

Atherosclerosis Risk in Communities Study Protocol

Manual 15

Echocardiography

Visit 3

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FOREWORD

This manual, entitled Echocardiography is one of a series of protocols and manuals of operation for the Atherosclerosis Risk in Communities (ARIC) Study. The complexity of the ARIC Study requires that a sizeable number of procedures be described, thus this rather extensive list of materials has been organized into the set of manuals listed below. Manual 1 provides the background, organization, and general objectives of the ARIC Study. Manuals 2 and 3 describe the operation of the Cohort and Surveillance Components of the study. Detailed Manuals of Operation for specific procedures, including those of reading centers and central laboratories, make up Manuals 4 through 11 and 13 through 15. Manual 12 on Quality Assurance contains a general description of the study's approach to quality assurance as well as the details for quality control for the different study procedures.

ARIC Study Protocols and Manuals of Operation

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The Atherosclerosis Risk In Communities Study Echocardiography Operations Manual

1. INTRODUCTION AND GENERAL OBJECTIVES

ARIC participants comprising the Jackson, Mississippi, cohort will have an echocardiographic examination as a part of Visit 3 of the study.

As its general objectives, the echocardiography study will (1) characterize a variety of cardiac structural and functional parameters in a large population-based sample of black men and women, ages 51 to 70, and (2) examine these data for relationships with conventional risk factors for cardiovascular disease, prevalent cardiovascular disease, and cardiovascular disease incidence, adding to similar information collected in other important population-based studies.

The echocardiography protocol will incorporate currently accepted standard echocardiographic techniques to enhance comparison with preceding and future studies. Structural parameters to be studied include left ventricular (LV) wall and chambers dimensions, and LV mass (calculated from dimensions). Cardiac functional data will be derived from measurements of systolic performance such as fractional shortening, regional wall motion, and wall stress, and from Doppler data describing left ventricular diastolic filling.

Responsibility for various procedural aspects of the ARIC Echo Study will be shared with the ARIC Coordinating Center. The Jackson center will be responsible for technician and reader training, for exam performance, interpretation, and data entry, and for internal quality control functions. The Coordinating Center will be responsible for developing and maintaining the official analysis file and for official analyses of the data, and will provide support for publications, including primary responsibility for statistical analyses. Some data analysis may be done locally at the Jackson center as well, and its investigators will have primary responsibility for scientific publications.

The echocardiographic examination will be conducted in the ARIC Clinic facilities in Jackson. Two staff nurses will be training to perform the echo studies. The clinical echo lab in the University Hospital, located about 1 block from the ARIC Clinic, may be used to facilitate a high volume of studies in the early months of the study, and will be available as backup in the event of equipment failure or ARIC staff absences. The Hospital's lab, staffed by two experienced technicians, and the ARIC lab have identical echo equipment. The "reading center" will also be located in the University Hospital's Heart Station at the offices

of Drs. Skelton and Waterer who will be analyzing all the echo studies. Facilities for data entry, backup, and archival will also be located at the reading center, and will be managed by Dr. Skelton.

2. RATIONALE

LV hypertrophy detected by electrocardiography is associated with a significant risk of cardiovascular morbidity and mortality.^{1,2} More recently, echocardiography has provided a more sensitive tool for determination of LV hypertrophy. In addition, the method is quantitative, reproducible, and noninvasive.^{3,4,5,6} Echocardiographically measured LV hypertrophy improves the prediction of cardiovascular disease compared with the prediction using only blood pressure and ECG-LVH criteria in a representative population of black men and women aged 51-70. Reference values for LV mass and criteria for LV hypertrophy were established in the large study population of the Framingham Heart Study.⁷ To date, there are no outcome-guided criteria for defining the presence of LV hypertrophy. Echocardiography provides an objective means of prospectively studying the relationship between LV mass and cardiovascular events.

The pathophysiology of LV hypertrophy in a population may be rather diverse. The impact of age⁸, obesity⁹, alcohol intake¹⁰, body size, physical activity, and blood pressure¹¹ on LV mass have been examined. A small proportion of LV hypertrophy is associated with valvular heart disease, but most is not, and the overall prevalence of hypertrophy based on Framingham criteria in their population was about 15-20%.¹² Dannenberg⁸ suggested that the increase in LV mass associated with aging was prominently related to extracardiac factors (such as obesity and hypertension) that accompany advancing age and "not by virtue of an intrinsic myocardial aging process".

Importantly, several reports have documented an increased risk of cardiovascular events and mortality in subjects with LV hypertrophy and some show the risk to be independent of the other known risk factors for coronary heart disease.^{12,13,14,15,16,17} For the black population, there are insufficient data on the distribution of LV mass and its association with cardiovascular risk.

As the genetic influence of race is seen on some aspects of essential hypertension, so might the risk associated with LV hypertrophy in blacks vary from that of a general or predominantly white population. Also, the impact of other factors such as age, obesity, and alcohol intake has not been studied in blacks.

In essential hypertension, LV hypertrophy may be thought of as one type of end-organ damage often leading to two predominant sequelae, congestive heart failure and arrhythmias¹⁸ including sudden death. Georgiou and Brundage¹⁹ published a cogent review of the significance and pathophysiology of hypertensive LV hypertrophy and of factors influencing its regression. Several animal and human studies point to the multiple hemodynamic, humoral, and structural factors that influence hypertension and the development of LV hypertrophy and of its sequelae. Perhaps as a result, antihypertensive therapy appears to have diverse effects on the regression of LV mass. Data are not yet available from current long-term clinical studies designed to assess the change in cardiovascular risk associated with regression of hypertensive LV hypertrophy.

Despite complex interactions among the factors that influence it, the presence of LV hypertrophy may be a clinically useful summary of the integrated adverse effects of hemodynamic loads and vascular disease on the heart.²⁰

Recent years have seen a surge of interest in the diastolic function, and dysfunction, of the left ventricle and in the hemodynamic characterization of this "diastolic dysfunction" from both invasive and noninvasive techniques. Hypertensive left ventricular hypertrophy, now well defined as a risk factor for cardiovascular morbidity and mortality is an important cause of diastolic dysfunction, but some other prevalent disorders such as ischemic heart disease are causes as well. There is an important need for population data which may improve our understanding of the relationship between cardiovascular events and diastolic dysfunction in general.

