

# ORIGINAL REPORTS: RESEARCH DESIGN

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## RATIONALE AND DESIGN

### OF THE ECHOCARDIOGRAPHIC STUDY OF HISPANICS / LATINOS (ECHO-SOL)

**Background:** Information regarding the prevalence and determinants of cardiac structure and function (systolic and diastolic) among the various Hispanic background groups in the United States is limited.

**Methods and Results:** The Echocardiographic Study of Latinos (ECHO-SOL) ancillary study recruited 1,824 participants through a stratified-sampling process representative of the population-based Hispanic Communities Health Study – Study of Latinos (HCHS-SOL) across four sites (Bronx, NY; Chicago, Ill; San Diego, Calif; Miami, Fla). The HCHS-SOL baseline cohort did not include an echo exam. ECHO-SOL added the echocardiographic assessment of cardiac structure and function to an array of existing HCHS-SOL baseline clinical, psychosocial, and socioeconomic data and provides sufficient statistical power for comparisons among the Hispanic subgroups. Standard two-dimensional (2D) echocardiography protocol, including M-mode, spectral, color and tissue Doppler study was performed. The main objectives were to: 1) characterize cardiac structure and function and its determinants among Hispanics and Hispanic subgroups; and 2) determine the contributions of specific psychosocial factors (acculturation and *familismo*) to cardiac structure and function among Hispanics.

**Conclusion:** We describe the design, methods and rationale of currently the largest and most comprehensive study of cardiac structure and function exclusively among US Hispanics. ECHO-SOL aims to enhance our understanding of Hispanic cardiovascular health as well as help untangle the relative importance of Hispanic subgroup heterogeneity and sociocultural factors on cardiac structure and function. (*Ethn Dis*. 2015;25[2]:180–186)

**Key Words:** Echocardiography, Epidemiology, Hispanics, Cardiovascular

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## INTRODUCTION

In 2010, 50.5 million Hispanics represented 16.7% of the total United States population making them the largest racial/ethnic minority group in the United States, surpassing African Americans (13.1%), Asian Americans (5.0%), and Native Americans (1.2%). Moreover, while the non-Hispanic White population older than aged 65 years is expected to grow by 83% between 2000 and 2030, Hispanics of this same age group are projected to grow by 328%, making Hispanics the fastest growing aging population in the United States.<sup>1</sup>

Heart failure (HF) incidence in the United States is rising with approximately 670,000 new cases per year and a 20% lifetime HF risk for persons aged  $\geq 40$  years.<sup>2</sup> Clinical HF represents the tip of the iceberg because individuals can have abnormal cardiac structure and

function (stage B, HF) without the diagnosis of clinical HF.<sup>3</sup> The prevalence of asymptomatic systolic and diastolic dysfunction in the general population is not insignificant (approximately 7%–14% and 20%–30% respectively).<sup>4,5</sup> However, these estimates were derived from non-Hispanic populations and may not accurately describe Hispanics because certain Hispanic groups are more likely to be hypertensive and to have diabetes than non-Hispanic Whites.<sup>6,7</sup> Recognition and treatment of preclinical systolic and diastolic dysfunction is suggested in HF prevention guidelines as a potentially powerful strategy for averting the development of overt HF.<sup>3</sup> With average life expectancy increasing and HF continuing to grow as a major public health concern, knowledge of cardiac structure and function (systolic and diastolic) among Hispanics could significantly impact public health in the United States.

The Echocardiographic Study of Latinos (ECHO-SOL) is to date the largest study designed to characterize the prevalence and correlates of cardiac remodeling and systolic/diastolic function exclusively in Hispanics overall, as well as differences among the various Hispanic background groups in a population- and community-based cohort design using comprehensive echocardiographic techniques including two-dimensional (2D), volumetric assessments, spectral Doppler, tissue Doppler imaging and speckle-tracking strain. Herein, we describe the design,

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*We describe the design, imaging acquisition and analysis methods, and quality assurance metrics of ECHO-SOL.*

imaging acquisition and analysis methods, and quality assurance metrics of ECHO-SOL.

