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CRC Rotation and IRB protocol

A. Study Purpose and Rationale

Atrial fibrillation is associated with stroke, heart failure, and premature death. Overall prevalence in the general population has been estimated at 1-2% with much higher prevalence in older populations: about 5% in those over 65 years old and 9% in patients older than 80 years old.[1] There is an extensive literature on atrial fibrillation but limited data on the effect of atrial fibrillation on stroke in minority populations. Because the incidence of stroke in blacks and Hispanics is higher than in whites (by two-fold), studies exploring the association between atrial fibrillation and stroke in these minority populations will affect which future studies to pursue and may eventually influence management decisions.[2]

The prevalence of atrial fibrillation in a diverse community composed of whites, blacks, and Caribbean Hispanics was investigated in the Northern Manhattan Stroke Study (NOMAS) and was found to be 8%, 5%, and 4%, respectively.[3] When matched for age and sex and adjusted for the effects of hypertension, diabetes, coronary artery disease, physical activity, and education, the study suggested that atrial fibrillation in blacks and Hispanics contributes less to the etiology of stroke as compared to whites. These findings suggest that atrial fibrillation is both less common and contributes to a lesser degree to stroke in black and Hispanic populations even though stroke from all causes is more common in these patients.

However, in order to make more confident conclusions about the interaction between atrial fibrillation and stroke in these minority populations, it will be important to determine the incidence of atrial fibrillation. Previous incidence studies have looked at predominately white or black populations[4,5,6]; however, studies looking at a mixed population including Hispanics are lacking.

It is our intention to determine the incidence of atrial fibrillation within a mixed population of whites, blacks, and Hispanics in Northern Manhattan. Given what is known about the population that we are proposing to study, it is our prediction that the incidence of atrial fibrillation in Hispanics and blacks is less than that in whites. If this is the case, then it would influence future priorities about whether to pursue more detailed studies on atrial fibrillation in this population. It would also provide insight into the etiology of stroke in this high risk population.

B. Study Design and Statistical Analysis

Design: We will test the hypothesis that the incidence of atrial fibrillation in Hispanics is less than in whites. This study will use a previously described database which contains 3500 subjects enrolled in a prospective cohort study between 1993-2001 who were stroke-free at baseline.[7] We will further refine the database by excluding any patients who had atrial fibrillation on enrollment. We will review our records and record the first diagnosis of atrial fibrillation as reported by in-person or telephone interview within 10 years after enrollment in the study. We will confirm the diagnosis by chart review through WebCIS and may contact study subjects by telephone for further follow up questions. We will also investigate the risk factors for atrial

fibrillation: age, presence of heart disease (congenital, valvular, MI, post-surgery, sick sinus, etc.), HTN, thyroid dysfunction, sleep apnea, lung disease, alcohol or illicit drug use, use of stimulants, and recent infections.

Analysis: The average incidence of atrial fibrillation will be recorded over a 10 year period after enrollment and a Chi-square test will be performed to assess the differences in incidence for the 3 major ethnic/racial groups studied.

Power: Calculations were made based on a cohort of 3500 individuals, 15% (525) white, 20% (700) black, and 65% (2275) Hispanic. We will assume a power of 80%, an alpha of 0.05, and an observation time of 10 years after enrollment. Given a 4 per 1000 person-year incidence in whites, we would be able to observe a statistically significant difference of <1.4 or >7 per 1000 person-year incidence in Hispanics and <1.2 or >7.9 per 1000 person-year incidence in blacks. Given a 2 per 1000 person-year incidence in blacks, we can observe a difference of <0.4 or >4 per 1000 person-year incidence in Hispanics.

C. Study Procedure
WebCIS chart and NOMAS database review. May contact subjects with incident atrial fibrillation by telephone to assess for further risk factors.

D. Study Drugs
None

E. Medical Device
None

F. Study Questionnaires
None

G. Study Subjects
A total of about 3500 patients have been enrolled. Patients were enrolled if they (1) have never been diagnosed with stroke, (2) greater than 39 years old, (3) resided in Northern Manhattan for greater than or equal to 3 months, and (4) resides in a household with a telephone. Patients with atrial fibrillation on enrollment will be excluded from this study. The race/ethnic mixture consists of 65% Hispanic, 20% black, and 15% white. Northern Manhattan is defined as the area of New York City north of 145th St, south of 218th St, bounded by the Hudson on the west, and separated from the Bronx by the Harlem River.[7]

H. Recruitment of Subjects
Study subjects were enrolled between 1993-2001 and were identified by random digit dialing. There was a 68% response rate.

I. Confidentiality of Study Data
All data collected will be stored in a secure location, accessible only to the investigators and NOMAS staff.

J. Potential Conflict of Interest
None

K. Location of Study
The Department of Neurology and Sergievsky Center, Columbia College of Physicians and Surgeons.

L. Potential Risks
There is minimal risk associated with this observational study. There will be no interventions and no additional testing required.

M. Potential Benefits
There is a minimal chance that a change in diagnosis will be made due to the chart review associated with the study. Upon review of records, it may be decided that a patient previously thought to have atrial fibrillation may not have atrial fibrillation; conversely, it is possible that a patient with no diagnosis of atrial fibrillation may be found to have atrial fibrillation. The result of such a change in diagnosis could possibly be a change in how the patient is managed.

N. Alternative Therapies
Not applicable

O. Compensation to Subjects
None

P. Costs to Subjects
None

Q. Minors as Research Subjects
None

R. Radiation or Radioactive Substances
None

References

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