Data from the Framingham study suggest that there is a significant learning curve in the acquisition of technically adequate echocardiographic studies. In that study, for participants over 60 years old, the percentage of acceptable M-mode echocardiograms rose from a minimum of 28% during the first 5 months to a maximum of 74-81% two years later. The percentage of acceptable echocardiograms declined with age and was slightly lower in men than in women. Thus, the development of procedures for technician training and utilization, image data management, and quality monitoring are essential for providing data of excellent quality. A major goal of the ARIC echo study is to insure the acquisition of echocardiograms of sufficient quality and reproducibility to produce unbiased estimates of structural and functional variables.

3. SPECIFIC OBJECTIVES

- 3.1 Define the population distribution of various echocardiographic measurements of left ventricular size,

mass, and function (both systolic and diastolic) using techniques which will allow, to the extent possible, comparisons between these data and those of population-based studies such as Framingham and others.

- 3.2 Examine the association of LV hypertrophy with clinical outcomes including myocardial infarction, congestive heart failure, stroke, and sudden death. The latter is of special interest both because of the suspected contribution of LV hypertrophy to arrhythmias and because of the high proportion of out-of-hospital deaths seen in ARIC blacks.
- 3.3 Describe the association of LV hypertrophy with current and previous sitting, standing, and supine blood pressure; and the temporal relationship between the development of hypertension and LV hypertrophy (or of other structural and functional parameters such as diastolic filling properties).
- 3.4 Evaluate the association of LV hypertrophy and antihypertensive therapy.
- 3.5 Examine the association between LV hypertrophy and other target organ manifestations of hypertension such as retinal artery changes, or of atherosclerosis measured as the presence and progression of carotid atherosclerosis.
- 3.6 Describe the relationship of LV hypertrophy or dysfunction with factors such as age, physical activity, obesity, and alcohol intake.
- 3.7 Examine whether functional parameters (e.g., left ventricular diastolic filling) may have a stronger relationship than LV mass to target organ manifestations or prevalent cardiovascular disease.
- 3.8 Describe any measurable difference between a technique of direct digital image storage and computer analysis and that of digitization of videotaped images or of analog measurement from hardcopy data.
- 3.9 Collect and archive both procedural and echocardiographic data in a manner which will allow for comparison with follow-up echocardiograms on these study participants should the opportunity arise in future years.

4. ECHOCARDIOGRAPHY EQUIPMENT AND GENERAL OPERATING FEATURES

The Acuson 128XP/10c machine is a cardiac ultrasound system incorporating current generation technology for image optimization and quantification. A digital imaging system by Freeland Systems has been added to allow recording, transport,

analysis, and storage of selected images to be analyzed without introducing the image degradation that accompanies an analog device such as videotape.

4.1 Echocardiography instrumentation - General

In general terms, the Acuson 128XP/10c system is comprised of a video monitor for viewing the ultrasound data; a keyboard for entry of study identification and for selection of system options; a panel containing image, Doppler, and recording device controls; ports for connection of the ultrasound transducers; ECG display controls; and two recording devices, a B/W video page printer and a Super VHS videotape recorder. Details of the operation of the system are found in the Acuson *User Manual for Cardiovascular Applications*.

The Framingham study has successfully used an offline analysis system to perform the quantitative measurements from the echo data, freeing the technician from the need to spend valuable examination time performing measurements. The Freeland CineView system is comprised of a computer, a function-key "keyboard", and a footpedal for activation of its functions. The Acuson video display unit is shared with the Freeland computer for its own display needs by a video multiplexer board jointly designed by Acuson and Freeland specifically for this application and installed by Acuson engineers. Details of the operation of the system are found in the Freeland *Systems Operations Manual*.

4.2 Echocardiography instrumentation - Transducers

The echo machine is equipped with three 128 element, dual frequency, phased array transducers. In general, the studies will be performed with the primary operating frequencies of the V219 transducer (imaging at 2.5 MHz, Doppler at 2.0 MHz) or the V319 transducer (imaging at 3.5 MHz, Doppler at 2.5 MHz). In unusual circumstances, the V714C transducer may be used (imaging at 5.0 MHz). Steerable 2-D directed M-mode is performed at the same imaging frequency. The transducers also are capable of steerable continuous wave (CW) and pulsed Doppler (including color flow mapping). Two probes (typically the V219 and V319) are connected to the machine with the V219 on the right port. Selection between the two is by way of a front panel button. The right port is the default transducer at power-up.

4.3 Echocardiography instrumentation - Digital image storage

The Freeland Systems CineView for Acuson is an Intel 80486-33 MHz based computer system which receives video

input from the Acuson echo system and which digitizes images for display, analysis, and storage onto optical disk media. The Freeland computer uses (shares) the Acuson display screen as its display monitor. The technician can choose to view either the Acuson or the Freeland display on the single monitor by a simple keypress on the Freeland keypad. The Freeland software is customized to provide efficient protocols for capturing images.

The Acuson image screen is a digital image in a 512 by 512 pixel matrix. This matrix size defines the limits of resolution in the ultrasound image. The digital image is converted to a standard 525-line video signal which is made available to the Freeland image capture system. The Freeland is capable of digitizing at a maximum pixel density of 512 (horizontal) by 480 (vertical), similar to that of the original Acuson image. Thus, in theory, the image captured in the Freeland system should retain a high degree of resolution and faithfulness to the original image. One of the quality assessment issues in this study will be to measure the resolution characteristics of the Acuson system, and to define any detectable loss of resolution attributable to the digitization process. Once in digital format, the image is not subject to degradation by repeated viewing, copying, or deterioration of media with the passage of time.