**METHODS**

**The Parent Cohort**

The Hispanic Community Health Study - Study of Latinos (HCHS-SOL) is a comprehensive multicenter community-based cohort study of Hispanics/Latinos in the United States designed to examine risk and protective factors for chronic diseases and to quantify morbidity and mortality prospectively. Details of the sampling methods and design have been published.<sup>8,9</sup>

At baseline, the HCHS/SOL examined 16,415 self-identified Hispanic/Latino persons aged 18 to 74 years. Study enrollees were recruited from four US communities (Bronx, New York; Chicago, Illinois; Miami, Florida; San Diego, California) using a probability

sample design. HCHS/SOL consists of participants from each of the following origin designations: Mexican, Puerto Rican, Dominican, Cuban, Central American and South American. Baseline examinations, conducted during February 2008 through July 2011, involved extensive sociodemographic and medical assessments that have been previously described.<sup>8</sup> The HCHS-SOL baseline cohort did not include an echo exam.

**Study Population**

ECHO-SOL established a network of investigators to recruit and enroll a well-characterized subsample of Hispanics/Latinos within HCHS-SOL (*n*~450 at each Field Center [FC]; total *n*=1,824) over a three-year period as shown in Table 1. Participants were not actively recruited for ECHO-SOL before they completed all HCHS-SOL baseline exam procedures. HCHS-SOL participants were eligible for ECHO-SOL if they were at or over the age of 45, self-identified as Cuban, Mexican, Puerto Rican, Dominican, Central American or South American and were within 36 months from their initial HCHS-SOL visit.

**Study Design**

A unique feature of the HCHS-SOL is the recruitment of groups of Hispanic/Latinos of differing backgrounds from centers across the United States with a vast array of clinical, psychosocial, behavioral (including diet and

physical activity), and socioeconomic data. ECHO-SOL was designed so that Hispanic participants drawn from the HCHS-SOL reflected the general constituency of the respective study FCs using a stratified random sampling design. This ensures: 1) a balanced number of participants are enrolled at each FC; and 2) that ECHO-SOL is representative not only the overall HCHS-SOL population but also the Hispanic subgroup distribution per FC in HCHS-SOL. (Table 1)

**Study Objectives**

Data suggest that the consequences and risk factor burden of HF are magnified among the Hispanic population.<sup>5,6</sup> ECHO-SOL characterizes a comprehensive list of echocardiographic parameters to determine the prevalence and correlates of abnormal cardiac structure and cardiac function (systolic and diastolic) among a Hispanic community-based cohort as well as between-group differences among Hispanics. ECHO-SOL also assesses the contributions of acculturation and sociocultural factors, such as familial and social ties (*familismo*),<sup>10</sup> to cardiac structure and function among Hispanic adults.

**Recruitment**

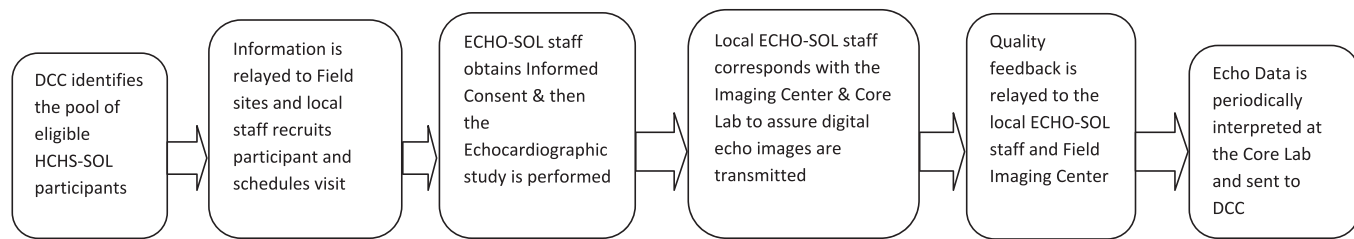
As HCHS-SOL participants completed the baseline exam, the Data Coordinating Center (University of North Carolina-Chapel Hill) identified

