressure and presence of hypertension in long-term resident West African immigrants, and that this relationship will remain significant after adjustment for known biologic risk factors for hypertension. The secondary hypothesis is that known biological risk factors for hypertension will be also associated with higher SES in this group of immigrants.

B. Study Design and Statistical Analysis

a. Study groups

This study will involve three groups of participants. All participants will be men and women between 45 and 65 years old at the time of enrollment, who self-describe themselves as "Black, Non-Hispanic" under US Census guidelines. One study group will be immigrants from West Africa who arrived within two years of the study visit, the second group will be West African immigrants with ten or more years of residence in the US, and the third study group will be African Americans who are life-long residents of New York City. Each group will have six hundred participants.

b. Number of subjects to be enrolled

Eighteen hundred participants will take part in the study.

c. Method of Randomization

None.

d. Crossover

None

e. Method of statistical analysis

The main statistical methods will be standard methods for the analysis of cross sectional studies.

Subjects will be recruited to the three study groups in order to match for age (decade 45-54 or 55-64 years), neighborhood of residence (using zip code), and gender, both on a 1:1 scheme. SES level will be assigned to occupation categories before the study, and participants will also be matched for one of two SES levels.

After data collection, variables which are not normally distributed will be log-transformed so that parametric tests may be employed. Hypertension will be defined according to JNC VII criteria (systolic blood pressure over 140 mm Hg, diastolic blood pressure over 90 mmHg, or treatment with anti-hypertensive medications) (1). The population distributions of systolic and diastolic blood pressures of newly arrived West Africans, long-term resident West African immigrants, and African Americans will be compared by the ANOVA test for independent samples and a test for trend. Prevalence of hypertension between West Africans immigrant groups and African Americans and long-term West African immigrants will be compared using a chi square test. For these tests, the null hypothesis is that there will be no difference in the mean blood pressures or prevalence of hypertension between African Americans and newly arrived or long-term resident West African immigrants.

All other comparisons will be made within the three study groups (West African immigrant groups and African Americans). Socioeconomic status will be defined according to occupation level and occupations listed in the SOC will be assigned to low or high level before the study begins. SES level will be compared to presence or absence or hypertension by chi square test. Other independent variables will be tested within strata of SES by chi square for evidence of confounding or interaction. Univariate logistic regressions will first test the association of independent study variables, including continuous SES scale, with the dependent dichotomous variable, hypertension. Variables that are significant to the $p<0.10$ level will be entered into a multivariate logistic regression with hypertension (yes/no) as the dependent variable. For these tests, the null hypothesis is that socioeconomic status, defined by occupation level, is not associated with blood pressure in long-term resident West African immigrants.

Additional analysis will take into account missing values.

C. Study Procedures

All procedures in the study will be done solely for research purposes.

Two weeks will be devoted to training the research nurses in standardized data collection procedures. The data collection phase of the study will last six months. The data analysis and reporting phase of the study will last sixteen months.

Participants will arrive to the study examination at eight A. M. on the scheduled day. They will have fasted since midnight the night before, and will have avoided caffeine, alcohol, and cigarettes. Participants will be encouraged to take their blood pressure medications on the morning of the exam. On arrival, the participant will review the informed consent form orally with a study nurse.

Should the participant agree to participate in the trial, he or she will change into an exam gown and place slip-free slippers on his or her feet. Participants will then be weighed, and their height, upper arm circumference, and waist circumference will be measured. Participants will then rest quietly for ten minutes. After this rest, the blood pressure will be measured three times with the appropriate cuff size, with five-minute pauses between measurements. After the blood pressure measurements, venipuncture will be performed by the research nurse, and blood samples will be collected. After venipuncture, participants will be given a light healthy breakfast.

Participants will then fill out the Food Questionnaire, Demographics Form, the Socioeconomic Status/Occupation Form, the Social Support Form, the tobacco and alcohol use forms, and the Physical Activity Form orally with the research nurse. Lastly, the participant will be given a container for collection of a 24-hour urine sample.