The protocols have been designed to acquire at axial resolution similar to that of the data generated by the Acuson, so that the digitization process results in no significant loss of resolution information. In general, the images which will undergo quantitative analysis will be stored on the Freeland CineView system's 128 MB optical disks, analyzed on the Freeland Prism 5000 workstation at the reading center (see below), and copied for permanent digital storage on 650 MB optical disks. Because of the digital format, there is no loss of resolution data resulting from the transfer. The entire study, including the data selected for digital storage, will be recorded on Super VHS format videotape for permanent storage. In the event some digital data is lost, it can be reproduced by digitizing from videotape with some image degradation which should be acceptably small in most cases. Similarly, if videotape data is inadvertently lost, the critical images are still available from the digital disks.

4.4 Workstation Instrumentation - Analysis at the reading center

The echo videotapes and digital disks will be delivered regularly to the physicians at the reading center in the University Hospital's Heart Station near the ARIC Clinic building. The videotape will be reviewed to provide a basic clinical interpretation of the study, in particular to look

for important or unexpected echocardiographic findings (for example, moderate or severe aortic stenosis or regurgitation) which may impact on the participant's health care or which may affect the usefulness of the data for the purposes of the ARIC echo study. This videotape will be viewed on a Super VHS videotape player and monitor similar to that used to record the study. The 128 MB digital optical disk data will be loaded onto the Freeland Prism 5000 workstation for analysis. Details of the analysis procedures are found in the Reading Protocols Manual. The studies and analysis results are copied onto 650 MB optical disks for permanent archival. The 128 MB disks are erased for reuse after confirming that the data has been successfully stored into the archival media. Details of the operation of the Prism 5000 system are found in the Freeland Systems Operator's Manual, with core information reviewed in the ARIC Echocardiography Reading Center Manual

4.5 Reading Center Database for analysis results

For the purpose of efficient data management and transmission to the Coordinating Center, the data items and pertinent participant information will be entered into a database on an 80486-based computer with appropriate disk storage and backup. Individual data items are defined in the Reading Center Manual. Study identification and tracking data as well as qualitative analysis results will be entered by keyboard into the database from the Technician and Reader Worksheets. Errors in manually entered data will be avoided by range checking of numeric data by the database software and by regular comparison of the database information with the Worksheets. Data generated by the Freeland workstation is available in that system in a DBase III format. The Reading Center Database, developed using Microsoft Access by Microsoft Corporation, will directly import the Freeland Systems data files, avoiding keyboard entry errors. Additional data fields in the Reading Center Database will accommodate the manually entered items. Participant and study identification data, critical to proper data tracking, will be imported from the technician's entries into the Freeland data files and will be cross checked from the Technician Worksheet for accuracy during the manual keyboard entry of the additional qualitative study results. This Reading Center Database will provide a versatile means of organizing the data, analyzing it for quality control, and formatting the data for transmission to the Coordinating Center. Details of the database structure and operations are provided in the reading protocol manual.

5. TECHNICIAN TRAINING, CERTIFICATION, QUALITY MONITORING

5.1 Technician training

Under direction of the cardiologist co-investigator, two Registered Nurses of the ARIC center staff will undergo training to perform echocardiography examinations. Training will begin with basic didactic and videotape sessions on ultrasound physics and principles of the ultrasound examinations. The Acuson 128XP operation and control settings will be taught during actual examinations by the technicians-in-training under cardiologist supervision on ARIC volunteers. The cardiologist offers guidance, suggestions for improvement, and answers questions as they arise. Approximately 5 scans per weeks are performed by trainees (initiated in March, 1993) following the ARIC scanning protocol. In addition, two more technicians (clinical sonographers from the University Hospital's laboratory already familiar with the Acuson 128XP and Freeland systems) will be trained in the ARIC scanning protocol. Under the cardiologist co-investigator's direction, the clinical technicians will perform 10 scans at the ARIC field center during the 2 week period prior to the pilot study.

In addition to the on-site training, each technician will spend one week (40 hours) in training with technicians and investigators at the Framingham Heart Study echocardiography laboratory. Since the Framingham study uses similar scanning procedures, the training session will review the operation, standard control settings, and the important aspects of assuring high quality data in population studies (i.e., following a standardized protocol).

5.2 Technician Certification

After the initial training (and in conjunction with the pilot testing procedures), each technician will undergo certification by performing 10 complete echocardiogram examinations (performed during week 1 of the 2 week pilot phase). The cardiologist will perform the examination independently as well to establish the standard by which the technician's studies will be graded, referred to below as the "standard exam". The technician's examination will be scored for each 2-dimensional imaging view, M-mode, and Doppler examination. For imaging modes, grading will be based on proper spatial orientation and definition of good endocardial and epicardial boundaries. For Doppler modes, grading will emphasize proper orientation of the interrogating beam and measurement gate, and of the ability to obtain clear Doppler data demonstrating smooth velocity contours with highest velocity for spectral Doppler, and

consistent beat-to-beat data for the Doppler color flow mode.

For each imaging view, 2-D, M-mode, and Doppler exams, a quantitative score of 3 is given for "excellent" reproduction of the cardiologist's study quality, 2 for "good" (slightly below the technical quality of the standard exam), 1 for "fair" (usable but significantly below the standard exam), and 0 for an exam component which is not usable for the study and is unacceptably worse than the quality of the cardiologist's examination. A simple average of at least 2.0 will be required for the technician to be certified as having adequate skills to perform the study protocol. Any technician failing to meet certification requirements will undergo additional training and re-testing before performing independent examinations on study participants.

While the technicians will be expected to complete the echocardiogram study within 30 minutes, a strict time limit will not be imposed during certification procedures.

In the event that a new technician joins the study staff, the same initial training and certification procedures will be followed as described above.

In addition to these certification procedures, technician training and refinement of techniques will be an ongoing process, facilitated by the fact that the technician trainer is also the primary study reader, and there will be a close working relationship with each of the technicians involved in this single-center study.