**Table 1. ECHO-SOL projected recruitment compared to HCHS-SOL Hispanic subgroup per field center**

	Bronx		Chicago		Miami		San Diego		All ECHO-SOL Participants		
	HCHS-SOL % <sup>a</sup>	ECHO-SOL % <sup>b</sup>	HCHS-SOL % <sup>a</sup>	ECHO-SOL % <sup>b</sup>	HCHS-SOL % <sup>a</sup>	ECHO-SOL % <sup>b</sup>	HCHS-SOL % <sup>a</sup>	ECHO-SOL % <sup>b</sup>	Proposed n's	Actual n's	%
Central / South American	14.3	15.4	29.9	0	51.8	46.2	4	0	325	330	18.1
Cuban	2.1	0	1.5	.3	96.1	100	.3	0	350	352	19.3
Mexican	2.6	0	37.4	38.5	.7	0	59.5	100	450	460	25.2
Puerto Rican	68.1	50	27.9	50	2.4	0	1.6	0	350	356	19
Dominican	93	100	1.7	0	5.1	0	.1	0	325	326	18.4
Total									1800	1824	100

<sup>a</sup> HCHS-SOL % refers to the percentage of each Hispanic subgroup in HCHS-SOL that came from the respective Field Center.

<sup>b</sup> ECHO-SOL % refers to the percentage of each Hispanic subgroup in ECHO-SOL that came from the respective Field Center.



DCC = Data Coordinating Center

**Fig 1. Recruitment, workflow and data transfer schematic DCC=data coordinating center**

participants within each Hispanic background group who met ECHO-SOL eligibility criteria and directly forwarded the participant identification number to the respective HCHS-SOL FC to initiate contact. (Figure 1) Interested participants were scheduled for a separate site visit to have the echocardiographic study conducted. Informed consent and HIPAA release was provided for each participant. Among eligible HCHS-SOL enrollees, participation in ECHO-SOL averaged ~80% across all of the FCs.

### Study Timeline, Workflow and Data Transfer

ECHO-SOL Field Imaging Centers were established utilizing existing echocardiography equipment at the respective HCHS-SOL FCs. A standard echocardiography protocol was instituted, a manual of operations was drafted, and each Field Imaging Center underwent in-person training, quality assurance and pilot testing of the ECHO-SOL study protocol. ECHO-SOL participant enrollment and echocardiogram examinations began six months into Year 1 (2011) and continued throughout Years 2 and 3, and six months into Year 4. Readings of the echocardiograms were completed on an ongoing basis.

Digital echocardiographic image files were electronically transferred from the FCs to the Wake Forest School of Medicine Echo Core Lab using a password-protected, fully encrypted, regulatory compliant image transport applica-

tion. Field Imaging Centers also sent a corresponding electronic transfer form via a dedicated ECHO-SOL email account. The transfer forms were reconciled against the listing of images received at the Core Lab. Discrepancies between the Core Lab and Field Imaging Center were addressed promptly.

### Echocardiographic Protocol

#### *Echocardiographic Procedure and Measures*

To maintain consistency, Philips Ultrasound IE-33 or Sonos 5500/7500 ultrasound imaging platform were used across all the Field Imaging Centers. Standard echocardiography examination, including M-mode, 2D imaging with harmonics optimizing depth and sector to maintain a high frame rate, spectral Doppler, color flow and tissue Doppler was performed by experienced sonographers at each Field Imaging Center as per American Society of Echocardiography (ASE) recommendations.<sup>11-15</sup> At least two full cardiac cycles were recorded for each measure. Echocardiographic measured and derived variables of interest are noted in Table 2.