Study participants who have health insurance and a primary physician will have results from the study forwarded to their physicians if consent is given by the participant. Study participants with insurance and no primary physician will be referred to a physician at Columbia University Medical Center (CUMC), either at the Associates in Internal Medicine (AIM) clinic or Atchley Pavilion. All study participants without insurance, regardless of the blood pressure or laboratory test values found in the study, will be given a referral to the Columbia Student Outreach Clinic (CoSMO Clinic), which offers health care to the uninsured. The study will budget sufficient funds to treat uninsured individuals who are diagnosed with hypertension for a five-year period with culturally specific exercise and diet counseling, as well as pharmaceutical treatment, according to JNC VII guidelines.

Participants who with a blood pressure of >180 mm Hg systolic and less than 200 or a diastolic blood pressure >110 but less than 115 will be referred for a clinic appointment within one week. Participants with a systolic blood pressure >200 mm Hg will be directly referred to the CUMC Emergency Department immediately, and Columbia University and/or the patient's insurance provider will cover the cost of the emergency room visit or inpatient hospitalization, should either be required.

At the completion of the visit, the research nurse will assist the participant with any necessary referrals to a Primary Care physician, then give the participant one half of the stipend. The urine sample will be returned the following day and at that time will receive the second half of the stipend.

The study endpoints are shown in table 1.

Table 1. Study Outcomes, Data Sources, and Questionnaires

Study Outcomes	Data Source
Resting blood pressure	Average of the second two of three BP readings
Heart rate	radial pulse measured over 30 seconds by a research nurse
Hypertension	Diagnosis by JNC VII guidelines
Waist circumference	Measured during research visit to the nearest cm
BMI	kg/(m squared), from measurements during visit
Urine potassium	24-hour urine collection
Urine sodium	24-hour urine collection
Urine sodium/potassium ratio	24-hour urine collection
Triglycerides	Blood sample
High Density Lipoproteins	Blood sample
Fasting insulin	Blood sample
Uric acid	Blood sample
Alcohol intake	NHIS questionnaire
Smoking status	NHIS questionnaire
Dietary salt intake	BLOCK 95 Food Questionnaire*
Physical activity	NHIS questionnaire
Familty income	NHIS questionnaire
Years of education	NHIS questionnaire
Socioeconomic status	by occupation: SOC (US government), Duncan SES Index
Social support	ESSI questionnaire
Duration of stay	Number of years residing in the US, from demographics questions
Access to Care	Health insurance status, from demographics questions
Use of antihypertensive meds	Study questions

*Staple foods of the West African diet will be translated to BLOCK 95 equivalent foods.

D. Study Drugs

None.

E. Medical Devices

The study will employ the Datascope Accutorr Plus, an automated oscillometric blood pressure measuring device that has been validated in a non-industry review of such devices and was found to meet the highest quality standards for these devices(10). The advantage of an automated blood pressure measuring device in the research setting is that observer error is not introduced as a source of bias. The Datascope Accutorr Plus not only demonstrated internal validity, but its measurements approximated mercury sphygmomanometer readings.

F. Study Questionnaires

We will administer a series of questionnaires that will take one hour to complete. The questionnaires can be administered in English or in French, according to the preference of the participant. The study questionnaire will be composed of a face page that collects demographic information (age,

gender, zip code of residence, number of years in country of origin, year of immigration, number of years in New York City) as well as the questionnaires described in Table 2:

Table 2: Study Questionnaires

Questionnaire	Source
Alcohol intake	NHIS
Smoking	NHIS
One year food diary	BLOCK 95 Food Questionnaire
Physical activity	CARDIA Study Activity Scale
Family Income	NHIS
Years of education	NHIS
Social support	ESSI(11, 12)
Occupation/SES	Duncan SES Index (13), SOC (US Bureau of labor statistics)
Demographics/insurance status	Study questionnaire

G. Study Subjects

Based on epidemiologic studies of hypertension in urban West African and African American populations, we expect there to be at least a 15% total prevalence of hypertension among low SES West African immigrants, and a 25% prevalence of hypertension in high SES West African Immigrants. With a two-sided alpha of 0.05, and a power of 80%, the study will require at least 270 subjects per SES level within each study group. Accordingly, there will be 600 participants in each of the three study groups, and 1800 total participants.