5.2 Monitoring

Echocardiographer performance is monitored throughout the ARIC study at the Jackson field center. The cardiology co-investigator will randomly review one examination per month by each technician to ensure data quality and adherence to the scanning protocol. The appropriateness of spatial orientation, the visualization of the endocardial and epicardial boundaries, and the transducer placement will be evaluated and recorded on the echocardiographer evaluation form. The forms are kept by the co-investigator and sent to the quality control investigator monthly.

A series of quality control procedures are monitored throughout the study. The quality control procedures consist of (a) comparing the results given by the same sonographer for repeat studies performed on randomly selected participants; (b) monthly reports containing statistics of the frequency of successful examinations by

sonographer (grade 2 or 3 on reader evaluation) and intra-sonographer correlation coefficients of all variables.

5.3 Recertification

Re-certification will be performed at 12 month intervals for the all technicians. At the certification anniversary, five randomly selected echocardiograph's scans performed during the prior month are reviewed and evaluated by the cardiology co-investigator. The results of these evaluations, in combination with the monthly quality control reports, are considered for re-certification.

A sonographer must complete a minimum of 20 echocardiograms each month to maintain certification. If less than 20 scans are performed for 2 consecutive months (but not more than 2 months), the technician must undergo recertification as follows:

- A. The cardiology co-investigator updates the technician regarding changes in procedures;
- B. The technician scans 20 participants per month;
- C. Routine quality control checks continue;
- D. The echocardiographer remains on the current annual recertification procedure.

If the echocardiographer performs no scans for more than two months, the recertification process is as follows:

- A. The cardiology co-investigator updates the technician regarding changes in procedures;
- B. The technician observes a minimum of four scans;
- C. The first four scans performed by the technician are performed under supervision by the cardiology co-investigator;
- D. When four consecutive scans are considered acceptable by the reader (cardiology co-investigator), the technician is recertified.

If a major change in the echocardiography protocol occurs, echocardiographers will undergo recertification as follows:

- A. The cardiology co-investigator will update echocardiographer on the new protocol;
- B. The technicians will observe four scans performed by the cardiology co-investigator;
- C. The technicians perform four scans on non-ARIC participants under the supervision of the cardiologist;
- D. When four consecutive scans are considered acceptable by the reader (co-investigator), the echocardiographer is recertified.

If quality assessment at the reading center indicates significant reduction in a technician's study quality,

individualized training and/or recertification examinations may be required.

5.4 Quality assessment

5.4.1 *GENERAL*: The utility of echocardiographic measures of cardiac anatomy and function has been demonstrated in clinical and population studies. Cardiac abnormalities assessed by this techniques (e.g., left ventricular hypertrophy) have been associated with an increased incidence of cardiovascular morbidity and mortality. Given the greater sensitivity and specificity of echocardiographic measure in comparison to other indirect measures of cardiac abnormalities, the echocardiogram may serve as a surrogate measure of preclinical manifestations of cardiovascular disease and as a prognostic indicator for future clinical events (i.e., hypertension, myocardial infarction, and/or stroke).

Since this is the first large scale population study of middle-age African-Americans, quality control is of particular importance. Previous population studies (Framingham Heart Study, CARDIA, and CHS) have indicated that considerable training and experience are required to assure optimal echocardiographic data acquisition of sufficient quality. The goals of this strict echocardiography quality control program are to (1) provide quantitative documentation of the reproducibility of the scanning and reading procedures, and (2) assess the comparability of the ARIC scanning and reading estimates of variability with other population studies of echocardiography.

5.4.2 *Essential features of the quality control program include:*

- (1) To assure adherence to study protocol, supervision of the performance of echocardiographic procedures utilized by technicians will be done by Dr. Skelton.
- (2) Regular (weekly) meetings among technicians and reading center physicians will be conducted. At these meetings, the staff will critically review studies to identify opportunities for improvement in data quality and security, and in efficiency and details of protocol. The technicians will better recognize the image quality and techniques necessary to allow the study readers to obtain accurate, reproducible quantitative information. At the same time, the study cardiologists can provide ongoing feedback to improve the technicians' skills, their understanding of ultrasound principles, and their recognition of echocardiographic abnormalities.
- (3) To identify potential protocol deviations, difficulties, or inefficiencies, Drs. Arnett, Liebson, and Benjamin may periodically visit the Jackson center to assess scanning and reading procedures.
- (4) Assessment of inter- and intra-technician/reader variability.

5.4.3 *Technician Quality Assessment Procedures:*

5.4.3.1 Assessment of Intra- and Inter-technician Variability during the Pilot Phase. Measurement variability between studies on the same participant performed by different (inter-) field center technicians (1 field center technician and 2 clinical technicians) and within the same technician (intra-) will be assessed in the pilot phase study. To enhance time efficiency, the pilot phase assessment of measurement variability will overlap with the technician certification procedures. After completion of training, each technician will perform echocardiograms on 10 volunteer participants. The volunteers will return the following week for rescanning by each sonographer (a total of 20 scans per sonographer). Volunteers will be assigned a phantom ARIC ID (obtained from the Coordinating Center). VHS videotapes and optical disks will be transported to the reading center at the end of each week. Readings will be performed for initial and repeated studies, with the combined data used to assess inter- and intra-technician variability. Additional repeat quality

control echocardiograms will be scheduled during the study to monitor intra-technician variability (as specified in further detail in the following section).

5.4.3.2 Assessment of Intra- and Inter-reader Variability During the Pilot Phase. To provide estimates of intra-reader repeatability, after initial reading of the pilot phase testing/certification, 50% of the scans will be reread by the same reader. The remaining 50% will be read by a second certified reader. Additional repeat readings will be performed throughout the study.

In addition to the above quality control procedures a random sample of 20 echocardiograms performed during the first three months of the study will be sent to consultants (Liebson and Benjamin) for reading.

5.4.3.3 Assessment of Intra-technician Variability during the Examination Period. Intra-technician variability will be assessed throughout the examination period by the performance of quality control repeat echocardiograms in a 10% random sample of participants. The Coordinating Center will generate a list of randomly selected ARIC IDs for Jackson for the purpose of QC repeat examinations. After the initial scan on each participant is complete, the technicians will check the QC master list to determine eligibility of the participant for repeat measurements. If the participant's ID matches the QC list, he/she will be asked to volunteer for a repeat echocardiogram.

