

ARIC Manuscript Proposal # 897 (Revised)

PC Reviewed: 08/14/02

Status: A

Priority:

SC Reviewed: 08/15/02

Status: A

Priority:

1.a. Full Title: Repeatability of the Spatial T Wave Axis Deviation Measures: The ECG Repeatability Study

b. Abbreviated Title (Length 26 characters): Spatial T wave axis Repeatability

2. Writing Group (list individual with lead responsibility first):

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3. Rationale:

Experimental and electrophysiological studies have shown that an abnormal ventricular repolarization is associated with arrhythmogenesis and cardiac events. Clinical- and epidemiological-applicable noninvasive measures of ventricular repolarization are currently limited. Electrophysiological studies have shown that T wave axis deviations, rather than QT dispersion, are an early manifestation of increased true dispersion of ventricular repolarization. Previous reports from the Rotterdam and CHS studies suggest that T wave axis deviation is a strong independent indicator of the risk of coronary heart disease and total mortality. The ability to ascertain T wave axis deviation association with coronary heart disease outcomes is however determined in part by the repeatability of its measurement. Unbiased and more precise estimates of the association could be derived from the existing ARIC data if the variability of the T wave axis measurement is known. Furthermore, there is the potential for future studies to make use of the repeatability information, in both clinical and epidemiological settings. Hence it is important to assess thoroughly the amount of total measurement variance and the source of this variance for the T wave axis deviation measurements.

4. Main Hypothesis/Study Questions:

This study will estimate the short-term (2-minutes) and longer-term (1 week) reproducibility of the T wave axis measures. This study will also use mixed models to partition the measurement error into various components. Finally, the study will compare the repeatability of the T wave axis with the repeatability of two other measures of ventricular repolarization, the QT Prolongation Index and the rate-corrected QTc of Bazett.

5. Study population, data collection, reading and processing procedures.

Study Population

In addition to using extant ARIC data, this study involves de novo data collection on a group of approximately 60 healthy volunteers, aged 45 to 64. These volunteers will be recruited through flyers from the UNC community and the Chapel Hill area. None of these volunteers will be ARIC cohort participants. We will attempt to match the original gender and race distribution of the ARIC cohort.

Data Collection

Volunteers will undergo two visits at the General Clinical Research Center at UNC Hospitals. For the purpose of studying spatial T wave axis repeatability, at each visit two resting, supine, standard 12-lead ECG recordings will be obtained, following the ARIC protocols as closely as possible. Four trained and certified technicians will obtain the ECG recordings. In addition, basic demographic information will be recorded on specially prepared forms. Information from the forms will be double entered into a spreadsheet program, and then converted to a SAS dataset.

Reading and Processing Procedures

The processing the ECG's will be coordinated by Dr. Ronald Prineas of the Epidemiological Cardiology Research (EPICARE) Center in Winston-Salem, NC. The ECG's will be obtained using the MAC PC Personal Cardiograph (Marquette Electronics, Inc., Jupiter, FL). The tracings will be sent via phone modem to EPICARE, where they will be computer coded and processed using the most recent version of the Marquette GE program version 12SL.

The resulting data files will be sent to UNC at Chapel Hill, where the record identification numbers will be matched with the master ID's, using a master list. The data files containing the basic demographic information and the information from the 12-lead ECG's will be merged.

7.a. Will the data be used for non-CVD analysis in this manuscript? ____ Yes No

b. If Yes, is the author aware that the file ICTDER02 must be used to exclude persons with a value RES_OTH = "CVD Research" for non-DNA analysis, and for DNA analysis RES_DNA = "CVD Research" would be used? ____ Yes ____ No

(This file ICTDER02 has been distributed to ARIC PIs, and contains the responses to consent updates related to stored sample use for research.)

8.a. Will the DNA data be used in this manuscript? ____ Yes No

8.b. If yes, is the author aware that either DNA data distributed by the Coordinating Center must be used, or the file ICTDER02 must be used to exclude those with value RES_DNA = "No use/storage DNA"? ____ Yes ____ No

9. The lead author of this manuscript proposal has reviewed the list of existing ARIC Study manuscript proposals and has found no overlap between this proposal and previously approved manuscript proposals either published or still in active status. ARIC Investigators have access to the publications lists under the Study Members Area of the web site at:
<http://bios.unc.edu/units/cscc/ARIC/stdy/studymem.html>

Yes ____ No