The SES and Hypertension in West Africans Study will recruit African Americans and West Africans who self-define themselves as "Black, non-Hispanic", and who are living in Northern Manhattan (defined here as living above 125th Street). For the purposes of this study "West Africa" will include the nations of Togo, Nigeria, Guinea, Senegal, Mali, Niger, Sierra Leone, Burkina Fasso, Ivory Coast, and Ghana (immigrants from Guinea Bissau will not be recruited as we will not be able to collect data in Portuguese). Inclusion criteria will be age between 45 and 65 years at the time of enrollment, current residence within the catchment area of the study, and ability to communicate in English or in French. For the cohort of long-term resident West African immigrants, only immigrants arriving after age twelve, and living in the US for ten years or more will be included. For the newly arrived West African immigrants, they must have spent two years or less in the US. African Americans will only be included if they have been life-long residents of New York City.

Exclusion criteria will consist of medical illnesses: cancer, end stage renal disease, congestive heart failure, hyperthyroidism, hypothyroidism, or diagnosis of secondary hypertension (renal artery stenosis, hyperaldosteronism, Cushing's disease, or pheochromocytoma). Participants will be excluded if they are chronically treated with steroids. Participants who are pregnant will also be excluded. Participants will be excluded if they spend more than four months on average over the past ten years outside of the catchment area.

No "vulnerable populations" will be included in this study. Specifically, we do not propose to recruit minors, pregnant women, mental patients, prisoners, elderly persons with cognitive impairments, persons who are institutionalized, or persons who are unable to give informed consent.

We will conduct the research in English and French, and examinations will be carried out by research assistants conversant in French. Subjects who do not speak English will not be excluded based on language, so long as they are able to participate in French.

H. Recruitment of Subjects

Pilot subjects will be recruited from the community by bilingual research assistants. Direct recruitment using IRB-approved pamphlets will take place at Northern Manhattan community groups (e.g. the Amado Diallo Foundation), mosques (e.g. the Malcom Shabaaz Mosque), churches, the Bronx West African open food market, barber shops and beauty salons. Recruitment will also occur via radio advertisements. All recruitment materials will be in English or in French, and will direct potential participants to phone a bilingual research assistant, who will screen subjects and arrange for a study visit. A research assistant will phone the potential participant the night before the study visit in order to ensure that the participant will arrive to the visit fasting, and that the participant will have taken all of his or her regular medications (except insulin or sulfonylurea medicines). At the study visit, the research nurse will review the eligibility criteria, ascertain that the subject is in fact eligible, and obtain written informed consent.

I. Confidentiality of the Study Data

The study will keep consent forms and recruiting forms, which will include identifying information such as name, address, telephone number and address, separate from the study data forms. Study data will be recorded on forms identified only by study ID number. Personal identifying information will not be entered into the computerized file to link study numbers to names and addresses that will be used to generate letters for appointments and notification of subjects. No participants will be identified individually by name or in any other way in any report of the study.

J. Potential Conflicts of Interest

None of the investigators associated with this study at Columbia has proprietary interest in any drug or device that might be used in this study. None of the investigators stand to benefit financially from the results of the investigation.

K. Location of the Study

Recruitment for the study will take place in the community, and appointments for research visits will be made over the phone. The research visit will take place at the Irving Center for Clinical Research at Columbia University.

L. Potential Risks

The potential risks to participants are minimal. The risks associated with venipuncture are hematoma, local bleeding, and increased risk of infection. We will insure that participant visits are supervised by a senior physician, and that the appropriate referral for outpatient treatment is made.

M. Potential Benefits

Potential benefits to individual participants include screening for hypertension. The results from this examination will be communicated to the participants and to the participants' primary care physician with the participant's consent. These results may assist the primary care physician in the management of hypertension and general cardiovascular disease risk factors. For participants who have no health insurance, the benefit will be referral to a primary care provider. For participants who have no health insurance and are presumptively diagnosed with hypertension, the benefit will be referral to a primary care provider and treatment of hypertension.

N. Alternative Therapies

None

O. Compensation to the Subjects

Participants will be paid $80 as compensation for time and travel costs for participating in this study.

P. Costs to Subjects

None

Q. Minors as Research Subjects

None

R. Radiation and Radioactive Materials

None

S. References

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