5.5 Overview of data handling

The study procedures have been designed with consideration for optimizing completeness, integrity, and safety of the data collected. There is redundancy in data collection and storage, automation and/or range-checking during data entry, use of analog and digital media in industry-standard formats, and appropriate quality monitoring activity.

Technicians record image and Doppler data onto standard Super-VHS videotape with plans to permanently save these tapes for potential future analysis. A subset of the study (data to be used for qualitative analysis) are also captured as digital images which are stored (temporarily) onto 128 megabyte rewritable optical disks. Both media (videotape and optical disks) are transported to the reading center on a daily basis for analysis. Written logs will track the delivery and location of the media, and will provide a backup method of locating a specific participant's studies on videotape or disk.

On the reading center's workstation, the images read from the 128 MB optical disks are copied along with the quantitative data generated by the analysis protocol onto 650 MB optical disks which are kept as permanent archives. The 128 MB optical disk is erased (and recycled to store a new series of studies) only after confirmation of the successful archival of its data.

The reading center will maintain a computer database for storage of all the data relevant to the echo studies. Participant identification and qualitative observations made at the examination will be input from written data on the technician worksheets. Qualitative data generated by the reading center's review of the study will also be entered from written worksheets. Quantitative results of measurements on the analysis workstation will be directly imported into the database without keyboard data entry. This process will not only duplicate other written and electronic records of this information but also consolidate data for local analysis and for ease of archiving the study results onto digital tape, a routine part of daily backup on the Heart Station's computer network.

All data required for analysis will be transmitted to the Coordinating Center where the official analysis files will be maintained.

5.6 Monitoring technician performance

Regular assessment of each technician's performance will be conducted throughout the study. The use of a single imaging lab and its close relationship with the study cardiologist who is responsible for technician training and for interpretation and analysis of the studies will facilitate critical feedback to the technicians and efficient recognition of technical problems or areas for potential improvement. The local database will generate monthly reports of study quality and useability scores recorded for each technician. Study readers will look for completeness of the data, adherence to protocol, and ability to consistently maintain a high level of image and data quality.

6. THE ECHOCARDIOGRAPHIC EXAMINATION

This section will detail the instrument preparation, patient preparation, and performance standards for the echo examination. A flow sheet summary of the procedure found in Appendix A is used by the technicians. The Technician Worksheet is enclosed as Appendix B.

6.1 Presets on the instruments

6.1.1 *ECHO MACHINE'S APPLICATION PRESETS*: The Acuson XP128/10c echo machine features programmable "application" presets to allow customization of preferred image and Doppler settings, and to allow efficient selection of alternate settings if needed, for example, in the case of technically difficult imaging studies. The definable parameters are listed in the Acuson *User Manual for Cardiovascular Applications*. A preset has been defined for the ARIC echo study based on typical imaging and Doppler parameters for cardiac ultrasound and on the crucial need for high quality M-mode and 2-D data. This preset is active automatically when the machine is powered up, and it can be re-selected from the keyboard prior to each study. The technician may modify some parameters during the course of a study to optimize data quality but these changes are returned to nominal settings when the ARIC "application preset" is selected.

6.1.2 *DIGITAL STORAGE SYSTEM PROTOCOLS*: The Freeland Systems CineView digital imaging computer also has definable application "protocols" which control the resolution and timing of image acquisition and storage. There are two basic requirements for the purposes of this study: (1) full-screen acquisition of M-mode and spectral Doppler data in highest resolution (512 x 480) for the purpose of quantitative measurements, and (2) acquisition of serial frames showing cardiac motion throughout an entire cardiac cycle ("R-to-R acquisition"). Two "protocols" have been defined to accomplish each of these tasks.

The first protocol, "ARIC Echo", defines the acquisition of 12 images spaced at even intervals from one R wave on the EKG to the next. When the technician presses and releases the "STORE" footpedal, the computer measures the R-to-R interval for the first beat and captures 12 evenly-spaced images (an "image loop") from the next beat. Multiple "loops" may be captured for a given view; the technician selects (or "locks") the single loop which is considered technically best. For economy of storage, only the portion of the screen with the 2-dimensional image data is captured (amounting to half the full screen width). The images are stored in highest axial resolution of 480 pixels (to accurately preserve dimensional data) and horizontal resolution of 256 pixels (adequate to match lateral resolution needs of the 2-D image and to allow endocardial boundary definition).

The second protocol, "ARIC M-Mode/Doppler", allows single frame storage of the full screen containing

either M-mode or spectral Doppler data. If the technician obtains better quality data after the first screen is already stored, additional screens can be saved as desired to provide the reader with options for selecting the best data for quantitative measurements. The acquisition is triggered by a press and release of the "STORE" footpedal.

6.2 Equipment preparation prior to each study

6.2.1 *ECHO MACHINE PREPARATION.* The Acuson should be physically clean and sanitary at all times. General care instructions are found in the documentation supplied with the machine.

Prior to each study the transducer heads should be wiped clean in accordance with the manufacturer's instructions. Disposable EKG electrodes are snapped onto the three leads of the EKG cable prior to attaching to the participant.

If any machine parameters have been altered by the previous study, reactivate the ARIC "application preset" (press CODE+RECALL APPLIC and select "ARIC").

Insert a numbered videotape into the Sony tape recorder. (The tape number will be recorded on the Technician Worksheet). The technician should be confident that the tape is positioned on the blank portion immediately after the preceding study to assure that data is not overwritten. (Pressing the "BLANK" search button on the Sony recorder will cause the tape to scan forward to the first unrecorded portion of the tape).

Press BEGIN on the Acuson keyboard, and fill in the study identification information on the screen. Record this ID screen onto videotape for about 5 seconds. *During the recording, press MARK on the Sony videotape remote control.* This will allow more efficient location of studies on tape during the review process. Finally, press BEGIN again to return to the image screen.