Speckle-tracking strain (STS) analysis was performed offline using the TomTec Cardiac Performance Analysis<sup>®</sup> package on 2D images acquired.<sup>16</sup> Using the end-diastolic frame, endocardial and epicardial borders were traced from the apical 4- and 2-chamber views for longitudinal strain; the parasternal

short axis views at the level of the mitral valve, mid-papillary muscle and apex for circumferential strain, radial strain and torsion. The software tracks speckles along the endocardial and epicardial borders throughout the cardiac cycle generating peak longitudinal and circumferential strain and strain rate data from regional segments and an average (global) value for each view. Specific views with inadequate image quality, defined as more than one segment dropout, were not measured for STS.

#### *Training and Certification of Sonographers*

Training material and ongoing support for study sites as it pertains to the acquisition of echocardiographic data were provided.

A manual of operations focused on image acquisition covering the topics such as detailed review of the full echocardiography protocol (with illustrations), a sample timeline for image acquisition, digital image capture instructions, instructions for image transmission, answers to frequently asked questions, technical tips, and contact information.

One dedicated registered diagnostic cardiac sonographer was chosen per site for ECHO-SOL to provide consistent quality.

Sonographers participated in live in-person training at the Echo Core Lab to review the manual of operations, discuss the ultrasound control settings and any other aspects to assure high quality

**Table 2. Cardiac measured and derived variables obtained in ECHO-SOL**

Variable
Left ventricular (LV) structure
LV end diastolic volume (MOD-biplane) mL
LV mass
Left atrial diameter cm
LVOT area cm <sup>2</sup>
LVIDd cm
LVIDs cm
Relative wall thickness
End Systolic Volume (MOD-Biplane) mL
LV Geometry
Normal
Eccentric hypertrophy
Concentric hypertrophy
Concentric remodeling
Left ventricular systolic function
LV ejection fraction (MOD-biplane) %
Stroke volume (LVOT) mL
LVOT VTI cm
Cardiac output
Left ventricular regional wall motion abnormality
Left ventricular diastolic function
Peak E/A ratio
E/e' ratio (average Septal & Lateral)
E/e' Lateral Ratio
E/e' Septal Ratio
Left Atrial Volume (MOD-Biplane) mL
Med Peak a' Vel cm/sec
Med Peak e' Vel cm/sec
Med Peak S Vel cm/sec
Lateral Peak a' Vel cm/sec
Lateral Peak e' Vel cm/sec
Lateral Peak S Vel cm/sec
MV A max vel cm/sec
MV E max vel cm/sec
MV dec time sec
PV A Revs Vel cm/sec
PV A Revs Dur sec
PV Dias Vel cm/sec
PV Sys Vel cm/sec
LV IVRT sec
Diastolic dysfunction
Normal
Grade I
Grade II
Grade III
Right ventricular (RV) parameters
RV end-diastolic area
RV fractional area change
Tricuspid Annular Plane Systolic Excursion (TAPSE) cm
TR max velocity
RV Area diastolic ap4 cm <sup>2</sup>
RV Area systolic ap4 cm <sup>2</sup>
RVOT area cm <sup>2</sup>
RV Peak S Vel cm/sec
Stroke Volume (RVOT) mL
RV V1 VTI cm

**Table 2. Continued**

Variable
Valvular assessments
Mitral regurgitation
Aortic regurgitation
Tricuspid regurgitation
Pulmonic regurgitation
Aortic valve area
Mean aortic valve gradient
Peak aortic valve gradient
Mitral annulus calcification
Mitral valve prolapse
Aortic valve calcification
Speckle-tracking analysis
Global longitudinal strain
Global circumferential strain
Global radial strain
Torsion
Other measures
Aortic root diameter
Pericardial effusion
Systolic BP mm Hg

image data acquisition. All sonographers performed the complete imaging protocol twice on volunteers while under supervision.

Site initiation (test cases) were performed at each Field Imaging Center, reviewed and approved by the Core Lab prior to participant enrollment. Each test case demonstrated the ability of the sonographer to acquire and properly archive all of the echocardiographic information required.

