ARIC MANUSCRIPT PROPOSAL FORM

Manuscript #275

1. Title:
Reproducibility of extracranial carotid atherosclerotic lesions measured by B-mode ultrasound in the ARIC study

2. Writing Group:
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3. Timeline:
The target date for a complete manuscript is December 1994

4. Rationale:
Consistently high-quality measurements are essential to the reliability of study results and correct decision making. B-mode ultrasound measurements are subject to variation from many sources, including instrumentation, observer (sonographer and reader), examinees' characteristics, scanning and reading protocol, and characteristics of the atherosclerotic lesion. Therefore, the demonstration of the validity and reproducibility of this measurement tool is critical to applications of this methodology in science and clinical practice.

Assessment of validity, indicated by sensitivity and specificity, requires a gold standard. In clinical studies, some investigators compared atherosclerotic lesions measured by B-mode ultrasound to those measured by angiography, and also employed pathology findings on the excised specimens as standards for comparison. They found B-mode ultrasound measurements to be of higher sensitivity and specificity than angiographic measurements of arterial lesions. With regard to reproducibility, a number of recent studies have assessed the reproducibility of quantitative measure of carotid artery intima-media wall thickness. By contrast, few studies have addressed the reproducibility of carotid atherosclerotic lesions identified by B-mode ultrasound. No studies have been published on the reproducibility of the measurement conducted in multicenter, community-based studies employing several sonographers and readers.

The ARIC study offers an important opportunity to assess the reproducibility of carotid atherosclerotic lesions measured by B-mode ultrasound in multi-center, community-based study with several sonographers and readers.

5. Main Hypotheses:
(1) The intra-sonographer, inter- and intra-reader B-mode ultrasound assessment of extracranial carotid artery atherosclerotic
    lesions in the ARIC study is repeatable; i.e., kappa statistic = > 0.40.
(2) Age, race, gender, BMI and center affect the measurement reproducibility.
(3) Both the Prevalence Index (PI) and the Disagreement Index (DI) influence the interpretation of the weighted kappa
    statistics in the study.

6. Plan of Analysis:
A weighted kappa statistic and the proportion of average agreement will be used to assess the overall reproducibility of B-mode ultrasound measurement of carotid lesions, including repeat reading and repeat scanning. Analysis will be stratified by same and different reader. Stratified weighted kappa statistics will be

employed to estimate the effects of potential covariates, i.e., age, race, gender, BMI, and study center.

7. Data Requested:
Plaque / shadowing variables at six carotid sites for visit 1 and visit 1 QC data; readers' ID and sonographers' ID; reading date, scanning date, participant age, gender and BMI; study center.