6.2.2 *DIGITAL STORAGE SYSTEM PREPARATION.* The Acuson echo machine's video monitor also serves as the Freeland computer's monitor. By default, at powerup the display is the Acuson image screen. To switch at any time between the Acuson and Freeland computer displays, press the "bypass" function key (F10) on the Freeland keypad.

Make sure a labelled 128MB optical disk is inserted in the disk drive

Show the Freeland display by pressing BYPASS (F10) on the keypad

From the top line menu, select PATIENT, then NEW. Fill in the study identification screen, then select QUIT. (Alternatively the identification data on all the participants for the day may be entered into a "roster" at the beginning of the day, and a given one may be activated prior to his study as follows: select PATIENT, select ROSTER, highlight the desired participant name, select ACCEPT.)

From the top line menu, select PROTOCOL, then "ARIC Echo".

Press LIVE on the keypad. (The Acuson image screen will be "fed through" the Freeland to the display)

6.3 Participant Preparation.

The participant should remove all clothing from the waist up and don a clinic gown which will provide access to the chest as needed for imaging.

Position the subject in the left lateral position with the head propped up at a slight angle on pillows and a wedge behind him to help maintain this position comfortably.

Attach three EKG electrodes as labelled. The "arm" leads (RA and LA) may be placed on the upper chest near the shoulders, and the "left leg" lead (LL) may be placed on the abdomen. The leads should be draped without tension in a way that they will not interfere with the subsequent examination. *Check that a clear EKG signal is displayed on the echo machine.* The EKG size control on the Acuson is generally best left in the "AUTO" position. Turn up the AUDIO VOLUME enough to confirm that the R BEEPER is active (a beep is heard coincident with each R wave of the EKG).

The technician will measure the participant's blood pressure in a comfortable supine position and record it on the imaging systems' information screens.

6.4 Imaging Views and Information Sought

This section reviews the standard set of acoustic windows to be used and the data sought from each view. In addition, a list of items to be recorded is given. Where "tape" is specified, several seconds of clearest-possible images are

recorded. Where "digital" is specified, the appropriate capture protocol is used, "ARIC Echo" to capture 2-D images as single cardiac cycles or "M-mode/Doppler" to capture single full-screen records of those data. Where "hardcopy" is specified, the technician will record a freeze frame image (generally M-mode data) on the thermal video page printer.

6.4.1 Parasternal Views. These views are usually performed in the left 3rd or 4th intercostal space adjacent to the sternum.

6.4.1.1 Parasternal Long Axis View

The ultrasonographer attempts to line the beam perpendicular to the interventricular septum and posterior left ventricular wall. Initially, the focus is on obtaining a clear 2-D image of the aortic valve, aortic root, left atrium, right ventricle, left ventricle, and mitral valve. Color Doppler interrogation is performed to assess aortic and mitral regurgitation.

Data recorded in the parasternal long-axis view:

- 2-D imaging (tape)
- Color Doppler (tape)
- 2-D images (digital)

6.4.1.2 Right ventricular inflow view

In a modification of the parasternal long axis view, the transducer is angled to the subject's right, demonstrating the tricuspid valve anatomy

Data recorded in the RV inflow view:

- 2-D imaging (tape)
- Color Doppler (tape)

6.4.1.3 Parasternal Short Axis View

From the long axis position, the transducer is rotated clockwise 90-degrees to obtain the short axis view.

The exam begins at the left ventricular (papillary muscle) level to demonstrate ventricular anatomy and wall motion.

Images are recorded at the mitral valve level to show valve anatomy and motion.

Images are recorded at the aortic valve level to show valve anatomy and motion. Color Doppler is performed at the pulmonary, aortic, and (if adequately visualized) tricuspid valves.

The technician returns to the aortic valve level to perform M-mode recording of the aortic valve and left atrium.

M-mode examination is performed at the papillary level taking care to orient the transducer for a view perpendicular to the long axis of the ventricle (creating a circular, rather than oblong, shape to the tomographic image). The M-mode cursor is positioned through the center of the chamber and gain settings are adjusted to optimize the boundary detection of the walls of the interventricular septum and posterior wall. While optimizing M-mode angle and image quality the Acuson display is a split screen showing both M-mode and a miniaturized 2-D image. When the data are optimal, the **SIZE** toggle is pressed once on the Acuson, increasing the M-mode display to full screen. The **FREEZE** button is pressed after a full sweep is displayed in the larger format. This frozen display is printed on the hardcopy device, recorded onto videotape, and captured into the Freeland digital system. The same procedure is carried out for the images at the aortic valve level, described above. NOTE: If the technician feels that the image data are technically better from the parasternal long-axis view, then that view will be used for M-mode data, positioning the cursor just beyond the mitral leaflet tips and carefully selecting the image plane to coincide with the long axis of the left ventricle. The M-mode data at the aortic valve level may also be obtained from the parasternal long-axis view if image quality is felt to be significantly better than short axis.

Data recorded in the parasternal short axis views:
 2-D at aortic, mitral, and papillary (tape)
 Color Doppler of valves at aortic level (tape)
 2-D images of LV at papillary level (digital)
 M-Mode of LV at papillary level
 (digital/tape/hardcopy)
 M-Mode of Aortic valve and LA
 (digital/tape/hardcopy)

6.4.2 Apical Views. These views are performed in the interspace where the ventricular apex is felt, usually in the left 5th or 6th interspace in the between the midclavicular and anterior axillary lines.

6.4.2.1 Apical 4 chamber view

The technician strives to achieve an imaging plane directly over the left ventricular apex, parallel to the interventricular septum, and rotated in a manner to show all 4 chambers and both the mitral and tricuspid valves simultaneously.

For efficiency in the protocol, the technician will perform pulsed wave spectral Doppler examinations first.