*Echocardiography Reading Center - Data Analysis*

Measurements for all M-mode, 2D and Doppler images were performed using Xcelera (Philips Healthcare). ASE standards were used for guiding all measurement conventions.<sup>12,13,17</sup> After each digital study was logged in by the Core Lab study coordinator, the images were made available to the Core Lab readers. Interpretation of echocardiographic studies was performed by an experienced echocardiographic technician (RD) blinded to the subject's clinical and demographic characteristics. If an urgent cardiac abnormality was

found, FC staff was contacted and the participant was called within 24 hours to discuss the results.

*Over-reading*

All echocardiographic studies were over-read by a cardiologist (CJR) with COCATS level 3 advanced training in Echocardiography and ASE Board Certification in Comprehensive Adult Echocardiography. Over-reading consisted of an overall review of each study for clinically important findings and assessment of accuracy of key quantitative measurements made by technicians. Each echocardiographic study was approved and finalized by the over-reader before study data were transferred to the HCHS-SOL Data Coordinating Center.

*Quality Assurance / Control*

Study image quality was based on various factors including completeness of the study protocol, the ability to visualize the endocardium, adequacy of ECG gating, clarity of Doppler signals, adequacy of depth and scale optimization of images. Sites with persistent deficiencies were contacted to review the study protocol and were offered technical assistance if needed.

Ongoing quality control was accomplished by: 1) rapid review (same day of study receipt) for completeness and adequacy of images with immediate feedback (both positive and negative) to each Field Imaging Center; and 2) detailed review (day of study interpretation) using a quantitative 40-point technical item quality checklist (≥90% of technical quality checklist items were required for the study to be graded as acceptable). Qualitative assessment studies were graded as excellent, if all technical items met and visual quality was superb; good, if all technical items were met and visual quality were good; fair, if ≥90% of technical items were met or all measurements were attained but visual quality was fair; and poor, if ≤90% of technical items were met and/or any primary study measurement was

**Table 3. Quality control inter-reader<sup>a</sup> variability breakdown (n=56)**

Measure	ICC <sup>b</sup>	TEM Relative <sup>c</sup>	Pearson	P Pearson
EDV2	.97844	3.6507	.97897	1.80E-12
EDV4	.97018	5.1355	.9708	2.43E-11
ESV2	.97209	5.6769	.97298	1.31E-11
ESV4	.96442	6.1972	.96554	8.98E-11
IVSD	.79735	10.4784	.80053	.000065959
LADIM	.97038	2.6329	.971	4.29E-10
LAV2	.99019	7.5035	.99067	2.80E-15
LAV4	.98998	5.1651	.9905	3.25E-15
LVIDD	.96245	2.3635	.96279	1.65E-10
LVPWD	.88813	7.4347	.89616	.000000488

<sup>a</sup> Intra-reader values were slightly better than inter-reader values for all measures.

<sup>b</sup> Intraclass correlation (ICC) is interpreted as follows: .3-.4 indicates poor agreement; .5-.6 indicates fair agreement; .7-.8 indicates moderate agreement; and >.8 indicates strong agreement.

<sup>c</sup> Relative technical error of measurement or TEM Relative (standardized measurement variability) is interpreted as follows: Agreement between readings was defined as differences of  $\leq 10\%$ ; borderline agreement as differences of 11-15%; and disagreement as differences  $>15\%$ .

not attainable. We attempted to extract as much information from the M-mode, 2D, spectral/color/tissue Doppler, and speckle tracking moduli, all of which may vary in quality even within a sub-optimal or poor study. Only 4.8% of ECHO-SOL studies were deemed to be of poor quality and  $\leq 2\%$  of all studies were missing primary study measures.

Inter- and intra-observer variability was assessed by use of intra-class correlation coefficients. (Table 3) A 5% random sample of studies were reread by the same reader (RD) and an experienced echocardiographer (CJR) on a quarterly basis. Re-reads were performed in a blinded fashion. If significant variability was identified, studies were reviewed by a consensus of all readers to identify sources of error and reconcile differences. Temporal variability was assessed using blinded sequential reference measurements of the same set of echo studies at three time points (baseline, 12, and 24 months) showing reliably low temporal variability (ICCs for LVM=.96; LVEF=.92) correlating with minimal change and excellent test-retest variability.

## DISCUSSION

We have designed what is currently the largest population community-based

epidemiologic study of cardiac structure and function focused on US Hispanics. By their sheer numbers, US Hispanics greatly impact the health care system. Hence, a study that helps us learn more about Hispanic cardiovascular health and understand how better to treat this population is potentially very important. As the Hispanic population grows, increasing numbers of individuals who migrated to the United States from the countries of Latin America will undergo changes in health behaviors and life-stress trajectories through the acculturative process with the potential for a significant impact on their cardiovascular health and disease. Given the relative paucity of information about HF risk among Hispanics, the medical and societal implication of the HF pandemic and

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the increasing size of the US Hispanic population, a study like ECHO-SOL is essential to help direct/inform preventive cardiovascular care in this important segment of the population.

ECHO-SOL is unique because unlike prior studies of Hispanics, this study addresses adequate representation of all Hispanic background groups. This feature of representativeness is especially important given the controversial concept of the 'Hispanic paradox,' which refers to the putative low risk of cardiovascular mortality and all-cause mortality among US Hispanics despite their low socioeconomic status, poor access to health care and high burden of unfavorable cardiovascular risk factors.<sup>18,19</sup> In this regard, Hispanics are often erroneously viewed as a monolithic, homogenous group with little research available elucidating subgroup differences. Thus, not only are Hispanics under-represented in HF and echocardiographic clinical trials and epidemiologic studies, but when included they are typically analyzed as one group despite potentially important differences among subpopulations defined by place of birth, national background and genetic ancestry. For example, in certain subgroups, Hispanics carry a higher burden of diabetes, hypertension, and West African ancestry, which can potentially affect cardiac structure and function.<sup>20</sup> A population-based estimate of abnormal cardiac structure function on Hispanics has not been performed previously and is being achieved in ECHO-SOL to provide insights into the epidemiology and etiologic factors affecting Hispanic cardiovascular health and thus, will be highly relevant to future public health planning.

## LIMITATIONS

There are some limitations to ECHO-SOL. First, cardiac MRI, a standard for quantification of cardiac structural parameters, is not being used. However, compared to echocardiography, cardiac MRI remains problematic

(due to patient claustrophobia), and contra-indications (pacemakers, defibrillators, or recent coronary stents), making it less feasible for ~20%–25% of participants in population-based studies. Second, echocardiographic studies were not performed simultaneously with other HCHS-SOL data. To alleviate this, all efforts were made to keep the time interval between baseline HCHS-SOL measurements and echocardiographic assessments as negligible as possible; additionally, key covariates (hypertension, diabetes, medications) are being ascertained and updated using available information from the most recent HCHS-SOL annual follow-up assessment.

## CONCLUSIONS

Comprehensive echocardiography in this well-phenotyped, representative population-based cohort of Hispanics will offer some of the first population-based prevalence estimates of abnormal systolic and diastolic cardiac function among Hispanic adults as well as untangle the relative importance of Hispanic heterogeneity and ascertain contributions of diabetes biomarkers and sociocultural factors on cardiac structure and function among Hispanic adults. This comprehensive cardiovascular assessment is necessary to: 1) identify Hispanics as a group with a high prevalence of abnormal cardiac structure and function that could be targeted for prevention of clinical HF; 2) emphasize Hispanic subgroup identification as relevant with regard to cardiovascular risk assessment; and 3) provide linkage of sociocultural factors, such as acculturation with abnormal cardiac structure and function in this critically understudied populations.

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