For mitral inflow data, the range gate is placed near the tips of the mitral leaflets with small adjustments in angle to obtain maximum flow velocity data with a narrow spectral dispersion. After 2-D directed placement of the range gate cursor using the split screen (Doppler and miniature 2-D) mode, a full screen sweep (activated using the **SIZE** toggle on the Acuson) of spectral Doppler is frozen on the screen, printed on the hardcopy device, recorded on videotape, and captured on the digital system.

For aortic outflow data, the transducer is tipped slightly anterior show the aortic valve and outflow tract (the "5 chamber" view). The range gate cursor is placed in the left ventricular outflow tract about 0.5 to 1 cm proximal to the aortic valve, again trying to demonstrate a pattern of narrow spectral dispersion and a well-defined velocity profile. Data are recorded as for mitral above. The Doppler mode is then switched to CW (continuous wave) and the interrogating beam directed through the aortic valve to measure peak velocity.

Next the focus in on clear 2-D images of the 4 chambers and AV valves. This view and its color flow Doppler data are recorded on videotape. The 4-chamber view is digitized into the Freeland system with particular attention to definition of LV wall boundaries and wall motion.

Data recorded in the apical 4 chamber view:

- Pulsed Doppler of mitral inflow
(digital/tape/hardcopy)
- Pulsed Doppler of aortic outflow ("5 chamber view")
(digital/tape/hardcopy)
- 2-D images of 4 chamber view (tape)
- Color Doppler (mitral, aortic, tricuspid) (tape)
- 2-D images of LV in 4 ch view (digital)

6.4.2.2 Apical 2 chamber and long axis views From the 4 chamber view, the transducer is rotated along its imaging axis 90 degrees counterclockwise to show the left ventricle and atrium from the apex (the 2 chamber view). This view is recorded on videotape and the 2-D images are captured on the digital system with particular attention to definition of LV wall boundaries and wall motion. The transducer is rotated

slightly to simultaneously image the mitral and aortic valves (the apical long axis view) and color flow Doppler data is recorded on videotape.

Data recorded in the apical 2-chamber and long axis:

2-D image of 2-chamber view (tape)
Color Doppler of mitral/aortic in long axis (tape)
2-D images of LV in 2 ch view (digital)

6.4.3 Supplementary views. With the important priority of measuring LV wall and chamber dimensions, inability to obtain useable images from other acoustic windows (especially parasternal) should prompt the technician to image from the **subcostal view**. Both a 4 chamber view and a short axis of the LV at the papillary level should be attempted. Recognition by the technician of significant abnormalities should prompt further examination which may require additional views. For example, a suggestion of aortic root dissection should prompt examination from the **suprasternal notch**. Sometimes supplementary Doppler interrogation from standard views is required, such as with the recognition of valvular aortic stenosis where continuous wave Doppler (CW) should be carefully employed to measure peak flow velocity through the valve.

6.5 Completing the study

6.5.1 **Completing data storage.**

On the Freeland digital image system, ensure that the desired images have been "locked" by noting that a magenta lock icon is displayed on each cardiac loop captured. Clear the other (unlocked and discardable) images from the system using the **Clear Unlocks (SHIFT-F5)** function.

Then, select **File** then **Save** from the top line menus. This process will take a few minutes as the selected data is stored onto the 128MB optical disk.

Then, when the above "save" operation is complete, clear the Freeland system completely using the **Unlock all (SHIFT-F9)** function followed by **Clear Unlocks (SHIFT-F5)**.

Record any additional comments or data on the technician worksheet.

6.5.2 **Completing the participant encounter**

During the file save operation is a convenient time to disconnect the Acuson EKG cable and remove the electrode

pads. Provide the participant with a towel to remove any residual ultrasound gel while he gets dressed.

7. TRANSMITTAL OF DATA TO THE READING CENTER

At the completion of the day's studies, the videotape(s) and the optical disk are removed from their respective systems. The tape(s), disk, and technician worksheets for each study should be packaged together for hand delivery to the Heart Station where the data will be analyzed. It is anticipated that studies will be delivered at least once a week. The studies will be logged in at the reading center using the information on the technician worksheets. Each study's progress through the reading and data entry processes will be noted in the logbooks of the reading center. More complete details of these procedures are found in the *ARIC Echocardiography Reading Center Manual*.

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07/26/94

ARIC ECHOCARDIOGRAPHY PROTOCOL

VIEW	DATA SOUGHT	DISPLAY	RECORD	PRIORITY	COMMENTS
<i>Measure BP; Connect EKG and verify R-beeper</i>					
<i>Enter Study ID on Freeland and Acuson</i>					
<i>Press "MARK" on VCR remote while recording Acuson ID screen</i>					
Para. Long	2-D	Acuson	Tape	High	angle to RV inflow view to image tricuspid valve
	Color flow (aortic, mitral)	"	"	Med	angle to RV inflow view for color flow of tricuspid valve
	Best 2-D	Freeland	Digital	High	emphasis on clear view of septal and posterior walls
Para. Short	2-D (sweep LV, mitral, aortic levels)	Acuson	Tape	High	
	Color flow (pulm, aortic, tricuspid)	"	"	Low	
	Best 2-D @ LV level	Freeland	Digital	High	emphasis on "true short axis" (round) and boundary def.
<i>Select "ARIC M-Mode Doppler" Protocol on Freeland</i>					
Para. Short	M-mode full screen of LV	Freeland	Digital & Tape	High	emphasis on clear boundaries; use long axis if better data
Para. Short	M-mode full screen of Ao/LA	Freeland	Digital & Tape	Med	emphasis on clear boundaries; use long axis if better data
Apical 4-ch.	Pulsed Dop. Mitral inflow	Freeland	Digital & Tape	High	position cursor in LV at mitral leaflet tips
Apical 5-ch.	Pulsed Dop. Aortic outflow	Freeland	Digital & Tape	Med	position cursor in LV outflow tract (5 chamber view)
<i>Select "ARIC Echo" Protocol on Freeland</i>					
Apical 4-ch.	2-D	Acuson	Tape	Med	
	Color flow (mitral, tricuspid, aortic)	"	"	Med	use "5 chamber" for aortic
	Best 2-D of LV in 4 ch view	Freeland	Digital	High	
Apical 2-ch.	2-D	Acuson	Tape	Low	
	Color Flow (mitral, aortic)	"	"	Low	
	Best 2-D of LV in 2-ch view	Freeland	Digital	Med	
<i>Check that desired images are "locked" on Freeland</i>					
<i>Clear unlocks (SHFT - F5)</i>					
<i>File, save</i>					
<i>Unlock all (SHFT - F9) and Clear unlocks (SHFT - F5)</i>					

ARIC Echocardiography

Technician Worksheet

Name : _____ ID : _____ Date : _____

Age : _____ BP : _____ / _____ HR : _____

Height : _____ (cm) (in) Weight : _____ (lb) (kg)

Opt.Disk # _____ Videotape # _____ Tech ID: _____

Position for study: 45° left OTHER: _____

LV M-mode from para. short para. long unobtainable

Ao/LA M-mode from para. short para. long unobtainable

Comments

2-D or color flow

[Empty box for 2-D or color flow comments]

M-mode

[Empty box for M-mode comments]

Pulsed Doppler

[Empty box for Pulsed Doppler comments]

Other

[Empty box for Other comments]

Alert findings:

Aortic dissection*

Thrombus*

Vegetation*

Large pericardial effusion*

* Called Dr. _____ Date/Time: _____

Aortic stenosis

Mitral stenosis

Mod/Severe _____ regurg

Marked LV dysfunction

Study Time: START: _____ STOP: _____

ARIC Echocardiography

Reading Worksheet

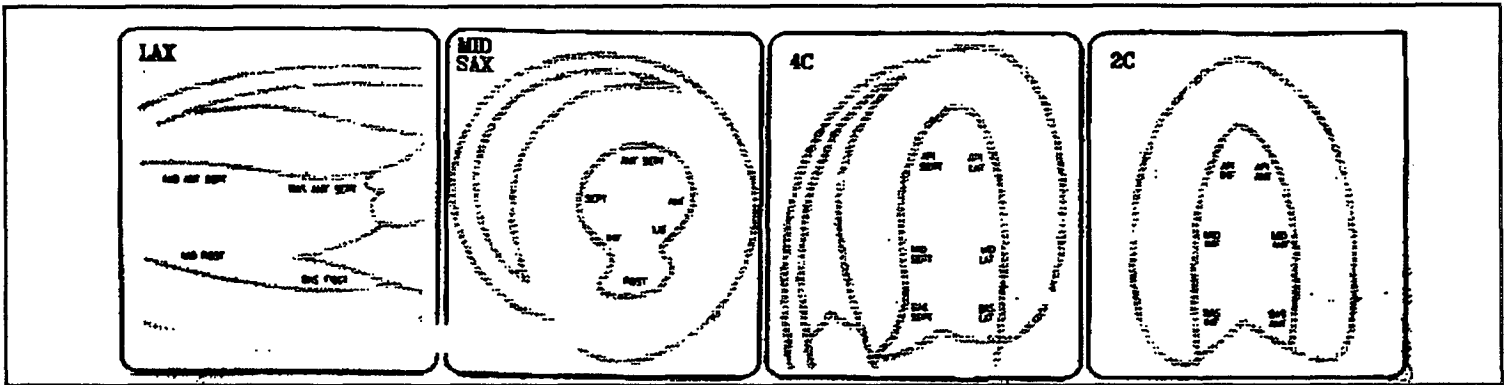
Reader ID _____ Date: _____ Stored to optical disk # _____

QUALITATIVE 2-D DATA

- LA enlargement None [0] Mild [1] Mod [2] Severe [3] Can't assess [9]
- LV enlargement None Mild Mod Severe Can't assess
- Ao root dilation None Mild Mod Severe Can't assess
- LV hypertrophy None Mild Mod Severe Can't assess
- LV ejection fraction Normal Mild ↓ Mod ↓ Severe ↓ Can't assess
- LV regional wall motion Normal [N] Borderline [B] Definitely abnormal [A] Can't assess [9]

MARK ABNORMAL SEGMENTS: H=hypokinetic A=akinetic D=dyskinetic X=can't assess segment

Can't assess view Can't assess view Can't assess view Can't assess view



- Aortic leaflets Min or no sclerosis [0] Definite sclerosis [1] Definite stenosis [2] Can't assess [9]
- Mitral leaflets Min or no sclerosis Definite sclerosis Definite stenosis Can't assess
- Mitral Regurgitation None [0] Trace [1] Mild (clearly abnl) [2] Mod/Severe [3] Can't assess [9]
- Aortic Regurgitation None Trace Mild Mod/Severe Can't assess
- Tricuspid Regurgitation None Trace Mild Mod/Severe Can't assess
- Pulmonary Regurgitation None Trace Mild Mod/Severe Can't assess
- Mitral anular calcif. None Mild Mod/Severe Can't assess
- Mitral prolapse None Mild Mod/Severe Can't assess
- Ao Root fibrocalcific chg None Mild Mod/Severe Can't assess
- LV aneurysm None [N] Ant/apical [A] Inf/posterior [I] Can't assess [9]
- LV thrombus No [N] Yes [Y] Can't assess [9]

2-D : LV Measured from para. long [L] para. short [S] Not measured [9]
 M-mode: LV Measured from para. long [L] para. short [S] Not measured [9]
 Septal orientation >30 ? No Yes

OTHER ECHO FINDINGS:

STUDY QUALITY

- | | EXCELLENT (3) | GOOD (2) | FAIR (1) | NOT USEABLE (0) | NOT RECORDED (9) |
|-----------------|--------------------------|--------------------------|--------------------------|--------------------------|--------------------------|
| 2-D parasternal | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| 2-D apical view | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| M-mode LV | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| M-mode Ao/LA | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PW Dop - mitral | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| PW Dop - LVOT | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |
| Color flow data | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> | <input type="checkbox"/> |

ALERT FINDINGS / ACTION TAKEN : none
 OTHER COMMENTS ON PROCEDURE OR DATA: