TU CORAZON Y MI PASION

by

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ABSTRACT

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Background: Coronary heart disease (CHD) continues to be a major public health problem and is the leading cause of death in the United States (US). The estimated cost of cardiovascular disease (CVD) and stroke in the US for 2007 was 431.8 billion dollars. CVD, including CHD and stroke, claims the lives of approximately 500,000 women a year, making it the number one killer of women in the United States and exceeds the number of deaths in men and the next 7 causes of death in women combined.

Review of Literature: Few studies have been completed evaluating atherosclerosis, non-invasive cardiovascular testing, ethnic minorities and women. Despite the increased prevalence of cardiovascular risk factors and increased mortality in women, there are few studies that evaluate women and cardiovascular risk factors and interventions for heart disease among women.

Methods and Design: A descriptive study design is the research design for this study. Eighty-four pre-menopausal Hispanic between the ages of 25 -45 completed coronary computed tomography angiography (CTA) to assess for presence of soft and hard atherosclerosis. The four

outcomes measures evaluated were coronary plaque accumulation, cholesterol components, body mass measurement and waist circumference.

Results: Coronary CTA was normal for 83 women. In only one case, coronary CTA revealed a non-obstructive <20% soft plaque accumulation in the proximal left anterior descending artery. Fifty percent of these women had undesirable low-density lipoproteins (LDL) and high-density lipoproteins (HDL) levels that should be treated but only 6% were on treatment for dyslipidemia. Fifty six percent of the women had BMIs $\geq$ 24.9 with some form of dyslipidemia. Eighty one percent of the women had waist circumferences $\geq$ 35 inches. Even though only one woman demonstrated a non-obstructive coronary plaque, 70% of these women had a metabolic syndrome (MS) which is manifested by 3 of 5 CVD risk factors: hypertension, elevated glucose levels, hypertriglyceridemia, HDL <50 mg/dL and an increased abdominal girth.

Summary: Despite having at least 3 CVD risk factors, one pre-menopausal Hispanic woman had coronary plaque. Seventy percent of woman had MS suggesting these women have a trajectory toward the development of coronary plaque formation and CVD in the future.

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INTRODUCTION

Coronary heart disease (CHD) continues to be a major public health problem and is the leading cause of death in the United States (US). The estimated cost of cardiovascular disease (CVD) and stroke in the US for 2007 was 431.8 billion dollars. The prevalence of CHD continues to increase as statistics for 2004 demonstrated that among adults age 20 and older, 8,500,000 males and 7,200,000 females had CHD (Rosamond et al., 2007). CVD, including CHD and stroke, claims the lives of approximately 500,000 women a year, making it the number one killer of women in the United States and exceeds the number of deaths in men and the next seven causes of death in women combined. Twenty five percent of men will die within one year of a coronary event, which is contrasted to the 38% of women who will die from the same type of event. McSweeney (2004) asserts that little is known about recognized prodromal and acute symptoms of CHD in women, which results in nearly two thirds of women who die of a myocardial infarction without any recognized symptoms.

The significance and nature of the problem is enormous for all women. One in four women will die of some form of CVD (http://www.nih.gov/news/pr/feb2007/nhlbi-01.htm). According to the 2007 American Heart Association's Heart Disease and Stroke Statistics, since 1984, the number of CVD deaths for females has exceeded those of males with females representing 52.9 % of deaths from CVD in 2004. In 2004, all CVD combined claimed the lives of 461,152 females while all forms of cancer combined killed 265,013 females (Rosamond et al., 2007). The prevalence of CVD for 2004, according to the American Heart Association (AHA), was 79.4 million men and 42.1 million women. Of the 42.1 million women, 35% were Caucasian, 49% were black and 34.4% were Mexican American or Latinas. According to the National Vital Statistics Report for leading causes of death in 2004, diseases of the heart were the number one

cause of deaths in the Hispanic population (http://www.cdc.gov/nchs/data/nvsr/nvsr56/nvsr56_05.pdf).

In 2003, according to an AHA sponsored study, 46% of the respondents to a standard interviewer-assisted questionnaire spontaneously identified heart disease as the leading cause of death among women (Mosca et al., 2004). An updated 2006 AHA survey revealed that 57% of women identified heart disease as the leading cause of death in women. However, awareness among African American women and Hispanic women was lower than among Caucasian women, 31% and 29% vs. 68%, respectively (Christian et al., 2007). Lack of awareness among Hispanic women is especially concerning since recent evidence suggests that being Hispanic may be an independent risk factor for heart disease (http://www.theheart.org/article/773797.do).

As shown in Table 1, little data are available with regard to mortality of Mexican Americans/Hispanics and coronary heart disease. The absence of this information provides additional relative risk to the Hispanic population, more specifically women, because the scope of the problem has not been measured. If there is a problem, it needs to be measured in order to appropriately address the issues and provide adequate solutions.

While Caucasian and African American women have a slightly higher prevalence of CHD in comparison to Mexican American women, African American and Mexican American women have a slightly higher prevalence of myocardial infarction (MI) in comparison to the Caucasian women, as identified in Table 2. The prevalence of CHD in white women was 6%, black women 8% and 5 % of Mexican American women.

Table 1. Women and Cardiovascular Diseases in 2007, Prevalence and Mortality

Diseases and Risk Factors	Both Sexes	Total Females	White Females	Black Females	Mexican American Females
CVD Prevalence 2004	79.4M (37.1%)	42.1M (36.6)	35.0%	49.0%	34.4%
CVD Mortality 2004	871.5K	461.2K	398.8K	53.5K	Data not available

Table 1. – *Continued*

HTN Prevalence 2004	72.0M (33.6%)	39.0M	31.9%	46.6%	31.4%
HTN Mortality 2004	54.2K	31.4K	24.1K	6.6K	Data not available
Tobacco Prevalence 2004	46.0M (20.9%)	20.9M (18.5%)	20.4%	17.2%	10.9%
Cholesterol ≥ 200 mg/dL	105.2M (48.4%)	55.2M (48.6)	49.7%	42.1%	50.0%
Cholesterol ≥240 mg/dL	36.6M (16.8%)	19.7M (17.1%)	18.2%	12.5%	14.2%
LDL Cholesterol ≥130mg/dL	79.3M (32.5%)	38.6M (32.4%)	33.8%	29.8%	30.7%
HDL Cholesterol <40mg/dL	44.1M (16.7%)	12.3M (9.1%)	8.8%	6.9%	13.0%
Physical Activity 2004	30.1%	29.0%	31.8%	19.6%	21.8%
Overweight BMI 25 or >	140.0M (66.0%)	68M (61.6)	57.6%	79.6%	73.0%
Obesity BMI 30 or >	66M (31.4%)	36.0M 33.2%	30.7%	51.1%	39.4%

M= million K= thousand

http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideText.pdf

Table 2. Summary of Coronary Heart Disease in Women

2004	White	Black	Mexican American
Prevalence CHD	6 %	8%	5 %
Prevalence of MI	3 %	3 %	2 %
New and recurrent CHD	425K	60K	No data available
Mortality CHD	191K	24K	No data available
Mortality MI	65K	8K	No data available

http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideText.pdf

Problem

As the Hispanic or Latino community in the United States increases, one may assume that there will be an increased growth of CHD in this population. This community has the same treatable risk factors for development of CHD as other populations, but they may also have

cultural influences that can increase their likelihood of developing CHD. Factors such as acculturation, access to care, lower socioeconomic levels and lower educational achievements also contribute to the prevalence of CHD in this population (Smith, Risser, Lisabeth, Moye & Morgenstern, 2003).

Because there have been few studies in the literature specifically describing the relationships of CHD and women, especially Hispanic women (HW) and CHD, this study examined the relationships between etiology and pathophysiology associated with the development of CHD in HW. Because coronary artery calcification is, absent in a normal vessel wall, adherence to practice guidelines, such as those provided by the National Cholesterol Education Program - Adult Treatment Panel III (NCEP), is imperative, as it is coronary artery calcification and cholesterol plaque buildup that lead to atherosclerosis and CHD. Early detection of coronary artery calcification, plaque accumulation and CHD is important for all of those at risk for CHD. Screening such as stress testing or evaluating for coronary calcium are two testing modalities that can assess for coronary plaque accumulation. Early detection is especially important for women who tend to experience sudden myocardial death in the absence of prodromal symptoms (McSweeney, O'Sullivan, Cody & Crane, 2004).

To prevent and/or slow the process of coronary plaque formation requires some form of lipid control. Prevention of dyslipidemia is the key to decreasing the potential of plaque formation. Lipid control can be achieved through such lifestyle modifications as diet, exercise and weight loss or through pharmacologic intervention. Early detection of coronary artery plaque accumulation may well be the best health promotion strategy for those at risk for CHD. Health promotion and education include educational booklets, informative commercials, information classes and healthcare provider teaching and guidance. For example, education and screening have markedly reduced the number of deaths from breast cancer (http://www.ahrq.gov/clinic/3rduspstf/breastcancer/brcanrr.htm). Similar strategies are needed to reduce death from CHD among women. CHD affects many women, but little is known about the presence of plaque in the coronary arteries of pre-menopausal women. This study begins to

provide the information that healthcare providers need to determine if the established guidelines are appropriate to women, especially Hispanic women. Such studies are needed to begin to develop the interventions needed to reduce CVD among women.

Framework

The framework for this study is presented in Figure 1. It depicts the concepts that contribute to the etiology and development of CHD. Elevated cholesterol levels and obesity are contributing factors to the etiology and pathophysiology of coronary plaque formation leading to the development of CHD. In addition, other treatable factors such as hypertension (HTN), diabetes, tobacco use, waist size and physical inactivity, coupled with elevated cholesterol panels and obesity, can contribute to the development of CHD as noted by Mosca et al. (2007) in the evidence-based guidelines for CVD prevention in women. Elements such as age, gender, genetic predisposition and ethnicity are non-treatable factors that may contribute to the development of CHD. This framework is not unique to any specific population. These contributing factors for CHD are recognized by the AHA and are applicable to all people but are based on men. In this study, the framework was utilized to evaluate the development of CHD in Hispanic women.

Pathophysiology of Coronary Plaque Formation and Development of CHD

Arteriosclerosis is a chronic disease of the arterial system characterized by abnormal thickening and hardening of the vessel walls. The prefix *athero*, from the Greek athere, or mush, was selected "to designate the amorphous lipid accumulation in the intima which is the hallmark of the developed lesion" (Sabine, 1977, p. 247). Atherosclerosis is a form of arteriosclerosis, which involves the thickening, hardening and calcification of the vessel walls, which is the development of plaque. This process is caused by soft deposits of fat and fibrin that harden and calcify over time and adhere to the lining of the arterial wall, which eventually can lead to an occlusive process (Naghavi et al, 2003). The structure of the arterial wall is classified into two categories: elastic or muscular. Arteries such as the aortic artery, carotid arteries and iliac arteries are considered to be elastic arteries and have no auto-regulatory control of the diameter

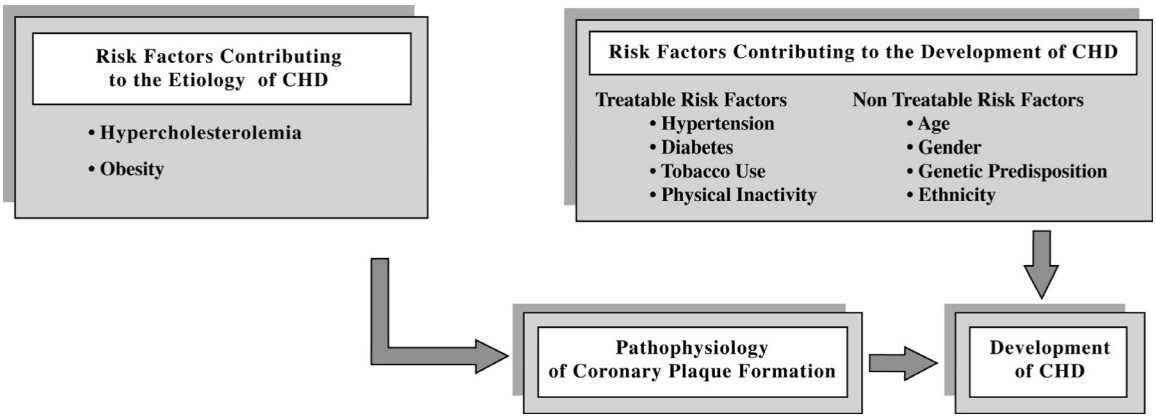


Figure 1. Framework for Development of CHD

of conductance vessel by smooth muscle. These large peripheral vessels serve as channels leading from the heart. Coronary, brachial, radial and femoral arteries are medium sized muscular arteries that contain more smooth muscle than the elastic arteries. As a result, these muscular arteries are able to change in diameter and regulate blood flow in response to end-organ need (Murphy, 1997). Within these arterial walls are four layers: the endothelium, intima, media and adventitia. The lesion of atherosclerosis, or atheroma, and atherosclerotic plaque usually occur within the intima. Initially, a fatty streak, the earliest lesion of atherosclerosis demonstrated as a flat, yellow, and lipid filled smooth muscle cell causes no obstruction. This fatty streak is present in all ages and is often found in the aorta of children older than 1 year (McCance & Huether, 1994). As the aging process continues, late atherosclerotic plaque develops an increasing amount of fibrous tissue and becomes fibrous plaque (Naghavi et al, 2003). However, fibrous plaque is rarely found in people younger than 25 years of age (McCance & Huether, 1994). The fibrous plaque consists of lipid laden smooth muscle cells surrounded by collagen, elastic fibers and a mucoprotein matrix. As the lesion develops, it can protrude into the lumen of the artery, and a fibrous cap can form. This development of a fibrous cap, soft plaque or vulnerable plaque, is potentially dangerous because if it ruptures in the coronary artery, this process can expose the surface and a coronary thrombus results. This coronary thrombus is platelet rich, which can precipitate a total or subtotal occlusion of the artery resulting in a

myocardial infarction or acute coronary syndrome (Naghavi et al 2003; Libby & Theroux, 2005). If the plaque formation remains stable, atherosclerotic lesions generally cause no symptoms until 60% or more of the tissue's blood supply is occluded (Redberg et al., 2004). A person with such an occlusion can experience exertional or non-exertional angina, jaw pain, dyspnea, diaphoresis, or fatigue. Lipids play a direct role in plaque formation and are the culprit for CHD. Figure 2 demonstrates the stages of vulnerable plaque formation and how lipids play an important role in the formation of plaque, which can lead to an occlusive disease process. Figure 3 demonstrates the stages of plaque formation and identifies the type of testing that can detect the plaque at various stages. Computed tomography angiography is the only testing modality that identifies plaque in the very early stages of the disease process.

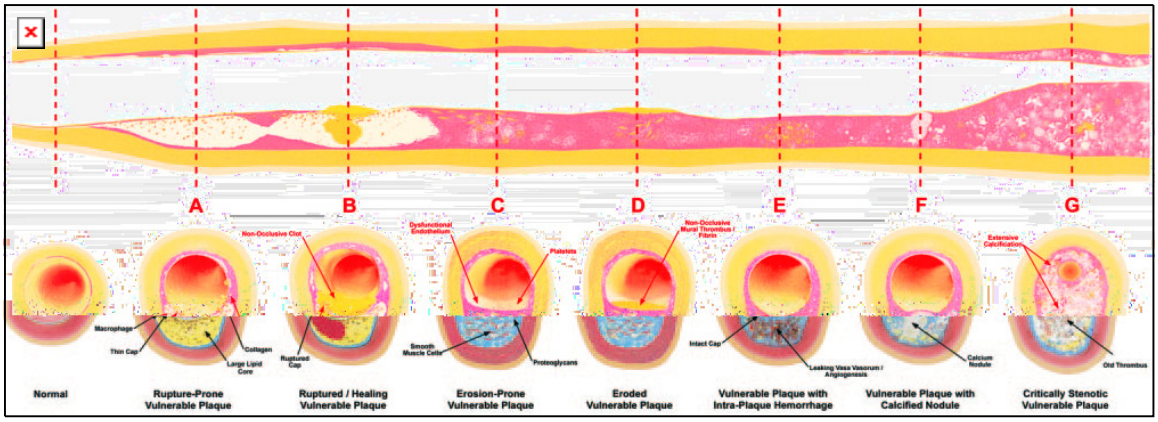


Figure 2. Stages of Vulnerable Plaque

Different types of vulnerable plaque as underlying cause of acute coronary events (ACS) and sudden cardiac death (SCD). A, Rupture-prone plaque with large lipid core and thin fibrous cap infiltrated by macrophages. B. Ruptured plaque with subocclusive thrombus and early organization. C, Erosion-prone plaque with proteoglycan matrix in a smooth muscle cell-rich plaque. D. Eroded plaque with subocclusive thrombus. E. Intraplaque hemorrhage secondary to leaking vasa vasorum. F. Calcific nodule protruding into the vessel lumen. G. Chronically stenotic plaque with severe calcification, old thrombus, and eccentric lumen.
Naghavi et al., 2003, Circulation, 108 (15), p. 1666.

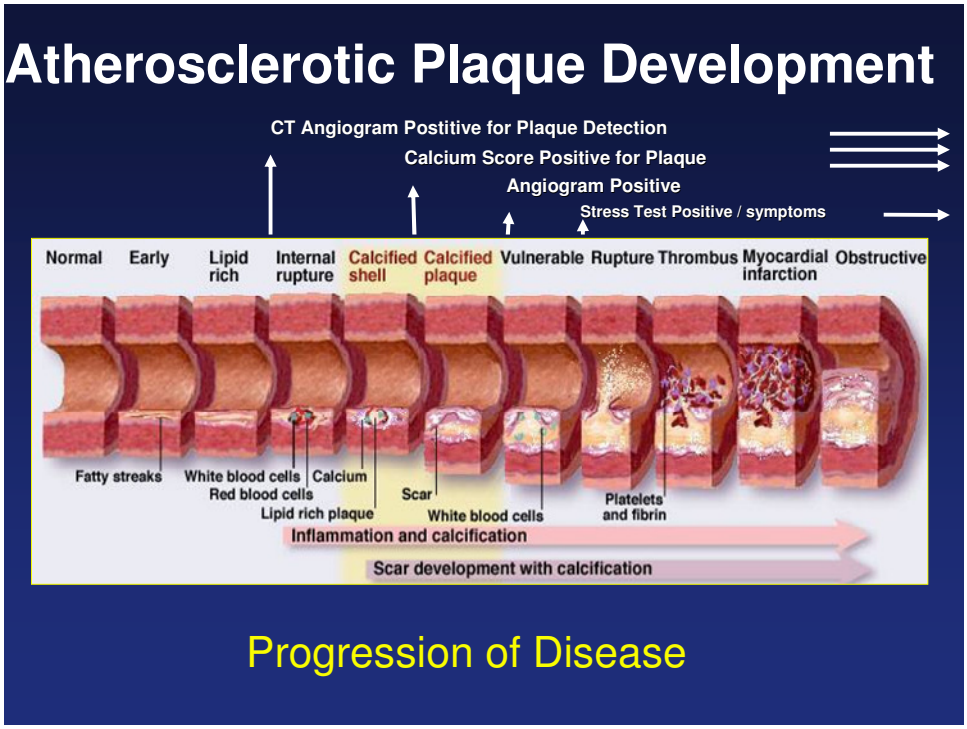


Figure 3. Atherosclerotic Plaque Development and Progression of Disease From John Osborne, M.D., personal communication, July 2008.

Etiology of Coronary Heart Disease

Etiology is defined as the set of factors that contributes to the occurrence of a disease. As identified in the literature and by the American Heart Association (AHA) (www.americanheart.org, 2007), certain risk factors contribute to the development of CHD (see Figure 1). The treatable risk factors include hypercholesterolemia, obesity, HTN, diabetes, tobacco use, and physical inactivity. Non-treatable risk factors include age, gender, genetic predisposition and ethnicity. These non-treatable risk factors cannot be modified. Cultural influences such as types of food, exercise regimens, and resource availability are factors that may contribute to the development and progression of plaque burden. Each ethnic group may have non-treatable risk factors specific to their population, which may contribute to an increased prevalence of CHD in their group.

Treatable Risk Factors

Hypercholesterolemia

As noted on Table 1, cholesterol levels greater than 200mg/dL affect almost 50% of Caucasian and Mexican American women and 42% of African American women. Cholesterol levels greater than 240mg/dL occur in 18% of Caucasian women, 14% of Mexican American women and 12% of African American. There is not much difference in the ranges of the low-density lipoproteins (LDL) among the groups of women. However, there was a slight difference with regard to the high-density lipoproteins (HDL) with 13% of Mexican American women having an HDL less than 40mg/dL. An HDL greater than 40 mg/dL is desired because a high HDL adds a cardio-protective measure. Accepted cholesterol levels (see Table 3) are identified by the Third Report of the National Education Program (NCEP) expert panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (ATP III). ATP III guidelines also suggest that triglyceride levels should be lower than 150 mg/dL.

ATP III guidelines suggest that lifestyle modifications such as regular exercise and a diet low in saturated fats can assist in decreasing total cholesterol below 200 mg/dL and LDL levels below 160 mg/dL. According to the guidelines, if a person has one cardiovascular risk factor, the accepted LDL goal is less than 160mg/dL. If a person has two cardiovascular risk factors, the LDL goal is less than 130 mg/dL. If a person has CVD, the LDL goal is less than 100. The risk factors of concern are cigarette smoking, HTN, HDL < 40 mg/dL, family history for CHD and age (men $\geq$ 45 years, women $\geq$ 55 years).
(http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.pdf).

Table 3. ATP III Classification of LDL, Total, and HDL Cholesterol (mg/dL)

• Total Cholesterol

<200	Desirable
200-239	Borderline High
240	High

• LDL Cholesterol - Primary Target of Therapy

<100	Optimal
100-129	Near Optimal/Above Optimal
130-159	Borderline High
160-189	High
190	Very high

• HDL Cholesterol

<40	Low
60	High

http://www.nhlbi.nih.gov/guidelines/cholesterol/atglance.htm

HDL offers cardio-protective measures while the non-HDL level is a stronger predictor of CHD (Liu et al, 2006). Exercise can increase the HDL level to a certain extent. Pharmacologic intervention may be required to raise the HDL if exercise does not significantly increase the level to the acceptable guideline range.

The guidelines for prevention of CVD in women suggest women should be encouraged through lifestyle modifications to achieve an LDL < 100mg/dL, HDL >50mg/dL, and triglycerides <150mg/dL. If a woman is unable to achieve these goals with lifestyle modifications, pharmacologic intervention with statins, fibrates or niacin is suggested (Mosca et al., 2007).

Obesity

The National Heart, Lung and Blood Institute (NHLBI), in cooperation with the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), released the first Federal guidelines on the identification, evaluation, and treatment of overweight and obesity. A person classified as overweight, obese or extremely obese can initiate lifestyle modifications such as

decreasing caloric intake and exercising to assist in the reduction of weight. However, in extreme cases such as being classified as extremely obese, pharmacologic and surgical interventions may be required (http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf). A body mass index (BMI) greater than 30 is considered obese. Mosca et al. (2007), and the guidelines for prevention of CVD in women, suggest that a woman should maintain a BMI between 18.5 and 24.9 kg/m2 and a waist circumference of $\leq$ 35 inches. An enlarged waist circumference of $\geq$ 35 inches is a primary risk factor for CVD and Type 2 diabetes in women (Appel & Bannon, 2007). Waist circumference has been endorsed as the best anthropometric surrogate of abdominal adiposity (Ross, Shaw, Martel & Avruch, 1993: Rexrode et al., 1998). Table 4 illustrates the BMI classification in determining obesity (http://www.consumer.gov/weightloss/bmi.htm). According to the U.S. Department of Health & Human Services Centers for Disease Control Prevention, obesity, in the U.S., doubled from 1976-1980 to 2001-2004 with obesity in the total population jumping from 15% to 32%. For women, the rates jumped from 17% to 34% and for men, 12% to 30% (www.cdc.gov/nchs/data/hus/hus06.pdf). According to Table 1, in 2004, 73% of Mexican American women were overweight and had a BMI of 25 or greater. Approximately 39% of Mexican American women were obese with a BMI of 30 or greater.

Table 4. BMI Classification

BMI	
18.5 or less	Underweight
18.5 - 24.9	Normal
25.0 - 29.9	Overweight
30.0 - 39.9	Obese
40 or greater	Extremely Obese

Hypertension

The diagnosis of HTN is defined by the Seventh Report of The Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure (JNC VII). As shown in Table 1, Mexican American and Caucasian women have lower prevalence rates for

HTN than do African American women. Table 1 also demonstrates that there are no data available on the mortality of Mexican American women due to HTN. Table 5 shows the classifications for diagnosing HTN according to the JNC VII guidelines (http://www.nhlbi.nih.gov/guidelines/hypertension/express.pdf). According to these guidelines, if a person's blood pressure is categorized in the pre-HTN stage, lifestyle modifications such as weight loss, exercise and eating a low sodium diet are suggested in an effort to reduce the blood pressure to a normal range. If a person's blood pressure is categorized in Stage I HTN, the person is also encouraged to have lifestyle modifications, in addition to instituting an anti-hypertensive medication for blood pressure control. A person in Stage II HTN may require two or more anti-hypertensive medications, in addition to lifestyle modifications, for blood pressure control. According to the guidelines for women and the prevention of CVD, women are encouraged to have an optimal blood pressure of <120/80 mmHg. This goal can be achieved through lifestyle modifications such as weight control, physical activity, alcohol moderation, low dietary fats, and increased consumption of fresh fruits, vegetables, and sodium restriction.

Table 5. JNC VII Classification of HTN

Blood Pressure Classification	Systolic Blood Pressure	Diastolic Blood Pressure
Normal	< 120 mmHg	And < 80 mmHg
Pre-HTN	120-139 mmHg	Or 80-89 mmHg
Stage I HTN	140-159 mmHg	90-99 mmHg
Stage II HTN	≥ 160	Or > 100 mmHg

Diabetes

Diabetes was not included in Table I, but it is an important treatable risk factor for CVD. Diabetes is diagnosed by the guidelines established by the National Institute of Diabetes and Digestive and Kidney Disease and American Diabetes Association (see Table 6) (http://diabetes.niddk.nih.gov/dm/pubs/diagnosis). At the pre-diabetes stage, clinicians

recommend lifestyle modifications such as weight loss, exercise and carbohydrate food intake reduction to avoid the development of diabetes. If diabetes develops, oral anti-glycemic agents are initiated for better glycemic control. If necessary, insulin is required for glycemic control. According to the National Diabetes Surveillance System, the Centers for Disease Control (CDC) demonstrated that among Hispanics, the age adjusted prevalence of diabetes among females increased 21% from 1997 through 2005 (http://www.cdc.gov/diabetes/statistics/prev/national/figraceethsex.htm). Mosca et al. (2007) suggest an optimal HgbA1C level of < 7%.

Table 6. American Diabetes Association and National Institute of Diabetes and Digestive and Kidney Disease Diagnosis Guidelines Fasting Plasma Glucose Test

Plasma Glucose Result (mg/dL)	Diagnosis
99 and below	Normal
100 to 125	Pre-diabetes (impaired fasting glucose)
126 and above	Diabetes

Tobacco Use

Statistics, from the CDC, from 1990-1992 and 2002-2004 found that smoking in men dropped from 28% to 24% and in women from 24% to 20% (www.cdc.gov/nchs/data/hus/hus06.pdf). Table 1 identifies that almost 11% of Mexican American women smoke, in comparison to 20% of Caucasian women and 17% of African American women. Smoking can increase the risk for CVD by raising blood pressure and decreasing the HDL, which decreases cardio-protective measures of the arteries (http://www.americanheart.org/presenter.jhtml?identifier=3048036). According to the AHA guidelines for women and prevention of CVD, women should not smoke (Mosca et al., 2007). In addition, the National Cancer Institute promotes a smoke free environment (http://www.cancer.gov/cancertopics/types/lung).

Physical Inactivity

The National Heart, Lung and Blood Institute (NHLBI) and the AHA promote guidelines for physical activity. Regular leisure-time activity is defined as 3 or more sessions of vigorous activity per week lasting 20 minutes or 5 or more sessions a week lasting at least 30 minutes. Mosca et al. (2007) suggest women should accumulate a minimum of 30 minutes of moderate intensity physical activity most days of the week according to the evidence-based guidelines for CVD prevention in women. In 2004, regular leisure-time activity among females was 31% for Caucasians, 23% for African Americans, and 22% for Hispanics (www.cdc.gov/nchs/data/hus/hus06.pdf). According to the statistics on Table 1, only 22% of Mexican American women engage in physical activity, in comparison to the 32% of Caucasian women and 20% of African American women. Regular leisure-time physical activity is defined as light–moderate activity for ≥30 minutes, ≥5 times per week; or vigorous activity for ≥ 20 minutes, ≥ 3 times per week. (http://www.americanheart.org/downloadable/heart/1166712318459HS_StatsInsideText pdf). Exercise is an important element to lifestyle modification and cardiovascular risk reduction because it facilitates the expenditure of excess calories, decreases blood pressure, lowers LDL cholesterol, raises the HDL, and assists with glycemic control, all of which add to healthy heart living.

Non-treatable Risk Factors

Gender, age and genetic predisposition are three non-treatable, contributing factors and cannot be modified. At this point, their significance and prevalence has not yet been properly assessed (www.americanheart.org). More than half of all cardiovascular events in men and women under the age of 75 are associated with CHD.

According to the Centers for National Health, CHD rates in women after menopause are 2 to 3 times those of women the same age before menopause (CDC 2007).

Heart disease risk is also higher among Mexican Americans, American Indians, native Hawaiians and some Asian Americans, which may be associated with higher rates of obesity and

diabetes. Most people with a strong family history of heart disease have one or more other risk factors (www.americanheart.org). Family history for premature CVD, CVD at less than 55 years of age in a male relative and less than 65 years of age in a female relative, is considered to be 'at risk' on the risk status scale for classification of CVD in women (Mosca et al., 2007). Interestingly, a small study of Hispanic men and women that evaluated predictors of adverse events after percutaneous transluminal coronary angioplasty found that residual stenosis of 50% or greater and family history for CVD may be additional risks for future adverse events (Padilla, 2001).

Purpose

CHD rates in women after menopause are 2 to 3 times those of women the same age before menopause. Women who have had treatable CVD risk factors such as HTN, hyperlipidemia, obesity, increased abdominal girth, and diabetes during their pre-menopausal years can change their increased risk for developing CVD by lifestyle modifications and medications, and achieving national guideline standards for HTN, hypercholesterolemia, and diabetes. It seems logical that the incidence of CVD would decrease if these preventative measures were taken to decrease the lifetime risk for CVD development, helping reduce the prevalence of CVD. However, at this point, scientists and researchers have not determined the exact roles and influences of female hormones and menopause on CVD. If women at risk for developing CVD were all treated to national guidelines for treatable risk factors, would they still develop CVD even during the menopause stage? Can the hormones really alter the arterial state in the setting of a non-diabetic, normotensive, normal weight female with a normal cholesterol panel?

Sensitive cardiac testing now demonstrates how CVD develops in early stages of the life cycles (See Figure 3). New technologies permit non-invasive evaluation of coronary artery plaque accumulation. One such new technology is the multi-slice Computed Tomography Angiography (CTA). Kortelainen and Huttunen (2004) completed forensic autopsies on 52 pre-menopausal women between the ages of 18-49 years of age. Findings indicated that pre-

menopausal women with increased central body fat accumulation, enlarged waist, had advanced coronary lesions in the left anterior descending artery (LAD). In this study, CTA was used to assess the relationship among plaque formation, lipid levels, BMI and waist circumference. In an effort to determine the prevalence of CHD in pre-menopausal Hispanic women (PMHW) between the ages of 25 -45, the assessment of coronary plaque through a noninvasive visualization tool will allow for better understanding of the development of CHD in this age group and help to inform prevention and treatment plans for CHD. Because there is a small amount of research available in this particular population, an understanding of the relationships between lipid levels, obesity and coronary plaque accumulation serves as the first step in devising interventions that may help reduce the incidence of sudden cardiac death among Hispanic women.

Research Questions

The specific research questions that guided this study were:

1. What is the relationship between plaque burden, cholesterol levels, BMIs and waist circumference among pre-menopausal Hispanic women?
2. To what extent are these relationships influenced by treatable risk factors?

Assumptions

The practice guidelines and protocols established for hypercholesterolemia, HTN and diabetes were developed by assessing predominantly white men. Assuming that the etiology and development of CHD in white men holds true for women, and PMHW, the established practice guidelines and protocols are appropriate for PMHW.

Summary

CVD is the single largest cause of death among women. At this point, it is uncertain if there are any pathophysiologic differences in the development of CVD in women in comparison to men. Furthermore, there are no studies specific to minority women and the development of CVD. Practice guidelines for HTN and hypercholesterolemia have been established primarily by evaluating men. Mosca et al. have established evidence based guidelines for CVD prevention for women in an effort to reduce the prevalence of obesity, HTN, hypercholesterolemia, tobacco use

and physical inactivity (2007). The problem of CVD specific to women and ethnicity has many unknown facets. The limiting factor in the prevention of CVD in women is the lack of research and development of evidence based interventions tailored to women and more importantly women of various ethnic backgrounds.

CHAPTER 2

CRITICAL REVIEW OF RELEVANT LITERATURE

Introduction

New intricate testing modalities for evaluating and diagnosing CVD and its risk factors have surfaced in the past few years. The latest emergence of the electron beam computed tomography (EBCT) and computed tomography angiography (CTA) has allowed for additional complex evaluation of coronary plaque burden (Dorbala, Hachamovitvh & Di Carli, 2006; Schuiff et al., 2006). The review of the literature will present a summary of research on coronary plaque in all genders; a summary of research on coronary heart disease among women; recent advances in assessing plaque burden and recent advances in assessing obesity. In light of recent data demonstrating that increased waist circumference is a cardiovascular risk factor, independent of obesity, the review will also examine studies supporting this assertion (Laszló et al., 2005; Appel, & Bannon, 2007; Ryan, 2007).

Summary of Research on Plaque Burden

Few studies have been completed evaluating atherosclerosis, non-invasive cardiovascular testing, ethnic minorities and women. The small number of studies that have sufficient participation of women enrolled did illustrate potential of coronary artery calcium (CAC) in men and women (Budoff, Gopal, & Gopalakrishnan, 2006). The literature will show that, in general, the information generated demonstrates that Caucasian men and women have higher prevalence of CAC. As a result, data collected should not be applied to non-white women until ethnicity-specific data are developed (Mieres et al., 2005). This section of the paper will present the few studies evaluating men, men and women, ethnic minority groups, and women.

Most of the studies have a major representation from men. The New Age II Pilot study evaluated only men to determine the influence of statin therapy on calcified and non-calcified

coronary plaque. The study used 16 and 64 slice scanners to determine CAC. Findings showed that statin therapy did significantly reduce non-calcified plaque burden by 24% (Burgstahler et al., 2007).

The Dallas Heart Study evaluated the presence of coronary calcium in African American and Caucasian men and women between the ages of 18 and 65 years of age utilizing the EBCT modality. The findings demonstrated that there were no statistically significant differences between African American and Caucasian men (37% vs. 41%) or between African American and Caucasian women (29% vs. 23%) (Jain et al., 2004; Budoff, Gopal, & Gopalakrishnan, 2006). The study did not include persons of Hispanic origin. Table 7 illustrates the CAC scores and CAC prevalence by ethnicity and gender. Black and white men tended to have higher CAC scores in comparison to women. Black men and women had more CAC prevalence in comparison to white men and women.

The Coronary Artery Risk Development in Young Adults (CARDIA) study, sponsored by the NHLBI, was a multi-center study evaluating the determinants of CVD risk factors in young adults between the ages of 18 - 30 years of age. The study included 5,115 African American and Caucasian men and women who were recruited from 1985 -1986 in four large U.S. cities. This cohort was followed at years 2, 5,7,10 and 15 with 90%, 86%, 81%, 79% and 74%, respectively, returning for follow-up. Table 8 illustrates the prevalence of CAC at year 15. CT scans indicated that almost 10% of the adults had CAC, with a greater prevalence among men (15%) than women (5.1%), and with a greater prevalence among Caucasian men (17.6%) than African American men (11.3%).

Table 7. CAC Scores and CAC Prevalence by Ethnicity and Gender

	All		Women		Men	
	Black (n = 761)	White (n = 528)	Black (n =380)	White (n =242)	Black (n = 381)	White (n = 286)
CAC scores Mean ± SD	128 ± 456	101 ± 443	94 ± 321	52 ± 204	163 ± 560	143 ± 569
Percentiles						
25th	0	0	0	0	0	0
50th	3.8	1.4	3.1	0.5	4.5	4.3
75th	47	35	29	7.2	71	72
90th	294	203	236	97	338	295
Max	6,749	7,444	3,708	1,796	6,749	7,444
CAC+						
Prevalence						
Unweighted	38%	33%†	33%	24%‡	42%	41%‡
Weighted‡	33%	33%	29%	23%§	37%	41%§

Note. CAC = coronary artery calcium.
*Mean difference in levels of coronary calcium between whites and blacks by *t* test: women, p = 0.07; men, p = 0.67;
† The chi-square p value for unweighted (weighted) prevalence between blacks and whites is 0.08 (0.98);
‡ Difference in unweighted CAC+ prevalence between whites and blacks by binomial proportions test (H_0: $p_W = p_B$): women, p = 0.01; men, p = 0.80;
§ Difference in weighted CAC+ prevalence between whites and blacks by weighted binomial proportions test: women, p = 0.21; men, p = 0.36.
Jain, Peschock, McGuire, Willet, Yu, Vega et al, 2004, p. 1015.

Almost 5.2 % of Caucasian women had CAC with 4.9% of African American women having CAC. Adults between the ages of 40-45 had twice as much CAC in comparison to the group between the ages of 33-39, 13% vs. 5%, respectively. Interestingly, young adults with above optimal risk factor levels at baseline were 2 to 3 times as likely to have CAC, which can potentially lead to CHD. The study demonstrated that at an early age, plaque calcification is already begun and accelerates in the 40-45 years of age group (Loria et al., 2007).

Table 8. Prevalence of CAC at yr 15 in the CARDIA Study, 2000 to 2001

	n	%	p Value
Any CAC			
Overall	3,043	9.6	
Race-gender group			<0.0001
African-American men†	576	11.3	
White men†	807	17.6	
Gender			<0.0001
Men	1,383	15	
Women	1,660	5.1	
Age			<0.0001
33 to 39 yrs	1,464	5.5	
40 to 45 yrs	1,579	13.3	
Agatston score			
>0–10	95	3.1	
>10–20	46	1.5	
>20–100	102	3.3	
>100–400	40	1.3	
>400	8	0.3	

Loria, Liu, Lewis, Hulley, Sidney, Schreiner et al., 2007, p. 2015.

Plaque Formation: Summary of Research on Hispanics

The Multi-Ethnic Study of Atherosclerosis (MESA) is an ongoing prospective cohort study that continues to collect data about cardiovascular events in Caucasian, Chinese, Black and Hispanic populations. From 2000 – 2002, MESA evaluated the presence of sub-clinical coronary artery calcium in a multi-ethnic cohort free of cardiovascular disease. The presence of coronary artery calcium (CAC) was measured either by electron beam computed tomography (EBCT) or multi-detector computed tomography (MDCT) at 3 field centers. Each participant was scanned twice and the average of the 2 provided the score. The calcium score was quantified by the Agatston scoring method. The group investigated the sub-clinical atherosclerosis by race, gender and age of 6814 participants between the ages of 45-84 years of age. Table 9 illustrates the characteristics of the study population (McClelland, Chung, Detrano, Post, & Kronmal, 2005). In general, 25% of the women had hypercholesterolemia vs. 32% of the men; 43% of the women had HTN vs. 42% of the men; 31% of the women had a BMI less than 25 vs. 30% of the men;

34.6% of the women had BMIs between 25-30 vs. 40% of the men; 28% of the women had BMIs between 30-40 vs. 27% of the men; and 5% of the women had a BMI greater than 40 vs. 3% of the men.

Table 9. Characteristics of the MESA Study Population

	Women		Men		Total	
Age, y	n	%	n	%	N	%
45–54	980	30.1	842	29.5	1822	29.8
55–64	900	27.7	788	27.6	1688	27.6
65–74	929	28.6	832	29.1	1761	28.8
75–84	442	13.6	397	13.9	839	13.7
Race/ethnicity						
White	1308	40.2	1195	41.8	2503	41
Chinese	371	11.4	348	12.2	719	11.8
Black	903	27.8	710	24.8	1613	26.4
Hispanic	669	20.6	606	21.2	1275	20.9

McClelland, Chung, Detrano, Post, and Kronmal, 2005, p.32.

Table 10 illustrates the various estimated percentiles of CAC by a 10-year age group, gender, and race/ethnicity from the MESA study. White men had the highest CAC percentile (70%), Chinese men had the second highest (59.2%) with Hispanic men (55.6%) having the third highest. For women, Caucasian women had the highest CAC percentiles (44%) and Hispanic women had the lowest (34.9%). Chinese and African American women were intermediate with their order dependent on age (McClelland, Chung, Detrano, Post, & Kronmal, 2005; Budoff, Gopal, & Gopalakrishnan, 2006).

Table 10. Estimated Percentiles of CAC by Age Category, Gender, and Race/Ethnicity

	Women, n				Men, n			
	Age, y				Age, y			
Percentiles by Race	45–54	55–64	65–74	75–84	45–54	55–64	65–74	75–84
White, n	379	356	379	194	321	325	375	174
25th	0	0	0	20	0	0	21	103
50th	0	0	13	106	0	28	145	385
75th	0	16	119	370	22	155	540	1200
90th	8	102	391	921	110	452	1345	2933
95th	31	209	674	1535	207	743	2271	4619
Chinese, n	109	107	103	52	102	94	102	50
25th	0	0	0	0	0	0	0	11
50th	0	0	5	32	0	5	34	81
75th	0	18	70	146	14	67	174	305
90th	12	105	246	398	89	242	487	769
95th	44	213	436	656	184	429	803	1299
Black, n	274	241	278	110	214	192	206	98
25th	0	0	0	0	0	0	0	23
50th	0	0	0	47	0	0	32	141
75th	0	5	77	214	2	40	191	516
90th	9	74	310	582	45	173	575	1281
95th	38	173	561	953	105	318	945	2176
Hispanic, n	218	196	169	86	205	177	149	75
25th	0	0	0	0	0	0	1	36
50th	0	0	1	45	0	3	56	153
75th	0	2	51	205	9	75	247	494
90th	2	50	203	557	88	291	666	1221
95th	18	118	361	917	195	512	1091	1943

McClelland, Chung, Detrano, Post, and Kronmal, 2005, p.33.

Summary of Research on Coronary Heart Disease among Women and Risk Factors

Many studies and clinical trials have been conducted evaluating treatable cardiovascular risk factors such as HTN, hypercholesterolemia, obesity, physical inactivity and smoking and non-treatable risk factors such as age, gender, and genetic predisposition. However, these studies had a majority of men as their subjects. Despite the increased prevalence of cardiovascular risk

factors and increased mortality in women, few studies evaluate women and cardiovascular risk factors and interventions for heart disease among women.

The Women's Cardiovascular Health Network found that few studies have been conducted to promote cardiovascular health interventions that specifically target women (Krummel et al., 2001). This section of the chapter will present the few studies that evaluate women exclusively and cardiovascular risk factors.

A large portion of the studies involving women focused on the evaluation of physical activity. The Women's Ischemia Syndrome Evaluation (WISE) is an ongoing NHLBI study of 476 women without a history of CVD. A section of the study showed that questionnaires assessing functional capacity and physical activity have validity for prediction of functional capacity and cardiac risk factors (Merz et al., 2000). Safety concerns of the women, such as walking and exercising in safe areas, serve as barriers to regular exercise (Will, Farris, Sanders, Stockmyer, & Finkelstein, 2004; Marshall, Jones, Ainsworth, Reis, Levy, & Macera, 2007; Jilcott, Laraia, Evenson, Lowenstein, & Ammerman, 2007; Marshall, Jones, Ainsworth, Reis, Levy, & Macera, 2007). A cohort of the WISE study, 207 post-menopausal women, demonstrated a significant association with increased abdominal circumference, obesity and increased estrogen levels (Olson et al., 2006). This is important because increased abdominal waist circumference and obesity are 2 major contributors to CVD.

The Well-Integrated Screening and Evaluation for Women across the Nation (WISEWOMAN) study is a federally funded program with a design of 12 projects. The purpose of this study was to remove racial and ethnic disparities in health by addressing the screening and intervention needs of women. The women are between the ages of 40-64 and from eight different regions of the U.S. These women are enrolled in the National Breast and Cervical Cancer Early Detection Program. The WISEWOMAN projects are required to screen for hypertension and hypercholesterolemia but can also screen for obesity. As of 2002, 10 projects had been completed. Initial findings showed that disadvantaged, uninsured women are at high risk for CVD with 23% of women having hypercholesterolemia, of which 48% were newly

diagnosed during the study. In addition, 38% of women had hypertension, of which 24% were newly diagnosed. It was also noted that 75% of the participants were either overweight or obese. The projects increased physical activity and improved nutrition. Because the study involved various regions of the U.S., it was noted that certain women, especially black women, were unable to make certain lifestyle changes like exercising because of neighborhoods. For interventions to be effective, they will have to be tailored to the community and its surroundings (Finkelstein, Khavjou, Mobley, Haney, & Will, 2004).

The Women on the Move through Activity and Nutrition (WOMAN) study was the first randomized clinical trial to investigate non-pharmacologic intervention designed to modify lipids, weight loss and exercise among post menopausal, primarily Caucasian, women (Kuller et al., 2007). The women were randomized into two groups: Lifestyle Changes and Health Education group. At baseline, CAC, weight and waist circumference were measured. The mean baseline CAC was 27.68 ± 52.16 with a planned 5-year follow up evaluation. At the 18-month follow up, there was a significant 17 lb weight loss with a 10 cm waist circumference loss with the lifestyle changes group, which incorporated 150 minutes of moderate physical activity weekly (Kuller et al., 2007). The end point of the study will evaluate the impact of weight loss and increased physical activity by measurement of CAC and carotid intima media thickening.

The Women's Health Initiative (WHI), funded by the NHLBI, was started in 1991. The focus of this trial and observational study was to evaluate and address the most common causes of death, disability and decreased quality of life among postmenopausal women with regard to CVD, cancer and osteoporosis. Both the trial and observational study included 161,808 healthy postmenopausal women. The randomized control trial consisted of a hormone therapy trial, dietary modification trial and a calcium/vitamin D trial. The WHI Dietary Modification Trial concluded that postmenopausal women eating a low fat diet did not significantly reduce their risk for heart disease, breast cancer, colorectal cancer or stroke (Potera, 2006; Pignone, 2006; Howard et al., 2006). Women who walked 30 minutes a day did reduce their risk for CVD, breast cancer and diabetes (Querna, 2006). A 9-year follow-up study of 38,283 participants in the WHI

demonstrated that women had electrocardiographic ventricular repolarization abnormalities, which were strong predictors of congestive heart failure and CVD. (Rautaharju, Kooperberg, Larson, LaCroix, 2006; Rautaharju, Kooperberg, Larson, LaCroix, 2006).

In 2004, the AHA and Mosca et al established evidence based guidelines for CVD prevention in women, in addition to utilizing the low, intermediate, and high Framingham Risk scores for women. However, the Framingham Risk score does not take into account family history for CVD or C - reactive protein levels. The guidelines also outlined issues such as lifestyle interventions; risk factor interventions for HTN and hyperlipidemia; preventive drug interventions such as the use of aspirin, beta-blockers, angiotensin converting enzymes and angiotensin II receptor blockers; use of hormone therapy; and atrial fibrillation. In 2007, an update was published by Mosca et al. This revision noted that the Framingham Risk score method might not sufficiently define women at risk as appropriately as previously thought. The Framingham Risk score is calculated based on age, gender, total cholesterol, HDL level, smoking status and systolic blood pressure measurement. A new risk calculator, Reynolds Risk Score, has been devised to better assess the risk of CVD disease in women. This scoring system is similar to the Framingham risk score, but it also takes into account family history for CVD and C-reactive protein levels (www.reynoldsriskscore.org). The panel recognized that nearly all women are at risk for CVD. The panel provides an algorithm to assist healthcare providers in evaluating CVD risk in women. The algorithm for the prevention of CVD in women (Figure 4) outlines the steps for implementation of lifestyle modifications, women who are at risk for CVD, and recommendations for pharmacologic interventions for HTN and hypercholesterolemia (Mosca et al., 2007).

Women's Awareness of Heart Disease

In 1997, a national telephone survey conducted by the AHA demonstrated that only 7% of women viewed heart disease as a threat to their health and less than one third knew it was the leading cause of death in women. Despite a public health campaign to educate and raise awareness in women about heart disease, a follow-up survey in 2000 revealed only a slight

increase to 8% of women who viewed heart disease as a major health threat (Robertson, 2001; Mosca, Ferris, Fabunmi & Robertson, 2004). A follow-up AHA survey in 2000, of women

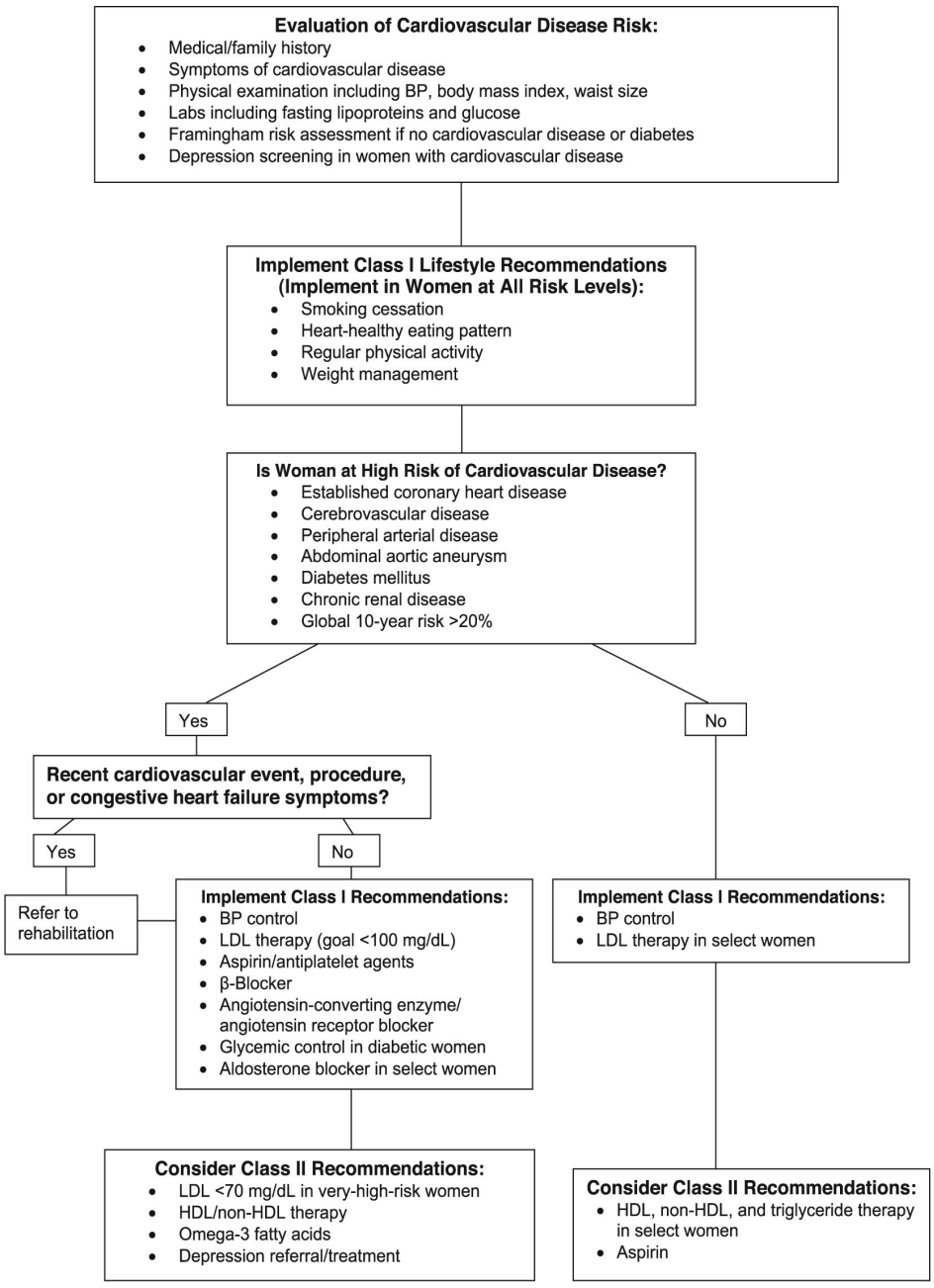


Figure. Algorithm for CVD preventive care in women. Labs indicates laboratory tests; BP, blood pressure; LDL, low-density lipoprotein cholesterol; and HDL, high-density lipoprotein cholesterol.

Figure 4. Algorithm for CVD Preventive Care in Women Mosca, Banka, Benjamin, Berra, Bushnell, Dolor, et al. 2007, p.1488.

between the ages of 25-34, revealed that nearly two thirds of the women surveyed believed that cancer was their biggest health threat. Interestingly, in this survey, 80% of the Hispanic women were more concerned about having a stroke, in contrast to the 1997 survey that demonstrated that 64% of the Hispanic women were concerned about having a stroke (Robertson, 2001). In the 2003 AHA survey, which had an over sampling of black and Hispanic women, 46% of women surveyed recognized that heart disease was the leading cause of death among women, which was an increase from the 30% in the 1997 survey (Mosca, Ferris, Fabunni & Robertson, 2004). In addition, a sub-study of women having mammograms in 2003 demonstrated that only half of the women accurately perceived their Framingham risk score as low (Christian, Mochari & Mosca, 2005).

As the national campaign for awareness continued, a 2005 AHA survey revealed that 55% of all women considered heart disease as the number one killer of women. Sixty-two percent of the Caucasian women perceived that heart disease was the leading cause of death. In contrast, 38% of African American women and 34% of Hispanic women had the same level of awareness (www.heart.org/presenter.jhtml?identifier=3037192). A 2006 AHA follow-up survey revealed that awareness of heart disease as the leading cause of death was significantly increased to 57%. Yet, again, awareness among blacks and Hispanics was significantly lower, 31% and 29%, respectively. This survey revealed that Hispanic women, in comparison to Caucasian women, were more likely to report that there was nothing that they could do to prevent themselves from getting CVD. In addition, findings revealed that awareness had been raised, but there still remains an ethnic gap of awareness resulting in the need to further focus on minorities, especially Hispanic women (Christian, Rosamond, White & Mosca, 2007). In a survey completed by the AHA, 57% of women were aware that heart disease was the leading cause of death among women (Rosamond et al, 2008).

Research on Women

The WISE studies have found that women developed a coronary micro-vascular syndrome where coronary plaque spread evenly throughout the walls of very small arteries. As a

result, in these small arteries there was insufficient flow to the heart that could cause chest pain, even though the woman may have presented with a normal stress, angiogram and CAC (Dougherty, Faucher, Gillman, Taubenheim, Wilton, & Woodson, 2006; Nicols et al., 2007). In addition, women tended to have low CAC scores or negative scans before menopause (Wexler et al., 1996; Mieres et al., 2005). In a study evaluating coronary calcification in 128 African American women and 733 Caucasian women, African American women had CAC scores similar to those of Caucasian women (Khurana et al., 2003). A study population evaluating 1,080 men and 531 women for CAC via EBCT illustrated men had a higher prevalence of any CAC scores (72% vs. 50%) as well as a moderate to severe CAC score (25% vs. 13%). The concern from this study is that NCEP guidelines underestimate cardiovascular risk in young asymptomatic individuals, especially women (Nassir, Michos, Blumenthal & Raggi, 2005). Actually, nearly two thirds of women who die suddenly have no previously recognized symptoms (Aronow & Ahn, 2002). Nichols et al. (2007) demonstrated that despite having more risk factors, the degree of atheroma in women with angiographic CAD is less than men.

Recent Advances in Assessing Coronary Plaque

Fluoroscopy and EBCT have been the non-invasive testing modalities commonly utilized to detect coronary calcification in the past decades, whereas, intravascular ultrasound (IVUS) and cinefluorography have been the modality for invasive evaluation of coronary calcification (Wexler et al., 1996). This past decade there have been great strides in the field of cardiac imaging with the last five years yielding a non- invasive modality of multi-detector row computed tomography (MDCT) or multi-sliced computed tomography (MSCT) (Dorbala, Hachamovitvh & Di Carli, 2006; Schuijf et al., 2006). The next section of this paper will briefly discuss the emergence and utility of the IVUS, EBCT, MDCT/MSCT and coronary computed tomography angiography (CTA).

IVUS is an invasive procedure that utilizes transducers with rotating reflectors mounted on the tips of the catheter. The sonograms taken from the transducers not only provide information about the lumen of the artery and atheroma burden but also various characteristics of the arterial wall, such as thickness and tissue characteristics (Wexler et al., 1996; Nicholls et al.,

2007). IVUS can image the entire lumen of the arterial wall and assess an atheroma, if present. By comparison to coronary angiography, IVUS is more sensitive to detecting coronary calcification. As a result, IVUS can be utilized in conjunction with coronary angiography to detect for coronary occlusive disease. However, a major disadvantage to the IVUS is that it has a limited visualization capability in portions of the coronary tree. In addition, because it is an invasive procedure, IVUS has no role in screening for CAD (Wexler, 1996).

Computed tomography (CT) is sensitive to detecting vascular calcification because calcium attenuates the x-ray beam. EBCT uses an electron gun and a stationary tungsten target, which permits very rapid scanning times. (Rumberger, Simons, Fitzpatrick, Sheedy, &Schwartz, 1995; O'Rourke et al., 2000; Schussler & Grayburn, 2005). EBCT is a fourth generation CT imaging process (Gopal & Budoff, 2006). It is a non-invasive testing modality that allows for the measurement of sub-clinical atherosclerosis and can be utilized as part of the process of risk assessment (Mieres et al., 2005; Carrascosa, Capuñay, Garcia-Merletti, Carrascosa & Garcia, 2006; Budoff, Gopal, & Gopalakrishnan, 2006; Kathiresan et al., 2007). As a result, EBCT testing is best used for coronary artery disease (CAD) risk factor analysis rather than as a diagnostic tool (Schussler & Grayburn, 2005). It has been suggested that calcium scoring accompany the established Framingham risk prediction score in an effort to more specifically predict risk in intermediate risk patients (Greenland, LaBree, Azen, Doherty, & Detrano, 2004). The 2007 American Heart Association scientific statement on cardiac CT recommended coronary calcium score for risk stratification in intermediate risk patients (Greenland et al., 2007). After the EBCT has been completed, a calcium score, Agatston score, is generated based on the amount of calcium identified from various parts of the coronary system. Table 11 illustrates the Agatston scoring system of calcification, probability of CAD, cardiac risk status and recommendations. An Agatston score of greater than 400 may benefit from functional stress nuclear testing to further assess for coronary ischemia (Budoff, Gopal, & Gopalakrishnan, 2006).

Table 11. Agatston Scoring

(Agatston)	Plaque burden	Probability of significant CAD	Implication for CV risk	Recommendation
0	No identifiable plaques	Very low	Very low	Reassure patient
1–10	Minimal identifiable plaque burden	Very unlikely	Low	Discuss guidelines for primary prevention of CAD
11–100	Mild atherosclerotic plaque	Mild or minimal coronary stenosis likely	Moderate	Counsel risk-factor modification, daily ASS
101–400	Moderate atherosclerotic plaque	CAD highly likely	Moderately high	Institute risk-factor modification, exercise testing
>400	Extensive atherosclerotic plaque burden	High likelihood of significant coronary stenosis	High	Aggressive risk-factor modification, exercise or pharmacological stress test

http://continuum.uta.edu:2060/content/561177wq3543035h/

EBCT is very sensitive in identifying and quantifying the amount of coronary calcification but it does not associate with site-specific stenosis (Rumberger, Simons, Fitzpatrick, Sheedy, &Schwartz, 1995; Wexler et al., 1996). Elevated coronary calcium scores are predictive of cardiovascular disease and events (Gopal & Budoff, 2006). Based on the Agatston scores, cardiac risk status is established and appropriate interventions can be employed. If multiple cardiac risk factors are involved, additional testing is usually required to further evaluate the specific site of the calcified atherosclerotic plaque. As plaque ages and calcifies, it develops fibrous tissue, which then becomes a fibrous plaque or an atheroma. This fatty deposit of cholesterol accumulating in the inner lining of the artery accounts for occlusion of the artery causing CVD (Murphy, 1997). The greater the amounts of calcification, the more likely that there is an obstructive plaque build up in that generalized location. A high calcium score can be consistent with a moderate to high risk of a cardiovascular event within the next 2 to 5 years (Wexler et al., 1996). Conversely, a negative EBCT score does not imply the absence of

atherosclerosis. Soft, lipid-laden plaque can present as a zero calcium score and is essentially deemed as “negative”. This soft plaque could be an unstable soft plaque that has not yet calcified, and it is more vulnerable to rupture causing platelet aggregation and thrombus formation, which can lead to an occlusive process in the artery (Wexler et al., 1996; Butler et al., 2007; Schussler & Grayburn, 2005; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Budoff, 2006).

MSCT scanning employs an x-ray beam and multiple detectors which provides 3-dimensional visualization of the coronary arterial tree, coronary veins, pulmonary veins, aorta, atria and ventricles (Carrascosa, Capuñay, Garcia-Merletti, Carrascosa & Garcia, 2006; Budoff, Gopal, & Gopalakrishnan, 2006). There are two approaches for obtaining images while the heart is in motion: prospective gating and retrospective gating. The EBCT modality utilizes prospective gating because the scanner has the ability to turn the scanner off and on and acquire images during a specified part of the heart cycle. MSCT uses retrospective gating where the entire cardiac cycle is acquired and then the images from the point of least cardiac motion, end diastole, are reconstructed (Schussler & Grayburn, 2005; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Pundziute, Schuijf, Jukema, de Roos, van der Wall & Bax, 2006). Retrospective gating requires a spiral MSCT scan at a low pitch while the patient’s electrocardiogram (EKG) is simultaneously recorded. Prospective EKG triggering is a sequential scanning technique that is derived from the patient’s EKG and during diastole data acquisition is started at a predefined delay. Acquiring this type of data requires a slow regular heart rate and no motion artifact from the patient, especially breathing. As a result, the patient is expected to hold his/her breath for at least 5 seconds to acquire adequate pictures if a 64 MSCT machine is used. If a 16 MSCT is used, the patient is required to hold his/her breath for approximately 25 seconds (Schussler & Grayburn, 2005; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Pundziute, Schuijf, Jukema, de Roos, van der Wall & Bax, 2006). The preferred heart rate during testing is less than 65 beats per minute (BPM) to ensure adequate testing results. Consequently, beta-blockers are usually given one hour prior to testing to slow the heart rate. The sensitivity, accuracy, and image

quality of the MSCT can be compromised as the heart rate increases above 65 BPM during the testing phase (Schussler & Grayburn, 2005; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Hausleiter, J., Meyer, T., Hadamitsky, M., Kastrati, A., Martinoff, S. & Schömig, 2006; Giesler et al., 2002).

Since the inception of the MSCT with the initial 4-detector row advancing to the use of the 16-detector row, we now have the 64-detector multi-slice CT. The accuracy and sensitivity of identifying coronary plaque using the 4 and 16 multi-slice detection had been established in the literature as an accurate modality to quantify coronary stenosis and is useful in excluding CAD (Hoffman et al., 2005; Lessick, Hoffman & CATSCAN Investigators, 2006). Since 1999, there have been various studies on MSCT and coronary angiography, but within the past five years, the new 64 MSCT technique, in conjunction with coronary CTA has emerged. This newer technique utilized in patients with an intermediate risk for CAD can also adequately detect for soft, vulnerable plaque (Hausleiter et al., 2006; Schuijf et al., 2006; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Burgstahler et al., 2007). The 64 MSCT technique has the benefits of higher accuracy and sensitivity, but it also requires a higher dose of radiation (Pundziute et al., 2006; Zanzonico, Rothenberg & Strauss, 2006). Radiation exposure is increased because of the thinner slices and shorter gantry rotation times. Head to head studies with coronary angiography versus 64 MSCT CTA demonstrate that MSCT CTA requires more millisievert (mSV) to sufficiently test and diagnose the patient for CAD (Coles et al., 2006; Hesse et al., 2006; Pundziute et al., 2006; Budoff, Gopal, & Gopalakrishnan, 2006; Mahnken, Mühlenbruch, Günther, & Wildberger, 2006; Jónsdóttir & Danielsen, 2006).

Despite the rise of new testing modalities, invasive and noninvasive, it was not too long ago, in 2004, that the United States Preventive Services Task Force (USPSTF) issued a recommendation statement against routine cardiac screening for low risk patients. The premise was that false-positive testing from electrocardiograms, stress testing and CT scans caused too much alarm and was harmful to low risk patients (www.theheart.org). In contrast, the recent statement by the Screening for Heart Attack Prevention and Education (SHAPE) Task Force calls

for a blanket CT and carotid screening for all “at risk” asymptomatic men and women, between the ages of 55-75 years of age, for the purpose of directly examining the arteries for sub-clinical atherosclerosis (Naghavi et al., 2006). As a result of various recommendations, the American College of Cardiology Foundation (ACCF) and key specialty medical societies have come together to form practice guidelines based on a wide variety of patient presentations in an effort to assist healthcare providers with guidelines in the selection of various testing modalities for cardiac risk stratification (Hendel, Patel, Kramer & Poon, 2006).

Recent Advances in Assessing Obesity

Obesity is a chronic disease and a major cause for morbidity and mortality due to its association with HTN, hypercholesterolemia, CAD and other metabolic disorders and can independently contribute to CVD in women (Mokdad, Bowman, Ford, Vinicor, Marks and Koplan, 2001; Okosun, Choi, Matamoros & Dever, 2001; Mokdad et al., 2003; Li et al., 2006; Penman & Johnson, 2006). Obesity is at epidemic proportions and is a major cardiovascular risk factor for CVD (Willet, Manson, Stampfer, 1995; Rexrode et al, 1998; Hensrud & Klein, 2006). Obesity is defined as having an excess of body fat (Hensrud & Klein, 2006). Currently, BMI is the most widely used anthropometric measure of overall body adiposity and is the standard used to determine obesity. BMI is weight (kg)/height (m) 2, which is essentially a height-adjusted weight. A simple calculation of height and weight can yield a body mass index, which will classify persons as normal weight, overweight, and obese (Okosun Tedders, Choi & Devers, 2000). A normal BMI is between 18.5-24.9, an overweight BMI is 25-29.9 and a BMI of greater than 30 or more is considered as obese (www.nhlbi.nih.gov/guidelines/obesity/ob_home.htm; Robert & Neither, 2004). A woman having a BMI greater than 25 may be at increased cardiometabolic risk (Bjorntorp, 1990; Marin & Bjorntorp, 1993). According to the Behavioral Risk Factor Surveillance System (BRFSS) (2006), 36% of the nationwide population was obese with an average BMI of 36.5 and 25% were overweight with an average BMI of 25.1, with 38% of the population being neither overweight nor obese with a BMI less than 24.9. Almost 26% of men were obese in

comparison to almost 25% of women (http://apps.nccd.cdc.gov/brfss/list.asp?cat=OB&yr=2006&qkey=4409&state=All; http://apps.nccd.cdc.gov/brfss/sex.asp?cat=OB&yr=2006&qkey=4409&state=UB). In a study evaluating racial and socioeconomic differences in risk factors for CVD among southern rural women, the strongest predictors for CVD were increased BMIs and education levels with women with the least amount of education having the highest risk (Appel, Harrell & Deng, 2002).

In the past, waist to hip ratio measurement was an appropriate method to report the distribution of fat and predict cardio-metabolic risk (Bild, Sholinsky, Schreiner, Hilner & Swanson, 1998). Because women tend to change their body shape when they increase their weight, the waist to hip ratio is not an appropriate modality of assessing risk. As a result, the NHLBI and NCEP ATP III suggest that waist circumference is the modality to determine central obesity (http://www.columbia.edu/itc/hs/medical/nutrition/guide/exec_summary_chol.pdf). Assessing BMI, in addition to measuring a woman's waist circumference, is suggested due to the fact that women can have a normal BMI but have central obesity (Appel, & Bannon, 2007). Few studies have assessed intra-abdominal fat (IAF) and sub-cutaneous fat (SQF) via CT scanning. Waist circumference is the best alternative to assess abdominal obesity due to the cost, radiation hazard of CT testing, and the demonstration that CT measurements of intra-abdominal fat and subcutaneous fat are not superior to BMI and waist circumference (Keller, Chintapalli & Lancaster, 1999; Okosun Tedders, Choi & Devers, 2000; Snell-Bergeon, Hokanson, Kinnery, Dabelea, Ehrlich, Eckel et al., 2004). In evaluation of BMI and central obesity via CT scanning, increased BMI is associated with central and peripheral fat (Seidell, Bjorntorp, Sjostron, Sannerstedt, Krotkiewski, & Krist, 1989).

Recent studies indicate that waist circumference is an indicator for cardiovascular risk and mortality and has a stronger association with CVD risk factors in comparison to other measures of adiposity (Laszló, Bagger, Qin, Alexandersen, Larsen & Christiansen, 2005; Merz, 2006; Menke, 2007; Ryan, 2007). Excess fat around and above the waist may be more of a predictor of cardiovascular risk than simple overall weight (Appel & Bannon, 2007). The Weight-

Control Information Network (WIN), a service of the NIDDK, states that a woman with a waist circumference of more than 35 inches or a man with a waist circumference of more than 40 inches may have a greater disease risk than people with smaller measurements because of where the fat is located (http://win.niddk.nih.gov/publications/tools.htm#circumf).

Lazlo et al. (2005) conducted a study on 557 postmenopausal women, between 48-76 years of age, evaluating waist circumference and triglycerides levels. These women were followed for an average of 8.5 years. Analysis of the data demonstrated that women who had an enlarged waist circumference greater than 88cm and triglyceride levels greater than 1.45 mmol/L had significantly decreased survival rates. The results of this gender specific long-term prospective study suggests that an enlarged waist and an elevated triglyceride level, in post menopausal women, can be a strong indicator of atherogenic trends related to increased cardiovascular risk.

A total of 44,702 women, between the ages of 40-65 years, involved in the Nurses' Health Study participated in a study to evaluate abdominal adiposity and coronary heart disease. This study concluded that elevated waist circumference and waist to hip ratios were independently associated with a significantly increased age adjusted risk for coronary heart disease (Rexrode et al., 1998). Additionally, Kortelainen and Huttunen (2004) completed forensic autopsies on 52 pre-menopausal women between the ages of 18-49 years of age. Findings indicated that pre-menopausal women with increased central body fat accumulation, enlarged waist, had advanced coronary lesions in the left anterior descending artery (LAD).

Esmaillzadeh, Mirmiran and Azizi (2006) demonstrated that even adolescents with elevated waist circumference and increased triglycerides had higher prevalence of metabolic cardiovascular risk factors. They concluded that elevated waist circumference in young persons has health risk factors similar to an adult. In addition, waist circumference is an equally important tool in predicting health risks in persons as young as 10 years old. Additionally, Savva et al. (2000) concluded, after evaluating a total of 1037 boys and 950 girls, that waist circumference and waist to hip ratios, rather than BMI, are better predictors for cardiac disease in children.

Summary

Despite the increased role of invasive and non-invasive testing modalities for assessing cardiovascular disease, the lack of studies evaluating cardiac risk in women, in general, and Hispanic women in particular demonstrates the need for such studies. The MESA study demonstrated that Caucasian women had the highest CAC percentiles in comparison to Hispanic women (McClelland, Chung, Detrano, Post, & Kronmal, 2005). Mexican American women were less likely than white women to have high cholesterol (Feresu, Zhang, Puumala, Ullrich, & Anderson, 2008).

There is a definite knowledge gap in ethnicity and treatment guidelines that are culturally competent and appropriate for all women. The testing modalities of IVUS, EBCT, and MSCT offer much promise in early assessment of CVD in an effort to promote heart healthy lifestyles to prevent the progression of this epidemic in men and women. However, the literature provides data generated primarily by evaluating men. As a result, medical providers are providing treatment to women based on results from studies primarily of men. As a start, recent evidence based treatment guidelines for women, suggested by Mosca et al. (2007), offer clinicians treatment guidelines that can assist in providing women with gender specific treatment to help reduce morbidity and mortality of treatable conditions. The lack of data and research, in this review of literature, pertaining to young women and CVD suggests that more research is required for a better understanding of CVD and women. Furthermore, aggressive intervention regarding treatable risk factors should be implemented early in a woman's life cycle rather than waiting for symptoms to occur in the menopausal state.

CHAPTER 3

METHODS AND PROCEDURES

Introduction

This chapter outlines the methodology of this descriptive study that evaluated CAC, cholesterol levels, BMI and waist circumference in PMHW. The routine testing and procedures completed in this study were similar to other state of the art cardiovascular testing in clinics and hospitals throughout the world in persons who demonstrate cardiovascular risk factors such as HTN, hypercholesterolemia, diabetes, obesity, increased abdominal girth, physical inactivity and family history for CAD.

Research Design

A descriptive study design was the research design for this study. This study described the presence of hard and soft coronary artery calcification and plaque presence in PMHW by multi-sliced CTA and examined the relationships among plaque, components of lipid levels, BMI and waist circumference.

Sample

The inclusion criteria (See Table 12) of the sample of this study consisted of Hispanic women between the ages of 25-45. Women were determined to be pre-menopausal if they reported still having regular monthly menses or had previously had a hysterectomy. English speaking Hispanic women who read and write English, who had at least 3 CVD risk factors, were included in the study. “Hispanic” includes persons who can trace their ancestry to Mexico, Puerto Rico, Cuba, Spain, the Spanish speaking countries of Central or South America, and the Dominican Republic.

The exclusion criteria (See Table 12) for the study were allergies to beta blockers, Iodine, shrimp, shellfish or x-ray dye; asthmatics requiring daily respiratory treatments; known pregnancy

or a positive pregnancy test completed on the day of testing. In addition, to avoid renal complications, the woman was excluded if her kidney serum creatinine level was greater than 1.2 mg/dL or estimated glomerular filtration rate (eGFR) less than 30mL/min per DaVita testing.

Table 12. Inclusion and Exclusion Criteria for the Study (Prior to Modifications)

Inclusion Criteria	Exclusion Criteria
1. Age: 25-45 yrs	1. Asthmatic
2. Hispanic female	2. Allergy to:
3. Pre-menopausal	Beta Blocker
4. English Speaking	Iodine
5. At Least 3 Risk Factors:	Shrimp/Shellfish
HTN	X-ray dye
Hyperlipidemia	3. Pregnancy
Diabetes	4. Serum Crt > 1.2
Obesity	5. eGFR < 30mg/dL
Waist > 35 inches	
Family History for CAD	

After 2 months of recruitment yielded only 4 participants, modifications to the inclusion criteria were made to include Spanish-speaking women. All of the forms were translated to Spanish and reapplication to the UTA Institutional Review Board (IRB) was submitted. After approval for the modifications was granted, women who spoke and wrote Spanish qualified for the study if other criteria were met. All of the other inclusion and exclusion criteria remained unchanged. Every woman who qualified for the study was invited to participate.

Power Analysis

Prior studies conducted by Jain et al and the Dallas Heart Study Investigators (2004) of the Dallas Heart Study, who evaluated middle aged African American and Caucasian men and

women, and by Tanko et al of the EWET study (2005), who evaluated African American, Caucasian, Hispanic and Chinese men and women between the ages of 45 to 84, revealed moderate associations between the cardiovascular variables. To achieve a moderate correlation coefficient of .30 or greater between the cardiovascular variable set with power = .80 and alpha = .05, required a sample size of 84 (PASS, 2000).

Sampling Method

The sampling method was network sampling, sometimes referred to as snowball sampling. Primary care and cardiology private practices that had a patient population consisting of Hispanic women in the north central Texas area were asked to post information about the study in their waiting areas and exam rooms. Flyers (see Appendix A and Appendix B) were emailed to members of the Dallas-Fort Worth Chapter of the National Hispanic Nurses Association and to nurses and nurse practitioners with access to Hispanics. After 2 months of recruitment yielded few subjects, recruitment efforts were modified. After the modification, the network sampling provided participants from church groups, small women's groups and referrals from study participants.

Setting

The study was conducted in a private practice cardiology office in north central Texas (see letter of support in Appendix C). This cardiology office evaluated and managed patients with CAD, HTN, hyperlipidemia, cardiomyopathies and peripheral vascular diseases. The office had a front office, desks for nursing personnel, 7 exam rooms, 1 physiologic stress testing room, nuclear camera room, two crash carts, laboratory room for collecting blood specimens and a room for CTA testing and a workstation. All 7-exam rooms had exam tables, chairs and a big screen TV. The physiologic stress testing rooms had exam tables and Quinton® monitoring devices. The nuclear camera room was equipped with an exam table and camera for imaging after nuclear stress testing was performed. There was a secured "hot" lab for containing the radioisotope for nuclear imaging. The CTA room was equipped with the Philips Brilliance 64 slice CT scanner and Workspace station. The lab room had a supply of gloves, refrigerator,

Cholestech machine and its required supplies, iSTAT machine and its required supplies, Coagcheck machine and its required supplies, alcohol swabs, band aides and a sink with a splash faucet.

Measurement Methods

The four outcome measures for this study were the percent of plaque burden in twelve identified coronary arteries, the amount of blood cholesterol components present, BMI and waist circumference. Each is described below.

Percent Plaque

Plaque build up and calcification in the coronary arteries were identified using a 64-slice multi-detector CT scanner. A board certified nuclear cardiologist measured and scored the percentage of coronary plaque calcification as shown by the Philips 64 slice multi-detector CT scanner. The measurement of plaque buildup and calcification, assessed by the cardiologist, was determined by measuring the length and diameter of the plaque characteristics, which may have included lipid rich-soft plaque, calcified plaque or mixed characteristics of soft and calcified plaque. Dependent upon the measurements, the percent of blockage was calculated. He recorded his findings on the data collection form presented in Appendix D.

Reliability of the Nuclear Cardiologist

Reliability of the cardiologist is established through his extensive cardiology background. He received his medical degree and doctorate of philosophy in physiology in 1990 from the Thomas Jefferson University in Philadelphia, Pennsylvania. He served three years as a research resident at Brigham and Women's Hospital and Harvard Medical School, Boston, Massachusetts (MA). He served as a Fellow in Cardiovascular Disease, Brigham and Women's Hospital and Harvard Medical School, Boston, MA for 4 years. He is a Fellow of the American College of Cardiology; Diplomat of the Certifying Board of Nuclear Cardiology; Diplomat of the American Society for Hypertension in Clinical Hypertension; and Diplomat of the American Society of Echocardiography in Echocardiography – Comprehensive. Since 2001, he has served as an Adjunct Assistant Clinical Professor, the University of Texas at Arlington, Arlington, Texas (TX).

Currently he serves as the administrative Radiation Safety Officer and Director of Nuclear Cardiology – CSANT Grapevine, TX; Director of Echocardiography – CSANT Grapevine, TX; Director of Preventative Cardiology – CSANT Grapevine, TX; Director of Non-invasive (CT) Cardiovascular Angiography- CSANT; and Director of Point of Care Testing and Clinical Laboratory – CSANT Grapevine, TX. He is one of a few level III trained readers/evaluators of CTA in Texas.

Validity and reliability of the 64 slice multi-detector CT scanner

In 2000, German cardiologists demonstrated accuracy and reliability of quantitative measurements of the coronary arteries with a 4-slice multi-detector CT scanner. Schroeder et al. (2001) compared coronary plaque observed via intra-coronary ultrasound (ICUS) and a 4 slice multi-slice scanner. The statistically significant data revealed comparable results between the two modalities. The comparison of vessel diameters revealed comparable results between the ICUS and MSCT (4.89 mm $\pm$ 0.67 mm vs. 4.91 mm $\pm$ .71mm, P= 0.79, r = 0.79, P < 0.0001) (Shroeder et al., 2001).

In 2006, the 16-slice multi-detector demonstrated that despite the fact that the scanners had a high number of non-evaluable cases and a high false positive rate, it still had a high sensitivity rate and negative predictive value when evaluating coronary plaque (Garcia, Lessick and Hoffmann, 2006). With more advancement of technology, evaluating plaque burden with the 64 slice multi-detector scanner now demonstrates the sensitivity, specificity and the positive and negative predictive values of 99%, 96%, 78% and 99%, respectively. All patients with significant CAD, greater than 50% coronary occlusion, were correctly diagnosed, and only a single vessel was missed on CT resulting in 100% sensitivity per patient and 99% sensitivity per segment when compared to conventional coronary angiography. All but one patient with angiographically normal coronary angiograms were identified at CT, which supports the reliability of the technique for ruling out significant coronary obstructions greater than 50% occlusion of the artery. Results reveal 90% specificity per patient and 96% per segment (Pugliese et al., 2006). In another study comparing intravascular ultrasound and multi-detector scanners, sensitivity for detecting plaque

obstruction greater than 50% was 86% (95% confidence interval 72.6 to 93.7) and specificity was 90.2% (95% confidence interval 83.9 to 94.4). There was no mention of inter rater reliability with regard to measurement methods (Carrascosa, Capuñay, Garcia-Merletti, Carrascosa and Garcia, 2006).

Cholesterol

The measure of cholesterol included total cholesterol measured in mg/dL and its components of LDL measured in mg/dL, HDL measured in mg/dL and triglycerides measured in mg/dL. Each was calculated by using the same Cholestech ® tabletop analyzer. The results of each of these cholesterol components were printed from the analyzer and the printed form, with an adhesive backside, was placed on the Data Collection Form (Appendix E) and Pre-Procedure Assessment Form which is an established form for the cardiology office and is utilized on all testing patients (see Appendix F and Appendix G). In an exam room, a BD Vialon Saf-T-Intima catheter was established to obtain IV access for testing purposes (See Appendix H for IV Access). Once the IV had been established by the CT technician, a 1cc syringe of blood was aspirated by the CT technician from the patent intravenous (IV) site. The CT technician then performed the Cholestech testing (See Appendix I).

In the evaluation of seven Cholestech® analyzers, correlational coefficients derived from comparison of total cholesterol values from the devices for each specimen versus the reference cholesterol values were all >.97 (Rogers et al.,1993). In 1994, a study using 2 Cholestech devices demonstrated that correlational coefficients were all >0.98. Mean slopes and intercepts for the Passing & Bablock regression equations of total and HDL-cholesterol was not significantly different from one and zero, respectively. For total cholesterol, the National Cholesterol Education Program Guidelines (NCEP) requirements for accuracy and precision of < or = 3% were met (Cobbaert, 1994). Volles et al. (1998) compared the precision performance of two cholesterol-analyzing devices. Both devices met the NCEP +/- 3% requirement for total cholesterol mean percent bias but did not meet the +/- requirement for coefficient of variance as a measure of precision. As a result, Volles concluded that the Cholestech® is not appropriate for

monitoring patients with high cholesterol even though it is an appropriate tool to utilize as a screening method. The manufacturer states that the Cholestech is able to calculate total cholesterols between 100-500 mg/dL, HDL levels between 15-100 mg/dL, triglyceride levels between 46-650 mg/dL and the calculated LDL is accurate when the triglyceride level is less than 400 mg/dL. If the triglyceride level is greater than 400mg/dL, the person should be sent to a laboratory to have additional testing completed to calculate the LDL level.

The Cholestech ® system has been certified by the Cholesterol Reference Method Laboratory Network (CRMLN). This certification validates that the system meets the standards for accuracy and reproducibility developed by the Centers for Disease Control and Prevention for the measurement of total and HDL cholesterol, consistent with the National Cholesterol Education Program analytic goals and is comparable to centralized laboratory testing (http://www.cholestech.com/products/accuracy&reproducibility.htm; http://www.cholestech.com/docs/ldx_accuracy/MKT13415_A%20CRMLN%20Technical%20Brief.pdf.).

To ensure reliability of the device, the controls, as identified by the manufacturer, were completed at the beginning of each day by the registered nurse as one of her daily functions working in the testing area. (See Appendix J for Controls Testing.) The validity, reliability and consistency of the testing were maintained because the same personnel completed the task as part of the daily requirements. The investigator witnessed one completion of controls testing by the registered nurse and checked the daily log entry, on each day of testing, for completion of controls testing for that day.

Waist Circumference

Waist circumference has been endorsed as the best anthropometric surrogate of abdominal adiposity (Ross, Shaw, Martel & Avruch, 1993: Rexrode et al., 1998). The tool was a standard flexible measurement tape. The investigator, a nurse practitioner, took two separate measurements with a standard measuring tape. The average of the two measurements was the

documented measurement in inches on the Data Collection form (Appendix E). The measurement was conducted as outlined below (Appel & Bannon, 2007).

1.) Waist measurements were obtained on bare skin.

2.) The woman stood erect with her weight on both feet flat on the floor.

3.) The woman was faced away from the examiner.

4.) The examiner placed her hands bilaterally on top of the woman's hipbones to identify the waistline.

5.) Waist circumference was measured in the horizontal plane at a site just above the anterior iliac crest (hipbone).

6.) A mark was made on the skin, just below the umbilicus, to circumscribe the location, and the tape measure was placed with the top edge at the level of the mark.

7.) The tape was wrapped snuggly around without compressing any skin.

8.) The tape was read when wrapped around the subject line marked on the skin.

9.) If necessary, the woman turned to the side so that the examiner could be sure the tape was placed at the same level anteriorly and posteriorly prior to reading the tape measure.

Body Mass Index

The BMI was calculated by using the calculator from the National Heart Lung, Blood Institute (http://www.nhlbisupport.com/bmi/bmicalc.htm). The height and weight, required to compute the BMI, were calculated via the only standing weight/height Detecto scale in the office as noted below.

1.) Subject to remove shoes and heavy removable articles of clothing.

2.) Both feet planted firmly on the middle of the platform.

3.) The investigator will press the on button for the weight calculation and a digital number (lbs) will appear on the screen.

4.) The sliding height rod on the scale will measure the height. The height rod will be placed on the top of the subject's head and the height in inches will be obtained.

Procedure

Recruitment

After initial approval from the UTA IRB, the investigator called offices of primary care physicians and cardiologists, a total of 17 offices, in the North Texas area within a thirty mile radius of Grapevine, Texas and surveyed if they had a Hispanic patient population. If the answer was yes, the investigator requested to speak to the physician and discussed the study and asked for assistance in recruitment by allowing flyers to be placed in the exam rooms and waiting rooms. The physician was not involved with recruitment. In addition, the flyer was sent to members of the National Association of Hispanic Nurses (NAHN)- Dallas Chapter and to nurses and nurse practitioners who had access to Hispanics.

The recruitment and enrollment phases extended over a 6-month span. Figure 5 illustrates the sequence of events during that period. See Appendix K for the original flowchart for the study. Initially, recruitment was focused on 17 physicians' offices and the NAHN website with handouts and flyers. As noted on Figure 5, an orientation meeting, which was established with women from the doctors' offices, yielded 6 women. The NAHN website posting of the flyer yielded only three emails of inquiry and four phone calls of inquiry regarding the study. However, because of the women's reported work schedules, they were not able to move on to the enrollment phase. Due to a 2-month period yielding only four participants, the protocol was modified in an effort to recruit more women.

The first adaptation and change in protocol required changing an inclusion criterion, which required the women to speak and read English. Documents were translated to Spanish; a Spanish translator was secured for the orientation meetings and testing site and the proposal was resubmitted to the University of Texas at Arlington IRB. After approval was granted, recruitment and enrollment involved both English and Spanish speaking women who qualified for the study.

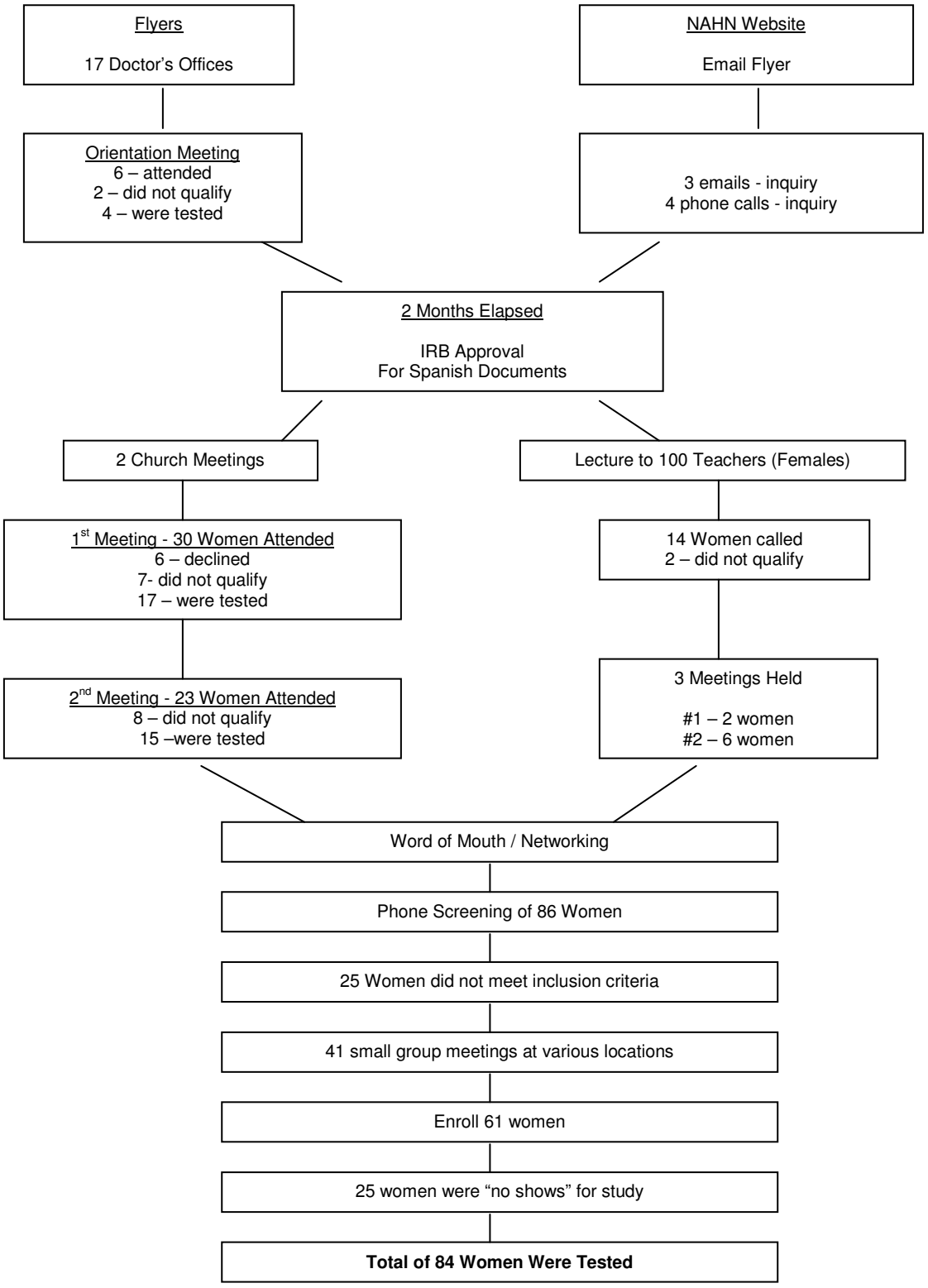


Figure 5. Recruitment and Enrollment Phases of Study

Figure 5 identifies two major recruitment audiences: two churches and a presentation to 100 female teachers. One church meeting occurred because one woman had received information about the study by word of mouth and knew of other women who were interested in participating. At this meeting, thirty women arrived at the church hall, and the meeting was conducted as outlined in Appendix L. After the information was provided, six women chose not to participate and seven did not qualify for the study because they did not meet the inclusion criteria. As a result, 17 women participated in the study. A Hispanic pastor of a predominantly Hispanic church who had the same CTA test completed at the physician's office where the study was being conducted and heard about the ongoing study established the second church meeting. After learning about his interest in the study from office staff members, the investigator spoke to the pastor and a meeting time after church service was established for the investigator and church members. As outlined in Appendix L and Appendix M, information regarding the study was presented by the investigator and translator. Twenty-three women attended the second church meeting resulting in 15 women meeting the inclusion criteria and participating in the study.

The second mass recruitment approach from among 100 female teachers, at the request of the school nurse, was an hour presentation, which provided information regarding women and heart disease in an effort to raise awareness about women and heart disease. Part of the presentation was a discussion regarding the research study. The presentation included the purpose of the study, inclusion/exclusion criteria, testing modality, compensation, risks and general vicinity of the testing site. At the end of the presentation, the investigator's phone number and flyers were distributed to all of the attendees who were interested in more information regarding the study. There was no screening completed at the end of the meeting. The women were instructed to contact the investigator for further information and arrange for a group or individual meeting at a later date. When a woman called inquiring about more information about the study, the investigator provided all of the information and answered questions. The investigator then reviewed the inclusion criteria and identified if the woman qualified for the study. Fourteen women called inquiring about more information and after telephone screening was

completed, 12 women met the inclusion criteria and participated in the study. For convenience purposes of the women, the primary place that these 3 small group meetings were held was at a restaurant in the school district in which these teachers worked. The women were required to meet prior to meeting at the testing site because, as outlined in Chapter 3, additional information regarding the study was provided.

After women were tested, they autonomously started networking and talking to friends and family members regarding the study. A few women who had completed the study asked for flyers for distribution to others. Some of the women provided other women with the investigator's phone number. At this point, the protocol was adapted again to assist in successful recruitment for the study. When an individual woman called the investigator about the study, the same information about the study was provided, but phone screening was completed by identifying the inclusion criteria. After all questions were answered and the woman, who met the inclusion criteria, wanted to proceed with the test, a meeting time and place was established. This type of phone recruitment yielded phone screening of 86 women with 61 women enrolling in the study.

In addition, if a woman was calling for information about the study and she knew of other women who were interested, a meeting was established for a small group. There was no phone screening completed at this time. In this case, women who attended the 45-60 minute meeting were all provided with information about the study (See Appendix L and Appendix M) and the inclusion criteria were identified. As illustrated in Figure 5, the investigator met with potential subjects at 41 small group meetings in various places such as private homes, backyards, front porches, restaurants, laundromats, coffee shops, ice cream shops, libraries, parks, and a doctor's office. These meetings involved anywhere from meeting with single individuals to groups of 2 -12 women.

Orientation to the Study

An overview of the study was given by the investigator if the potential subjects were English speaking (See Appendix K for Flowchart of the Study and Appendix L for Orientation Meeting Script). Spanish speaking women received all of the information through a translator in

the presence of the investigator (See Appendix M). The investigator, who is also Hispanic, understands Spanish but has limited conversation skills. As a result, the investigator was able to understand and answer all questions with the assistance of the translator. The overview and orientation meeting took approximately 45-60 minutes. The content of the overview, as outlined in Appendix L, included an introduction; the purpose of the study; discussion of inclusion/exclusion criteria; consent to testing; review of the Demographic Form (See Appendix N and Appendix O); discussion of medications required prior to and during testing (See Appendix P and Appendix Q); location of the study; overview of testing day; and, compensation for time. The translator read a Spanish version of the information to the women (See Appendix M). Any subject who attended the orientation and did not meet the inclusion criteria received a $10 gift card and was advised that she was not eligible for the study. If a potential subject was allergic to beta-blockers, Iodine, shrimp, shellfish or contrast dye, pregnant, or had asthma requiring daily bronchodilators, the subject was excluded and a $10 gift card provided. If the potential subject did not want to have radiation exposure, the subject was excluded and a $10 gift card provided.

The potential subjects were informed that on the day of testing, a urine pregnancy test would be completed in addition to a 1 cc blood draw to check the kidney function and cholesterol level. They were told that if they were pregnant or if their kidney functions was abnormal they would be excluded from the study and be given a $10 gift card. The renal function was to be calculated by the DaVita calculator, which is standard use of the office. If the kidney creatinine level was greater than 1.2 mg/dL, glomerular filtration rate (eGFR) was less than 30mL/min, or the urine pregnancy test was positive, the subject was excluded from the study and provided with a $10 gift card. In addition, if the Cholestech ® values were out of range as suggested by the manufacturer, the subject was excluded and provided with a $10 gift card.

Potential risks and benefits were presented to the potential subjects. Subjects were informed that the IV site that would be established by the CT technician would be the site where blood would be drawn for lab testing and where they would receive a radioactive dye injection for the heart scanning process. The IV insertion could potentially cause minor pain and discomfort at

the site. The potential subjects were informed they might experience a hematoma or bruising at the site. They were reassured that it would resolve in a few days if they developed a bruise or hematoma. Once the test was completed, the IV would be discontinued by the CT technician. Pressure would be held for 5 minutes at the site, and a dressing with gauze and hypoallergenic tape would be applied to the site. The subject was to call the investigator at any time, if bleeding, bruising or a hematoma had developed. Four hours after the test had been completed, the subject was permitted to remove the dressing and apply the Band Aide to the site. The Band Aide could then be removed the next day. An additional risk to participating in the study was the risk of taking the beta blockers required to slow the heart rate. A slower heart rate has the potential to cause lightheadedness, dizziness or nausea. Potential subjects were informed that the exposure to a small dose of radiation, three millisievert, a dose equivalent to living in the U.S. for one year, would not cause any physical symptoms. The heart scanning process would not cause any pain except for minor positional discomfort. The potential subjects were informed that pillows would be placed under their head and knees for comfort measures (See Appendix R). The potential subjects were informed that the CT technician, cardiologist and investigator, an acute care nurse practitioner, would be present at all times for the testing procedure. All were trained in emergency care with emergency equipment readily available if necessary. The potential subjects were reassured that they would not incur any cost from participating in the study and money would be provided to the subject to purchase the oral beta-blocker required for testing.

The potential subjects were told the benefits from participating in the study included free $2000 cardiac testing. The women could also learn about CVD risk factors and have their blood pressure and cholesterol levels evaluated for free. At the end of the study, if the subject requested, all testing results would be sent to her primary care physician and/or a copy would be mailed to the subject.

All potential subjects who met the inclusion criteria were invited to participate in the study and complete the same testing mechanisms. Once the inclusion criteria had been established

and met, and questions had been answered, the potential subjects were given copies of the consent forms. They had approximately 10-15 minutes to read the documents, and the investigator was available for questions. If a participant did not wish to sign the consent forms and proceed on with the study, the subject exited with a $10 gift card. After the subjects had signed the consent forms, the investigator distributed a Demographic Form (Appendix N and Appendix O). The investigator read the English version of the form to the women, and they circled their answers. When necessary, the translator read the Spanish version. The study consent form (See Appendix S and Appendix T), the CTA consent form (Appendix U and Appendix V) and the Demographic form were collected at the time when the investigator obtained the blood pressure and radial heart rate of each subject at the end of the orientation meeting. Two blood pressures in the non-dominant arm were conducted 2-3 minutes apart utilizing the same Amron® blood pressure device. The average of the two was the blood pressure reading utilized to determine the beta-blocker medication dosage. The blood pressure and heart rate values were documented on the Demographic form (Appendix N and Appendix O). It took approximately 5 minutes per subject. If the individual met the inclusion criteria, signed the consent forms, and baseline blood pressure and heart rate were established, the subject was included in the study.

The Instructions Prior to Testing Form (Appendix W and Appendix X) was given to each subject with medication dosages of Corgard, a beta-blocker, based on the individual's blood pressure and heart rate as titrated by the Corgard Titration Form (Appendix Y). The investigator determined the Corgard dosage according to the sliding scale. Part of the pharmacokinetics of beta-blockers includes decrease of blood pressure and heart rate. If a subject had a significant decrease in blood pressure and/or heart rate, she may have experienced lightheadedness, dizziness or nausea. In an effort to reduce the possibility of this occurring, the Corgard was prescribed, on an individual basis, based on baseline blood pressures and heart rate obtained with the Omron® device at the orientation meeting. If the subject experienced any of these adverse effects of the beta-blocker, she was to drink additional fluids, lie down with her feet

elevated and contact the investigator. As noted in the review of literature, the optimum heart rate for CTA testing is less than 60 BPM. If the systolic blood pressure was less than 100 or the heart rate was less than 60 BPM, no medication was required prior to testing. The subject was provided with a form discussing the types of medications used in the study and the risks involved (Appendix P and Appendix Q).

Testing Day

The subject took the prescribed dosage of Corgard the morning of the day of testing. Upon arrival to the testing center, the subject completed a urine pregnancy test. The investigator conducted the dipstick E.P.T™ urine pregnancy test once the subject had provided a urine sample. The results were verified by both the investigator and the subject to ensure the results were understood by both parties. The investigator and the subject initialed the Urine Pregnancy Form (See Appendix Z and Appendix AA). If the pregnancy test was positive, the subject was excluded from the test with a $10 gift card because part of the inclusion criteria of the study stated that the subject was not pregnant during the study. If the pregnancy test was negative, the subject proceeded on with testing after the investigator had verified the signed consent form for the study and for the CTA testing.

The investigator measured the height, weight, and waist circumference (see Figure 5 and Figure 6 for protocol) of each subject and docqmented the findings on the Data Collection Form (Appendix E). The Body Mass Index was calculated (See Appendix BB) and documented on the Data Collection Form. The subject was then escorted to an exam room where the CT technician or CTA registered nurse started an IV access with a BD Vialon Saf-T-Intima 18 or 20-gauge catheter (Appendix H). The trained CT technician or nurse established the IV site and patency. There was one CT technician for CT testing of all of the subjects to ensure consistency of testing protocols. The size of the catheter utilized depended on the size of the subjects' veins and was at the discretion of the CT technician or nurse. Three subjects required a second IV attempt for a patent IV site. One cc of blood was drawn from the established IV site from the BD Vialon Saf-T-Intima catheter port, and an "iSTAT" and a Cholestech were computed to establish normal kidney

function via BUN/creatinine testing and lipid panel testing, respectively. See Appendix CC for instructions for using the "iSTAT", Appendix DD for Determination of eGFR and Appendix I for lipid testing. The results of the "iSTAT" were logged in the lab Log Book for compliance issues of the testing site. No identifying subject information was documented in the Log Book. The results of the iSTAT, eGFR and lipid testing were documented on the Data Collection Form (Appendix E). As established by the inclusion criteria of the study, a subject needed to have a creatinine level of 1.2 mg/dL or less and an eGFR less than 30mL/min, in order to proceed with CTA testing.

The subject was positioned supine on the table of the Philips Brilliance ™ 64 slice CT scanner. A pillow was placed under the head and knees for comfort measures. The patient rested her arms over her head on the pillow. (See Appendix R) The established procedure for CTA of coronary arteries, as established by the cardiologist, was utilized (See Appendix EE for Procedure for CTA of Coronary Arteries). The patent BD Vialon Saf-T-Intima catheter was securely attached to the Medrad Stellant™ device by the CT technician, for dual injection of Normal Saline and Omnipaque® 350 per standard protocol programmed in the Philips Extended Brilliance™ Workspace. If the heart rate was not below 60 BPM, Lopressor 5mg was given slowly intravenously by the CTA staff registered nurse. If the heart rate did not decrease to 60 or below after 5 minutes, the subject was excluded from the study with a $25 gift card.

Prior to injection, the Philips Brilliance ™ 64 slice CT scanner gave a 5cc test dose of Normal Saline to assess for patency of the IV site. If the IV was not patent, the IV was discontinued by the CT technician and pressure was held at the site for 5 minutes to achieve hemostasis. After hemostasis had been achieved, a pressure dressing was applied and another IV site was established by the CT technician. During the scanning procedure, the blood pressure and heart rate were monitored by the Philips M3 ™ M3046A device. The trained CT technician, the investigator, a trained cardiology acute care nurse practitioner, and a cardiologist observed the procedure. The first view obtained was a "Scout" which was a non-contrast computed tomographic scan of the chest using the Philips Brilliance ™ 64 slice CT scanner with attention to the heart, great vessels and coronary arteries. The Philips Brilliance ™ 64 slice CT scanner

automatically said “Breath in and hold your breath” in either English or Spanish. This was a 5.2-second phase. The scanner then told the subject to “Relax” in either English or Spanish. Multiple high resolution 64 slice computed tomography images of the heart and adjacent vascular structures were obtained using 0.625 collimation with a slice thickness of 1.0 mm in the axial plane with 0.2 pitch with 400ms gantry rotation using 512-acquisition matrix.

A rapid intravenous infusion of 100cc of non-ionic radiopaque contrast media (iohexol 75%; Omnipaque ®-350) was administered during a single held breath, followed immediately with a 40cc saline infusion to optimize contrast density. Electrocardio-graphic retrospective gating was used with a rate-related gating protocol to minimize motion artifact. Unedited axial images were processed with the Philips Extended Brilliance ™ Workspace and displayed using two-dimensional and three-dimensional images in the axial, sagittal, and coronal planes. Left ventricular function and wall motion were assessed in the long and short axes and ejection fraction was calculated using the Simpsons Rule Technique programmed in the Philips Brilliance ™ 64 slice CT scanner.

After the scan was completed, the subject was assisted to the sitting position, and a blood pressure and heart rate were obtained. If the blood pressure was greater than 100 systolic or at baseline and the heart rate was greater than 60 BPM or at baseline, the subject stood from the table. A snack was provided to the subject. If the blood pressure was less than 100 or the heart rate was less than 60 beats per minute, the subject was provided with a snack and fluids and the vital signs were rechecked in 5 and 10 minutes. The subject was not discharged from the study until the systolic blood pressure was above 100 or at baseline and the heart rate was above 60 BPM or at baseline. The vital signs were documented on the Data Collection Form (Appendix E).The BD Vialon Saf-T-Intima catheter was then discontinued and immediate pressure was applied to the IV site until all bleeding had stopped and hemostasis was achieved. A pressure dressing of 4 2x2 gauze pads and hypoallergenic wrap was applied for security. The subject was sent home with a secure pressure dressing. The subject was to maintain the pressure dressing for 4 hours after the procedure, and then the dressing could be removed and a Band Aide,

supplied to the subject, could be applied to the site. The subject could remove the Band Aide the next morning. After hemostasis had been achieved and the vital signs were stable, testing was completed and the subject was provided with a $25 gift card. (See Appendix FF and Appendix GG for Instructions after Testing).

Once the scanning had been evaluated by the cardiologist, approximately one week later, the results were called to the subject. The results from the scanning, Cholestech and iSTAT were forwarded to the primary care physician if the subject requested. In addition, the results were mailed or emailed to the subject if she requested records for her file.

Ethical Considerations

This study, a minimally invasive procedure, required IV access through which an injection of a radioisotope was delivered and from which 1cc of blood was collected. The radioisotope exposed the subjects to 3mSv of radiation, which is essentially equivalent to what the subject would normally be exposed to in her daily living for one year in the U.S. To ensure subject safety, the study design ensured that risks to the subjects were minimized; informed consent for participating in the study was appropriately obtained; an informed consent for CTA was obtained; the investigator supplied adequate provisions for monitoring for subject's safety; and adequate provisions were made to protect the privacy of the subjects and to maintain confidentiality of data collected. To ensure safety of the subject, no subjects were selected if they were allergic to any of the medications utilized in the study. The subject had the right to participate voluntarily and the right to withdraw at any time. Informed consent for participating in the study (Appendix S and Appendix T) and an informed consent for the CTA of the coronary arteries (Appendix U and Appendix V) were obtained and the subject had the right to ask questions at any time. A board certified cardiologist and board certified acute care nurse practitioner, both certified to provide advanced life support measures, were always available for each aspect of the study. An emergency crash cart with emergency medications was always available in the testing area. All procedures completed during the study were completed by board certified nurses, board certified nurse practitioners, board certified nuclear technicians and a nuclear board certified cardiologist.

When data were collected, there were no identifying markers present to connect information to a participating subject to ensure confidentiality.

This study had no immediate benefits for the subjects, other than they received the results from all of the testing completed in the study. Results of the testing were also sent to their primary care physician, if the subject made this request. The findings from this study could have potentially demonstrated the premise and need for additional studies in this understudied population. The CTA of coronary arteries and Cholestech testing had been widely studied as demonstrated in the review of the literature. The proposed testing instruments were mechanisms utilized on a daily basis and were considered as part of prudent evaluative care in the field of cardiology. The testing instruments were all FDA approved and have had rigorous testing completed prior to marketing of the product. A benefit of this study is that the subject received approximately $2000 of free, state of the art cardiovascular testing. The potential risks involved were minimal. None of the subjects experienced discomfort that was not resolved within a few seconds during the procedure of starting the IV, which was completed by a trained board certified technologist or registered nurse. All of the subjects reported having a previous IV and were aware of the temporary discomfort. During the scanning procedure, the subjects did not experience any discomfort related to the injection other than a slight warm feeling throughout their body. While scanning, in a supine position, all positional comfort measures were taken to ensure a comfortable position for the subject. Obtaining height, weight, and waist circumference offered minimal if no harm or discomfort. The subjects' time during the study was minimal by concise organized scheduling during the testing day. Subjects were in the office no longer than 2-2 ½ hours on average. However, there were a few days when the waiting time was up to 4 hours due to office scheduling. The lipid testing results were discussed with the subject and forwarded to the primary care physician, if preferred by the subject. The cardiologist read the images and filled out the forms with the results (Appendix D). A formal letter with the CTA results and lipid results were mailed to the primary physician if the subject consented. In addition, a few subjects did not

have a primary care physician but requested a copy for their personal records. As a result, a record was either mailed or emailed to the subject at their preference.

Data Analysis

The data were collected by the investigator and transcribed onto the Coronary CTA Data Collection Form (Appendix D) and the Data Collection Form (Appendix E). The CTA Cors Data Collection Form (Appendix D) was stored on the investigator's personal computer (PC) and a back up copy stored to disk. The linkage log (Appendix HH) was stored on the investigator's PC with a back up stored disk at her home. The signed consent forms and the original data were stored separately under lock and key in room 508 in Pickard Hall at the University of Texas at Arlington and will remain there for 5 years. The Linkage Log and the Coronary CTA Data Collection Form variables were coded for data entry and data analysis, and there were no identifying marks on the data entry forms. Prior to saving data and in effort to reduce error, the investigator printed the data file and verified the PC entry on the Linkage Log and the Coronary CTA Data Collection Form with the hand written information transcribed on the Data Collection Form. This process of cleaning the data allowed for accuracy of data entry.

Descriptive statistics were used to describe the distributional characteristics of each variable. For interval level measures, means and standard deviations were computed. For ordinal levels measures, frequencies were examined. SPSS 15.0 for Windows software (SPSS, Inc., Chicago, IL) was used for statistical analysis.

Delimitations

In an effort to specifically explore the relationships between coronary plaque burden, cholesterol levels, and waist circumferences of PMHW, the investigator identified inclusion criteria specific to the population of interest. The subject had to be a female between the ages of 25-45 with a Hispanic heritage. Another delimitation was that the women had to have at least three risk factors to participate in the study.

Summary

This chapter outlined the steps of the research process evaluating CAC, lipid levels and waist circumference by current state of the science testing modalities. Modifications to the recruitment strategies were made in an effort to recruit more women. The recruitment flyer had the inclusion criteria posted which gave the women an option of self-selection if they were eligible for the study. If they were interested in participating in the study and self determined that they met the inclusion criteria, the women convened for an orientation meeting. A review of the study was outlined and the women, again, had the option to exit the study. There was no coercion in recruitment of these women. All of the women who qualified for the study were invited to participate. The women had an opportunity, at any time, to ask questions pertinent to the study. If a woman requested, all testing results were forwarded to her primary care physician. Subjects were informed of all the risks and benefits of participating in the study. All of the women were required to consent to participation of the study and to the CTA testing which required exposure to low dose radiation. The women were assured that the investigator, cardiologist and staff conducting the study were all board certified in their specialty areas, and emergency equipment was readily available should an adverse reaction occur. All of the testing modalities outlined in this chapter occur in clinical practice on a day-to-day basis and are considered as part of usual and customary cardiac care and are all approved by the U.S. Food and Drug Administration. This study assessed if there were any correlations between age, coronary plaque burden, cholesterol levels, BMI and waist circumference in this population.

CHAPTER 4

RESULTS

The recruitment phase of the study involved talking to approximately 175 women either by phone or at meetings. As illustrated in Figure 5, a total of 48 women were enrolled and tested from the recruitment strategies of flyers in the doctors' offices (4 women), church meetings (32 women) and the presentation to the teachers (12 women). The 41 small group meetings yielded enrollment of 61 women. Throughout the 41 various small group meetings (See Appendix L and Appendix M for Orientation Meeting), some women chose not to participate in the study after hearing the information about the study. Some women did not give a particular reason why they did not want to participate, and other women expressed reasons for not participating such as fear of the testing procedure, the distance to the testing site, lack of childcare availability, and fear of the results. After enrolling women who qualified for the study and who consented to participation, 25 women did not appear for the study on the scheduled date. Follow up phone calls were made and various reasons for not appearing for the study included the lack of interest, their husband did not allow them to participate, forgetting about the study, forgetting to take the medicine prior to the study, work and childcare related issues. Fifteen of the women did not return the follow-up phone call. Two women did reschedule their appointment for a later date and did participate in the study. A total of 84 women enrolled and completed the study. Of the 84 subjects, 29 subjects requested test results to be sent to their physician, 24 subjects requested test results be sent to them for their personal files, and 31 subjects did not want a copy of test results.

Three enrolled women who initially qualified for the study arrived for the study, but the urine pregnancy test determined that the women were pregnant. As a result, they did not participate in the study. Additionally, four women did not complete the study because their heart rate did not drop below 60 bpm as required for scanning purposes. No one was disqualified from

the study based on the eGFR measurement. Three women had allergic reactions to the Iodine injection and all received standard medications per office protocol. These three women completed the study without difficulty.

Sample Demographics

The study sample consisted of 84 PMHW (n = 84) with the mean age of 38 (SD 5). The subjects' ages ranged from 25-45 years with 6% between the ages of 25-29, 14% between the ages of 30-34, 40% between the ages of 35-39 and 40% between the ages of 40-45. The mean height was 62.62 inches (SD 3) and the mean weight was 175.62 lbs (SD 42). The range of the weights varied from 140 lbs to 287 lbs. The calculation of BMI demonstrated a mean of 31.40 (SD 7) (See Table 13). The percentages of BMI classification demonstrated that 21% of the subjects were in the normal BMI range (18.5 – 24.9), 24% were in the overweight range (25 – 29.9) compared to the 73% as noted on Table 1 (Chapter 1). Fifty five percent of the women in the study were classified as obese (>30). The women in this study were heavier in comparison to the prevalence of obesity (39%) in Mexican American women as noted on Table 1. The waist circumference measurements ranged from 28 inches to 53 inches (Mean of 39, SD 38) with 81% of the subjects having waist measurements >35 inches.

Table 13. Demographic Data of PMHW (n = 84)

Variable	Mean
Age	38 yrs Prevalence %: 25-29 yrs - 6% 30-34 yrs - 14% 35-39 yrs - 40% 40-45 yrs - 40%
Height	62.6 inches

Table 13. – *Continued*

Weight	175.6 lbs
BMI	31.4
BMI	BMI Range % 18.5–24.9 – 21% 25-29.9 – 24% >30 – 55%

Results of Risk Factors Contributing to the Development of CHD

Hypertension

Table 14 summarizes the percentage of women with risk factors contributing to the development of CHD: HTN, diabetes, tobacco usage, physical inactivity and family history for CHD. Ninety percent of these women reported no previous history of a HTN diagnosis, while 10% reported taking medication for HTN. At the time of enrollment into the study, 46% of the women were normotensive and 54% of the women demonstrated elevated blood pressures $\geq$ 120/80 mmHg, as classified by JNC VII guidelines (See Table 5), suggesting a need for potential pharmacologic intervention. Of the 54% of the women with elevated blood pressures $\geq$ 120/ 80 mmHg, 29% were Pre-Hypertensive, 20% were Stage I Hypertensive and 5% were Stage II Hypertensive.

The prevalence of HTN in this study was slightly higher in comparison to the national statistics with 54% of the women hypertensive at the time of the orientation meeting in comparison to the 25.1% of Mexican American women reported by the National Center for Health Statistics, 2007. In this study, 10% of the subjects were taking anti-hypertensive medications and were being monitored by their physician. According to the National Center for Health Statistics, 2007, 25.1% of Mexican American women between the ages of 20-74 years (age adjusted) had HTN. (http://www.cdc.gov/nchs/data/hus/hus07.pdf). Caution should be used in comparing the data in this study versus national statistics because of the age criteria for this study (25-45 years) in comparison to the age adjusted (20-74 years) data.

The prevalence of diabetes in this study was essentially reflective of the national statistics with 11% of the women diabetic, all of whom were on medications, in comparison to the 10.9% of

Hispanic women according to the National Center for Health Statistics, 2007 (http://www.cdc.gov/nchs/data/series/sr_10/sr10_235.pdf). Caution should be used in comparing the data in this study versus national statistics because of the age criteria for this study (25-45 years) in comparison to the age adjusted (18 years and older) data.

Table 14. Risk Factors Contributing to the Development of CHD Compared to Table 1 National Statistics

Risk Factor	Current Study Percentage (%)	National Statistics 2007 (Mexican American)
HTN	23%	31%
Diabetes	11%	Not available
Tobacco Use	7%	11%
Physical Inactivity	68%	22%
Family Hx for CHD	53%	Not available

Tobacco Use

Six percent (n = 5) of the women reported tobacco use with .5 pack year as the least amount smoked and 3 pack year as the highest amount smoked. There was essentially little difference in the women in this study in comparison to national statistics when evaluating tobacco usage in women of the same ethnic background and age group. According to the CDC's Morbidity and Mortality Weekly Report, approximately 10.5% of Hispanic women between the ages of 18-44 smoke. (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5731a2.htm).

Physical Inactivity

Sixty-eight percent (n = 57) of the participants reported that they do not exercise. One percent exercised once weekly; 6% exercised twice weekly; 16% exercised 3 times weekly; 1% exercised 4 times weekly; 5% exercised 5 times weekly; 2% exercised 6 times weekly and 1% exercised 7 times weekly. This is in contrast to the CDC's Behavioral Risk Factor Surveillance System (BRFSS) report (2007) indicating that an estimated 40.5 % of Hispanic women (age

adjusted) exercise moderately for 30 minutes five or more days a week (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5646a1.htm#tab). The women in this study were more inactive in comparison to the 22% reported in the 2007 BRFSS report.

Family History

Genetic predisposition is another identified risk factor for the development of CHD. With regard to parental family history (PFH), mother or father or both, for cardiovascular risk factors, 53% responded "yes" to having PFH of "heart problems", 43% reported a PFH for high cholesterol, 23% reported a PFH for having a myocardial infarction, 60% had a PFH for diabetes and 49% had a PFH for HTN. Of the subjects who responded "yes" to having sibling family history (SFH) for cardiovascular risk factors, 4% responded "yes" to having "heart problems", 23% of SFH had high cholesterol, 1% of SFH had had a myocardial infarction, 26% of SFH had diabetes and 23% of SFH had HTN. The women in this study reported a high incidence (53%) of positive CVD risk factors in family members. Unfortunately, national statistics for family history are not available for comparison.

Metabolic Syndrome: A Combination of CVD Risk Factors

Many of the women in this study had several elements that constitute Metabolic Syndrome (MS). MS is diagnosed by having at least three of these five risk factors: waist measurement $\geq$ 35 inches, a fasting TRG level $\geq$ 150 mg/dL, an HDL $<$ 50 mg/dL, blood pressure $>$ 130/85 and a fasting glucose $\geq$ 100 mg/dL (http://www.nhlbi.nih.gov/health/dci/Diseases/ms/ms_diagnosis.html). Descriptive data revealed five of the five factors of MS. However, the blood pressure factor could not be adequately assessed based on the isolated blood pressures taken during the enrollment phase and the beta blockade attenuated blood pressures the day of testing. Assuming that the blood pressures taken during the enrollment phase were an accurate reflection of their true blood pressure readings and could be used as an MS variable, 70% of the women had MS. Thirty percent of the women had at least 1 risk factor, 28% had 2 risk factors, 32% had 3 risk factors, 7% had 4 risk factors and 3% had all 5 risk factors for MS.

Results Contributing to the Etiology of CHD

Hypercholesterolemia

Table 15 summarizes the percentage of women with hypercholesterolemia and obesity risk factors, which contribute to the etiology of CHD (See Figure 1) as compared to data from Table 1. The values noted for hypercholesterolemia on Table 15 are the recommended values set by NCEP-ATP III. As shown on Table 14, 26% of the women had cholesterol levels ≥200 mg/dL in comparison to 50% of Mexican American women as reported in national statistics. The women in the study had cholesterol levels ranging from 117 mg/dL to 291 mg/dL.

The cholesterol data from the study can be compared to the national statistics. According to the National Center for Health Statistics, 2007, from 2001-2004 approximately 12.8% Mexican American women between the ages of 20-74 years (age adjusted) had serum cholesterol levels ≥ 240 mg/dL (http://www.cdc.gov/nchs/data/hus/hus07.pdf). Again, as noted with the decrease in the CVD prevalence in comparison to national statistics, these PMHW demonstrated cholesterol values that were below the national statistics. A factor that may be contributing to the variations of prevalence is that the national statistics are based on the ages between 20-74 years (age adjusted). The PMHW in this group were between the ages of 25 – 45 and may not have values that reflect the national characteristics. Additionally, the national statistics computed data based on cholesterol levels > 240 mg/dL referencing the Second Report of the National Cholesterol Education Program Expert Panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults as its standard. The recommendations mentioned in Table 3 are based on the Third Report of the National Education Program (NCEP) expert panel on Detection, Evaluation, and Treatment of High Cholesterol in Adults (ATP III).

Table 15. Demographic Data of Participants: Lipids, BMI and Waist Measurement Compared to Table 1 National Statistics

Hypercholesterolemia	Percentage (%)	National Statistics 2004 (Mexican American)
Total cholesterol >200 mg/dL	26%	50%
LDL >130 mg/dL	50%	31%
HDL < 40mg/dL	28%	13%
Triglycerides > 150 mg/dL	42%	Not available
Obesity	Percentage (%)	
BMI $\geq$ 24.9 BMI $\geq$ 30	79% 55%	73% 40%
Waist > 35 inches	81%	Not available

Approximately 50% (n = 42) of the subjects had an LDL level <100 mg/dL with 35% in the 100-130 mg/dL range. Fifty percent of the women had LDL levels > 130 mg/dL with 15% having LDL levels as high as 200 mg/dL. In contrast, 31% of the Mexican American women nationally had LDL levels > 130 mg/dL indicating that the women in this study had a higher prevalence of dyslipidemia in comparison to national statistics. Only 6% of the participants reported being on statin therapy for hypercholesterolemia despite many more demonstrating a dyslipidemic state as noted on Table 15. Four women, 5% of the participants, had LDL levels >160 indicating need for pharmacologic intervention based on ATP III guidelines for LDL reduction (Table 3). However, these four women were not on pharmacologic therapy. ATP III guidelines recommend an LDL level less than 130 mg/dL if a person has two cardiovascular risk factors. Risk factors for the development of CHD are noted in Table 14 with 23% having HTN, 11% having diabetes, 7% smoked, 68% were physically inactive and 53% had family history for CHD. Forty two percent of the women had at least one risk factor for the development of CHD with 43% having 2 risk factors and 15% having 3 risk factors. These data demonstrate that many more than the 6% who were

on pharmacologic therapy would benefit from pharmacologic intervention and lifestyle modifications according to national treatment guidelines.

Approximately 60% (n = 51) of the subjects had HDL levels < 50 mg/dL, which is considered to be the lower end of the goal HDL, with only 40% of the subjects at recommended national guideline levels. Of these women, 28% had an HDL less than 40 mg/dL. The national average for Mexican American women was 13% again indicating the women in the study have a higher prevalence of dyslipidemia in comparison to national averages.

Fifty-eight percent (n = 49) of the subjects had a desired triglyceride level of <150 mg/dL while 42% had hypertriglyceridemia according to national guidelines. The highest fasting TRG level in this sample was 394 mg/dL in comparison to the recommended goal of <150 mg/dL. The subject who had this elevated triglyceride level was not on medication and had never been previously screened for hyperlipidemia.

All of the women, as noted on Table 15, who demonstrated any of these lipid abnormalities (cholesterol levels >200mg/dL (26%), LDL >130 mg/dL (50%), HDL <40 mg/dL (28%)or triglycerides >150mg/dL (42%)) would benefit from lifestyle modifications and pharmacologic intervention to achieve a lipid panel within national guideline recommendations. Seven percent (n=6) of the women had all four forms of dyslipidemia.

Obesity

Seventy-nine percent (n = 67) of the women in the study were classified as being above normal weight with 24% classified as overweight (BMI $\geq$ 24.9) and 55% classified as obese (BMI $\geq$ 30) (See Table 4 for BMI Classification). Between the years 2001- 2004, 73.2% of Mexican American women between the ages of 20-74 years (age adjusted) were considered overweight with a BMI $\geq$ 25. Approximately 40.3% of Mexican American women between the ages of 20-74 years (age adjusted) were considered obese with BMIs $\geq$ 30. The PMHW in this study were heavier, according to BMI's, in comparison to national averages with 55% of the women having BMIs' $\geq$ 30 while the national statistic was 40.3% of the women having

BMIs ≥ 30. (http://www.cdc.gov/nchs/data/hus/hus07.pdf). Caution should be used in comparing the data in this study versus national statistics because of the age criteria for this study (25-45 years) in comparison to the age adjusted (20-74 years) data.

Forty-four percent (n = 37) of the subjects were classified as obese (BMI ≥ 30), with some form of dyslipidemia suggesting a need for lifestyle and pharmacologic intervention. Of the women with both of these CVD risk factors of a BMI > 30 and a form of dyslipidemia, 13% had cholesterol levels > 200 mg/dL; 7% had a cholesterol level > 240 mg/dL; 6% had an LDL > 130 mg/dL ; 24% had an HDL < 40 mg/dL and 42% had a triglyceride level > 150 mg/dL.

By virtue of meeting the inclusion criteria for the study with risk factors contributing to the etiology and development of CHD, all of the women are at risk for developing CHD. More than half (64%) of the women were obese with some form of dyslipidemia. Of the 81% of women who had a waist circumference > 35 inches, 51% had an HDL < 50 mg/dL. As previously mentioned, an increased waist circumference >35 inches and an HDL <50 mg/dL are both risk factors for developing CHD. Furthermore, an obese woman (BMI > 30) with an increased abdominal girth > 35 inches has two risk factors for CVD: obesity and increased abdominal girth. At this time, there are no national statistics regarding the prevalence of increased abdominal girths in any population.

Even though 52% of the subjects reported having medical insurance and were under the care of a physician, 26% of the women had cholesterol levels above national guideline recommendations; 28% had an HDL less than national guideline recommendations; 42% had triglyceride levels higher than national guideline recommendations, but only 6% of the women had prescriptions for antidyslipidemics. Almost a quarter of the participants, 23% of the women, had elevated blood pressures; however, only 10% had prescriptions for antihypertensive medications.

Assessment of Coronary Plaque Progression

Coronary computed tomography angiography was normal for 83 of these women. In only one case, coronary CTA revealed a non-obstructive <20 % of soft plaque accumulation in the

proximal left anterior descending artery. This subject reported having hyperlipidemia and HTN and had a family history for myocardial infarction, hyperlipidemia and HTN. She is being treated by her physician for her hyperlipidemia and HTN. However, her lipid panel remains suboptimal according to national lipid guidelines. She did have appropriate blood pressure management while on antihypertensive therapy. She did have a metabolic syndrome manifested by HTN, hyperlipidemia, obesity and increased abdomen girth.

Summary

The recruitment phase required two modifications in an effort to recruit and enroll women into the study. The recruitment phase involved speaking to 175 women during a 6-month span. Two large group recruitment meetings yielded approximately half of the women enrolled and tested. Many of these women then networked with family members and friends resulting in 41 small group meetings for recruitment and enrollment resulting in an additional 40 women being tested for a total of 84 study participants.

The four outcome measures evaluated were coronary plaque accumulation, cholesterol components, BMI measurement and waist circumference. Only one woman demonstrated coronary plaque in the setting of multiple CAD risk factors. Fifty percent of the women had undesirable LDL and HDL levels that would benefit from treatment, but only 6% were on treatment for dyslipidemia. Fifty-six percent of the women had BMIs $\geq$ 24.9 with some form of dyslipidemia. Eighty-one percent of the women had waist circumferences $\geq$ 35 inches. Even though only one woman demonstrated non-obstructive coronary plaque, 70% of these women had metabolic syndrome, which is manifested by three of five CVD risk factors: HTN, elevated glucose levels, hypertriglyceridemia, HDL <50 mg/dL and an increased abdominal girth. This suggests that 70% of the women have a trajectory toward the development of plaque formation and CVD in the future.

CHAPTER 5

DISCUSSION AND CONCLUSIONS

Relationships between Plaque Burden, Cholesterol, BMI and Waist Circumference In PMHW: Etiology of CHD

Plaque Burden

This study, with a sample of 84 PMHW, demonstrated only one woman with non-obstructive soft plaque in the proximal left anterior descending artery as detected by coronary CTA. This was somewhat surprising as the Hispanic women had multiple CV risk factors. The imaging from CTA specializes in detecting early development of CVD, in the smallest amounts, but in this group of women, with CVD risk factors, only one woman presented with minimal plaque burden via computed angiography. With the specificity that this testing modality offers, one would expect that more women would demonstrate the presence of soft plaque based on the risk factors present that contribute to plaque formation. The results of the study do not explain how or why more women did not demonstrate soft or hard coronary plaque despite the presence of at least three CVD risk factors. However, the CTA results do parallel the results from Kortelainen and Huttumens' (2004) study demonstrating that pre-menopausal women between the ages of 18-49 with enlarged waists and increased abdominal fat had advanced coronary lesions in the left anterior descending artery as the one woman in this study.

Cholesterol

As presented in the framework for this study, hypercholesterolemia and obesity are two risk factors that contribute to the etiology of CHD. The results revealed that 55% of the women were obese with some form of dyslipidemia. The prevalence of hypercholesterolemia in women in this study was notably lower compared to national statistics despite having higher BMIs. In addition, these PMHW had a higher incidence of dyslipidemia in comparison to the WISEWOMAN data where 23% of the women had dyslipidemia. All of the women were provided

with Cholestech results at the end of the study day. The women who were dyslipidemic were referred back to their physicians for additional recommendations. In addition, letters with the results were mailed to the physician. The women who did not have a physician were encouraged to establish a relationship with a physician and have the dyslipidemia addressed. For women in this study, the dyslipidemia was mostly in the LDL, HDL and triglyceride levels, which are often associated with obesity.

Obesity

About the same proportion of women in this study were overweight or obese as in the WISEWOMAN study (75%), but WISEWOMAN participants were older (45-65 yrs of age) (Finkelstein, Khavjou, Mobley, Haney, Will, 2004). A majority of the women in this study, 81%, had a waist circumference > 35 inches. At this time, there are no statistics regarding the prevalence of increased abdominal girths in any population.

Despite having treatable CVD risk factors with 70% of the women having MS, only one woman had minimal non-obstructive coronary artery disease. Even though these women have treatable CHD risk factors and had no plaque burden, they are presumed to be at risk for developing CAD in later years simply by the fact that 70% have MS. These PMHW women did not demonstrate coronary plaque burden, but statistics from 2004 show (Table 1) that at some point these women are likely to develop heart disease. The results of this study do not allow for a clear understanding of how the relationships of plaque burden, cholesterol levels, BMIs and waist circumference are influenced by treatable risk factors.

The role of estrogen was not explored in this study, but thought to have cardio-protective effects that may have contributed to the absence of coronary plaque (Kortelainen and Huttunen, 2004). In addition, adiponectin, a protein hormone secreted by the adipocytes, is associated with cardiac risk. High levels of adiponectin are associated with low cardiac risk and low levels, usually in obese people, are associated with high cardiac risk. Zyriax et al (2008) demonstrated a lower plasma concentration of adiponectin in women with CHD, BMIs $\geq$ 25 kg/m2, waist to hip ratios $\geq$ 0.85, HDLs < 50 mg/dL and smokers. Additionally, when evaluating angiographic coronary artery

progression of coronary lesions of men and women, primarily men, adiponectin plays a protective role in coronary artery disease progression (Liang et al., 2008; Patel et al., 2008).

Development of CHD

The prevalence of HTN (54%) in these PMHW was slightly higher in comparison to the women in WISEWOMAN (38%). An important consideration regarding the participants in this study is that the women were younger (25-45 yrs of age) than the women participating in the WISEWOMAN study (40-65 yrs of age), but the prevalence for HTN was higher.

The women in this study had less physical activity (68%) in comparison to the 22% reported in the 2007 BRFSS report (http://www.cdc.gov/mmwr/preview/mmwrhtml/mm5646a1.htm#tab). This study did not explore the reasons for not exercising. However, the increased physical inactivity rate correlates to the high incidence of dyslipidemia, obesity and increased waist circumference.

Limitations

The results must be considered in light of the limitations of the study. The sample was not a random sample; it was a sample of convenience. There may be a type of bias and clustering of the same type of characteristics in these women because of the convenience element of most women knowing each other and encouraging each other to participate. On one hand, it did assist in the recruitment process because when one or two women decided to participate, they realized that there was nothing to fear while participating. As a result, they in turn contacted their family members and friends and referred them for screening for the study.

To qualify for the study, women had to have CV risk factors such as HTN, hyperlipidemia and diabetes. Prior to participating in this study, many of the women had never been screened for these risk factors. As a result, many women may not have been recruited because of their answers on the demographic form. It is possible they did not meet the inclusion criteria because they were unaware that they indeed did have HTN or dyslipidemia. During recruitment, a diagnosis of HTN could not be made as only 2 blood pressure measurements were taken on one occasion. These women were able to participate in the study because of other inclusion criteria.

Additionally, approximately 50% of the subjects were not aware of their dyslipidemic state, indicating a need for pharmacologic intervention, according to national standard guidelines. Participating in the study inadvertently made them aware of their hypertensive and dyslipidemic states and they were referred to their primary care physician for additional recommendations.

Recommendations

Many of these women were not aware of their hypertensive or hyperlipidemic state because they had never previously been screened. The benefit to knowing that these women, even with CVD risk factors, do not have the early development of CAD is that healthcare providers can be proactive and focus on prevention of CAD and treat according to guidelines. Early screening for risk factors, such as HTN, hyperlipidemia and diabetes, and educating women, especially PMHW, about the importance of detection and treatment of CVD risk factors are essential. Preventive health surveillance is essential.

The screening and evaluation of cholesterol, blood pressure, and blood glucose levels can be monitored either by their personal physicians or at free health seminars and clinics. National guidelines for CVD risk factors such as HTN and hyperlipidemia have been established based on studies conducted primarily on men, but guidance such as the Algorithm for CVD preventive Care in Women has narrowed the gap in appropriate screening and treatment of women with CVD (Mosca et al., 2007).

The Framingham Risk Score does not adequately assess a woman's risk for CVD (http://hp2010.nhlbihin.net/atpiii/calculator.asp?usertype=prof); however, use of a risk calculation, specific to women such as the Reynolds Risk Score, is required to adequately provide a CV risk assessment for women (http://www.reynoldsriskscore.org). This study did not evaluate C-Reactive proteins; therefore, it was not possible to calculate a Reynolds Risk score. Calculation of the Reynolds Risk score is recommended because it would be beneficial as a cardiac risk assessment tool for women.

Women should be aware of risk factors that they can monitor on their own such as weight, waist circumference, smoking and exercise. All women should be screened and

monitored for CAD if they have CVD risk factors because, in women, it is not yet known what catalyst specifically triggers the production of coronary plaque that results in CVD being the number one cause of death among women.

Questions that need further study include: Why did only one PMHW demonstrate plaque burden? What was the deciding factor that made her demonstrate the plaque and not the others? What are the alternative explanations for the results of this study? It is not yet known what the role of hormones, lipid particle size, lipid levels and genetic variation plays in the progression of plaque development in women.

The role of hormones and cardiac protection in women remains unknown at this time. Researchers and scientists have yet to determine what protective measures, if any, hormones play in the aging process and the progression of CVD. It is not yet known if women develop CAD once hormonal levels start to change as women age. Before menopause, women tend to have low CAC scores and negative scans (Wexler et al., 1996: Mieres, et al., 2005) but yet have CVD possibly in the form of soft plaque. CAC scores and other conventional testing modalities reveal hard plaque: they do not provide assessment of soft plaque

It is unknown at what point plaque starts to develop and what circumstances cause the chain reaction of plaque progression leading to CVD. Given the results of this study, studies are needed to confirm the CVD risk factor characteristics of pre-menopausal women of all origins. A descriptive study is needed to evaluate hormonal levels of pre-menopausal women, specifically PMHW, with CV risk factors. The data would establish a baseline regarding hormonal levels of pre-menopausal women of all origins. In conjunction, a baseline coronary CTA would confirm the presence or absence of coronary plaque. A longitudinal study would allow for more descriptive data regarding hormonal levels as the women age. This longitudinal study is needed to evaluate all women, in the pre-menopausal stage through the menopausal stage, and the development and progression of coronary plaque accumulation via CTA in the setting of hormonal changes. Not only should the longitudinal study evaluate coronary plaque progression, it should also assess for treatable risk factors such as HTN, diabetes, hyperlipidemia, tobacco use, obesity and

physical inactivity. However, caution should be used in longitudinal studies and CTAs because of radiation exposure in childbearing age women. As technology advances and techniques improve, radiation exposure concerns may lessen, and the women can be tested more frequently. Additionally, the cost to benefit issue is a concern for future longitudinal studies given that the CTA testing modality is expensive. However, the results examined from the studies may provide information that will assist in prevention and delay of the disease process resulting in lower costs of CVD healthcare and decrease mortality.

Future longitudinal studies evaluating pre-menopausal women with CV risk factors and the presence of estrogen receptors and plasma adiponectin will allow for the evaluation of the levels as the women age. This study may assist in the evaluation of level changes as the women age and assess at which point CVD starts.

The influence of C-Reactive proteins, lipid particle size and lipid levels in this population have yet to be explored. Because clinicians are treating women according to national lipid guidelines that are based on studies from men, a better understanding is needed on the characteristics of lipid profiles and C-Reactive protein levels in pre-menopausal women. Pre-menopausal women may have protective measures due to their lipid particle sizes and C - reactive protein levels. Further evaluation is needed to assess the characteristics of lipid particle sizes, lipid panels and C - reactive protein levels in pre-menopausal women to evaluate a need for lipid guidelines pertinent to pre-menopausal women. A longitudinal study, with repeat advanced lipid particle size analysis, lipid testing, and C - reactive protein levels should be conducted annually as the women age. Additionally, a baseline coronary CTA will assist in the establishment of coronary plaque presence.

Genetic, ethnic and cultural variations may play protective roles in the development of CVD. This study evaluated PMHW who had backgrounds from Mexico, Central America, South America, Cuba and Puerto Rico. The women were categorized as “Hispanic”, “Latina” and “Mexican American” as done in national databases. It is unclear if each of these variations has separate characteristics or whether they can be clustered together. Future studies should include

a pedigree analysis to further assess the genetic influences of women. The results from these few suggested studies would provide data that may suggest additional studies that are to better understand the development and progression of CVD in women. Future studies will allow for information that will provide explanations as to why some women with CV risk factors develop coronary plaque and others do not. More studies will allow for a better understanding on when the CVD starts developing.

Prior to implementing a research study, future investigators need to adequately study characteristics of Hispanic women and assess the community and identify leaders and gatekeepers. These are the people who will help promote the study and assist in establishing trust, which is essential when attempting to recruit and enroll minority participants. Adaptations and modifications of protocols may be required to successfully recruit participants.

In general, there are challenges with recruitment, enrollment and attrition in research studies among Hispanic populations. Is the problem with recruitment, enrollment and attrition due to a knowledge gap and the understanding of CAD as the number one killer for women in this population? Future investigators attempting to recruit and enroll HW for research studies need to go directly to the community, community leaders and gatekeepers for assistance in recruitment. This study benefited from church leaders and teachers who implemented the concept of networking and “word of mouth” which resulted in successful recruitment and enrollment strategies. Future studies regarding the reasons for participating or not participating in research studies would also assist in recruitment efforts.

To date, most cardiovascular clinical trials have been conducted on men, and healthcare providers are treating women with CVD risk factors with risk profiles and guidelines proven to be helpful in men. Future studies evaluating the Reynolds Risk score will assist in a better understanding of CV risk in women. Scientists and healthcare providers do not know if the patterns of the development of CVD for men hold true for women who are either pre-menopausal or menopausal. In women, it is not known if there are specific influences of age, diet, hormones, genetics and culture with regard to the development of CVD.

APPENDIX A

ENGLISH FLYER

A RESEARCH STUDY TO LEARN MORE ABOUT

HISPANIC WOMEN AND HEART DISEASE

IF YOU ARE AN ENGLISH SPEAKING HISPANICFEMALE BETWEEN THE AGES OF 25-45 WITH REGULAR PERIODS (NOT PREGNANT) AND YOU HAVE 3 OF ANY OF THESE RISK FACTORS: HIGH BLOOD PRESSURE, HIGH CHOLESTEROL, DIABETES, SMOKER, OBESE, or HAVE FAMILY HISTORY OF HEART PROBLEMS**

AND

YOU ARE NOT ALLERGIC TO BETA BLOCKER MEDICATIONS, IODINE, SHRIMP, SHELLFISH OR X-RAY DYE

DO NOT HAVE ASTHMA REQUIRING DAILY TREATMENTS

PLEASE CALL TO GET MORE INFORMATION ABOUT RECEIVING FREE HEART AND CHOLESTEROL TESTING THROUGH A RESEARCH STUDY

FOR MORE INFORMATION, PLEASE CALL MARYGRACE- 214-478-4597

***IF YOU ARE CHOSEN FOR THE STUDY, YOU WILL RECEIVE**

$2000 OF TESTING FREE

AND A GIFT CARD

****HISPANIC: Family from Mexico, Puerto Rico, Cuba, Spain, Central or South America and the Dominican Republic**

APPENDIX B

SPANISH FLYER

PREGUNTASE A SU DOCTOR COMO PUEDA APRENDER MÁS DEL CORAZÓN

SI ESTA UNA MUJER HISPANA ENTRE LAS EDADES DE 25 Y 45**
CON MENSTRACIÓN REGULAR (NO ESTA EMBARAZADA) Y TIENE ALGUNAS DEL LOS ELEMENTOS DE RIESGOS: PRESIÓN SANGUÍNEA ELEVADA, COLESTERINA ELEVADA, DIABETES, FUMA, SOBREPESO, o TIENE UNA HISTORIA DEL PROBLEMAS DEL CORAZÓN EN SU FAMILIA
Y

NO ESTA ALERGIO A MEDICACIONES DEL BETA BLOCKERS (BLOQUEOS DEL BETA), YODO (IODINE), O TINTE DE RADIOGRAFÍA
NO TIENE ASMA QUE NECESITA TRATAMIENDO DIARIO
POR FAVOR LLAMA PARA RECIBIR MÁS INFORMACIÓN DEL PRUEBAS LIBRES DEL CORAZON Y COLESTERINA
PARA MAS INFORMACIÓN, POR FAVOR LLAMA A MARYGRACE- 214-478-4597

***SI ESTA ELIGIDO PARA LA PRUEBA, RECIBRÍA $2000 DEL PRUEBAS LIBRES**
Y UNA TARJETA REGALA

****HISPANA: Con familia de México, Puerto Rico, Cuba, España, La América del Centro o Sur, y la Republica Dominicana**

APPENDIX C

LETTER OF SUPPORT

May 5, 2007

Marygrace Leveille, RN, ACNP-CS
625 Meadow Crest Dr
Highland Village, TX 75077

Re: Research study

Dear Marygrace,

Please be advised that you hereby have permission to complete your study in our facility in Grapevine. Please guarantee that the subjects understand fully the purpose of the study and that they give full consent. I understand that the title of the study is "Tu Corazon y Mi Pasion" and you will be evaluating coronary plaque, lipid panels and waist circumference on pre-menopausal Hispanic women.

I will be present for all testing conducted in the office, which includes CTA of coronary arteries, cholesterol evaluation, iSTAT testing and the measurement of waist circumference. I will read and determine the plaque burden percentage as demonstrated on the coronary CTA's. I will also document my findings on the "Coronary CTA Data Collection Form" for your data analysis. My trained nuclear technologists and medical assistants will be available to help during the testing days. As you know, CTA testing is a routine procedure in our office. For your convenience, I am forwarding you our protocols for the CTA testing, iSTAT and Cholestech testing, titration of medication required for the testing and various other materials that may be helpful to you and your study. The protocols that I am sending you describe the routine way in which we perform CTA in our office. We will perform all CTAs using this protocol. All of the supplies required for the testing will be supplied by my office and staff.

It is my pleasure to offer my assistance and expertise in this important matter.

Sincerely,

John A. Osborne, MD, PhD, FACC

APPENDIX D

CORONARY CTA DATA COLLECTION FORM

TU CORAZON Y MI PASION

Coronary CTA Data Collection Form

(Plaque obstruction noted by % per MD reading CTA)

RCA	
Prox RCA	
Mid RCA	
Distal RCA	
PDA	

LAD	
Prox LAD	
Mid LAD	
Distal LAD	
CX	
OM1	
OM2	

APPENDIX E

DATA COLLECTION FORM

TU CORAZON Y MI PASION

Data Collection Form

Date: _____ DOB: _____AGE____ CTA#:_____
Consent form signed: Y N PCP (optional) _____

HT: _____ WT: _____ BMI: _____Waist:_____

IV START: Site: _____ Gauge: _____
# of attempts: _____ Started by: _____
Pre Procedure BP: _____& HR_____

Time	Medication, Amount, Route	BP	HR

End of Procedure BP: _____ HR: _____ Time: _____
BP: _____ HR: _____ Time: _____
BP: _____ HR: _____ Time: _____
BP: _____ HR: _____ Time: _____

IV discontinued: □Yes □No □ Site clean and dry/dsg applied
□Complications:_____
Treatment:_____
Discharge Instructions given: □Yes □No □Understanding verbalized

Signature: _____ Date: _____
iSTAT Results Cholestech Results Pregnancy Test/ eGFR__
*Print out from machine placed in these spots

Potassium	Total Cholesterol
Chloride	Triglycerides
Sodium	HDL
Crt	LDL
BUN	non-HDL

APPENDIX F

PRE-PROCEDURE ASSESSMENT FORM ENGLISH

CARDIOVASCULAR CT

Pre-procedure Assessment Form English

Date:_____

Patient Name:_____ Date of Birth:_____
Phone Numbers: ( ) _____ ( ) _____
Home Cell
Email:_____
Report to be sent to Dr._____
Are you pregnant/nursing? Yes No Not Sure
Are you allergic to radiology contrast? Yes No Not Sure
Are you allergic to iodine? Yes No Not Sure
Latex/tape allergies? Yes No Not Sure
Are you allergic to any medications? Yes No Not Sure
If yes, please list below.

Do you have any of these conditions?
Asthma Yes No Not Sure
Atrial Fibrillation/ Irregular Heart Rhythm Yes No Not Sure
Pacemaker/Defibrillator Yes No Not Sure
Renal Failure or Insufficiency Yes No Not Sure
Intolerance to Beta Blocker Yes No Not Sure
Do you have a history of:
High Blood Pressure Yes No Not Sure
Diabetes Yes No Not Sure
If yes, are you taking Metformin? Yes No Not Sure
High Cholesterol Yes No Not Sure
Prior Angioplasty/Stent Yes No Not Sure
Prior Heart Attack Yes No Not Sure
Prior Heart Bypass Surgery Yes No Not Sure
Myesthenia Gravis Yes No Not Sure
Have you received radiology contrast in the past? Yes No Not Sure
Patient Signature: _____ Date:_____
RN Signature: _____ Date:_____

APPENDIX G

PRE-PROCEDURE ASSESSEMENT FORM SPANISH

CONSENTIMIENTO PARA CT CARDIOVASCULAR

Nombre Piciente _____ Fecha de Nacimiento _____

Numero de Telephono ( )_____Celular ( )_____Email__ß_____

Informe para ser enviado a doctor. Dr. _____

Están yo embarazado o cuidar? Si ___ No ___
¿Usted es alérgico al contraste de radiología? Si ___ No ___
¿Usted es alérgico al marisco? Si ___ No ___
¿Usted es alérgico al yodo? Si ___ No ___
¿Alergias de látex/cinta? Si ___ No ___
Son usted alérgico a medicaciones: Si ___ No ___
Si, nombre de medicaciones:
_____
¿Tiene usted cualquiera de estas condiciones?

Asma/fiebre del heno Si___ No ___
Atrial Fibrillation/Irregular Ritmo de Corazón Si __ No ___
Marcapasos/Desfibrilador Si ___ No ___
Fracaso Renal o Unsufficiancy Si ___ No ___
Intolerancia a Beta Blockers Si ___ No ___
¿Tiene usted una historia de? Si ___ No ___
Hipertensión (Hipertensión) Si ___ No ___
Diabetes Si ___ No ___
Colesterol Alto Si ___ No ___
Angioplasty/Stent previo Si ___ No ___
Ataque Cardíaco Previo Si ___ No ___
Cirugía de desviación de Corazón Previa Si____No___

A recibido usted el contraste de radiología en el pasado? Si ___ No ___

¿Ha hecho hacer usted un análisis de sangre creatinine en el mes pasado? Si ___ No___

Para Uso de Clínica Sólo
For Clinic Use Only

RN notified:_____Date:_____RN Signature:_____

APPENDIX H

ESTABLISHING INTRAVENOUS ACCESS PROTOCOL

TU CORAZON Y MI PASION

Establishing Intravenous Access Protocol

1. Wash hands and dry. Apply gloves prior to invasive procedure.
2. Explain procedure to the subject.
3. Select vein from either left or right arm. Use the most distal site in the nondominant arm, if possible.
4. Apply tourniquet 4-6 inches above the proposed insertion site.
5. Avoid areas that are painful to palpation.
6. Select vein large enough for placement of 18g or 20 g catheter.
7. Palpate the vein by pressing downward and noting the resilient, soft, bouncy feeling as the pressure is released. Always use the same finger to palpate.
8. Promote venous distention by instructing the subject to open and close the fist several times, lowering the subject's arm in a dependent position, rubbing or stroking the subject's from distal to proximal below proposed site.
9. Avoid areas of hardened cordlike veins, bruised areas and areas of venous valves or bifurcations.
10. Avoid fragile dorsal veins or veins in an extremity with compromised circulation (mastectomy)
11. Cleanse the area, with 70% alcohol swab, in a circular motion and allow to dry for 60 seconds.
12. Perform venipuncture. Anchor vein by placing thumb over vein and by stretching the skin against the direction of insertion 5 to 7.5 cm distal to the site.
13. Look for blood return in the clear chamber of the Bd Vialon Saf-T-Intima catheter. If blood return is present, advance the catheter and then release the devise while further advancing the cathalon securely into the vein.
14. Stabilize the catheter with one hand by placing pressure on the hub or on the vein above the insertion site. Release the tourniquet and quickly attach the normal saline tubing to the catheter.
15. Secure the catheter with 1-inch tape, sterile 2x2 gauze and a transparent dressing.
16. If patent IV site is not established, discontinue the site and hold pressure to the site for approximately 5 minutes, or until hemostasis has been achieved, and then apply a sterile 2x2-gauze dsg. Repeat steps as noted above to re-establish a patent IV site.

Adapted from Potter, P.A. & Perry, A.G. (2001). Fundamentals of Nursing(5th ed.). St. Louis: Mosby, Inc.

APPENDIX I

CHOLESTECH LIPID TESTING

TU CORAZON Y MI PASION

Cholestech Lipid Testing

1. Blood sample will be collected with a 1cc syringe at the time of the IV start from a BD Vialon Saf-T-Intima catheter.
2. If cassettes have been refrigerated, allow them to approach to room temperature (at least 10 minutes) before opening.
3. Remove cassette from pouch. Hold cassette by the short sides only. Do not touch the black bar or the brown magnetic stripe. Place cassette on a flat surface.
4. Press RUN. The analyzer will perform a self-test. Screen will display 'Self test OK' when completed.
5. The cassette drawer will open and screen will display 'Load Cassette and press RUN'.
6. Blood sample from the 1cc syringe is placed on to test cassette sample well. *Important: A sample must be applied within five minutes after collection or the blood will clot.
7. Keep cassette level after the sample has been applied. Immediately place the cassette into the drawer of the Analyzer. The black reaction bar must face toward the analyzer. The brown magnetic strip must be on the right.
8. Press RUN. The drawer will close and screen will display "Test Running".
9. Discard all used testing supplies according to infection control guidelines.
10. The Analyzer will beep when test complete and screen will display "Test Name: Warning".
11. Press DATA to view and print calculated results.

APPENDIX J

CHOLESTECH TESTING CONTROLS

TU CORAZON Y MI PASION

Cholestech Controls Testing

1. Check Optics cassette for expiration date or damage before beginning test.
2. Press RUN button; verify Self test OK message, drawer will open automatically.
3. Place the Optics Check Cassette into cassette drawer.
4. Do Not place blood sample on cassette.
5. Press RUN button again, analyzer will automatically perform optics check.
6. Optics check and four numbers will appear on screen (one for each optical channel in the analyzer).

Optics Check Ch#1 – Ch#2 – Ch#3 – Ch#4

7. Check to see that the results are within the acceptable range (range is printed on the Optic check cassette).
8. Record the results on the Optics Check Log sheet.
9. If results fall outside the acceptable range, repeat test and contact Cholestech Technical Service 1-800-733-0404.

APPENDIX K

FLOWCHART OF STUDY

Flowchart of Study

APPENDIX L

ORIENTATION MEETING ENGLISH

TU CORAZON Y MI PASION

Orientation Meeting Script

1.) INTRODUCTION- Hello, my name is Marygrace Hernandez Leveille and I am an Acute Care Nurse Practitioner working in a cardiology office with 20 years of nursing experience. I am also a student at the University of Texas at Arlington working on my PhD in nursing. In order for me to graduate, I need to do a study on something that interests me. I am interested in looking at Hispanic women and heart issues. I want to look at Hispanic women and how they develop heart disease. There are not a lot of research studies done on women, and even less on Hispanic women. I have a few friends here who are nurse practitioners who will help me later in the meeting. They are #1, #2, #3 and #4. (They will be acknowledged and introduced to the group.)
2.) PURPOSE OF THE STUDY- This study will look at Hispanic women between the ages of 25-45 to see if the arteries of your heart are clear, what the cholesterol levels are and look at the body weight/waist measurements. I want to see if there are relationships between a woman's cholesterol levels and her weight and how open the arteries of the heart are. Information from this study will help us learn about what other studies need to be done to improve women's heart health. All of the measures I plan to take are considered a routine part of evaluating heart health.
3.) INCLUSION/EXCLUSION CRITERIA REVIEW- In order for you to participate in this study, you have to meet certain criteria. As a review, I want to go over what was on the flyer. If you are pregnant or have missed your last period, you cannot participate. We will do a urine pregnancy test the day of testing just to make sure the test is negative. If you allergic to a type of medicine called "beta blockers", you cannot be in the study because we will be giving you this medicine to slow your heart rate down for the testing. If you have asthma and need to take inhalers on a daily basis, you cannot be in the study because the beta-blocker medicine can cause wheezing. If you are allergic to Iodine, x-ray dye, shrimp or shellfish, you cannot participate because you will be given a dose of an Iodine based injection so that the machine can take pictures of your heart and we can see how clear the arteries of your heart are. If you have had a lot of radiation exposure or regular sessions of radiation for any illness that you might have, for your safety, I will ask you not to participate in this study because you will be exposed to a low dose of radiation. On the day of the test, I will do a blood test to see if your kidneys are functioning well. If your "creatinine" level is high, above 1.2, you cannot be in the study. The creatinine level tells me how well your kidneys are functioning. Because you are getting an Iodine based injection, I need to make sure that your kidneys can filter the Iodine thru your body. You can be in the study if you are "Hispanic" which means that you have family/ancestry from Mexico, Puerto Rico, Cuba, Spain, South and Central America and the Dominican Republic. You need to be between the ages of 25-45 and have regular periods. I am looking at women before menopause…"pre-menopausal". If you have had a hysterectomy and are between the ages of 25-45, you may participate. I am looking for women who can speak and read English so that you can read the consent form and we can communicate well. I want to be able to easily answer all of your questions, if you have any. If you do not meet this criterion, I will give you a $10 gift card for your time, but you will not be able to participate in the study. I am just going to stop here for a few minutes if any of you need to leave because you do not meet the criteria to be in the study…. There are some risks to this study. So that the heart test can be done accurately, we will need to give you a medicine, a beta-blocker, to slow your heart rate down below 60 beats per minute. I will check your blood pressure and heart rate today, if you plan to participate in the study, and based on your blood pressure and heart rate, I will give you the appropriate dosage of

medicine that you will need. You will also take this medicine the night before the study and the morning of your study. The medicine slows your heart rate down and it can lower your blood pressure. If you feel lightheaded and dizzy, sit down or lie down for a few minutes. Do not drive. If your first dose of medicine causes any problems, call me and do not take the second dose until I have given you more instructions. The chances of you having problems are slim, but you might have some lightheadedness, dizziness or nausea. I will give you a form with all of your instructions and a form that talks about the different kinds of medicine you will get for the study. When you arrive at the office, I will check you in and one of my technicians will start an IV. You will have an IV site put in your arm so that we can give you the Iodine injection for the heart pictures. Has anyone ever had an IV? You might have a pinch or a sting when the needle goes into your vein. After a few minutes, the discomfort should go away. You should not feel anything while your heart is being scanned. After the heart scanning is finished, the IV will be taken out and a small dressing will be applied. I will hold pressure on the site for at least 5 minutes to make sure that there is no bleeding. You need to keep the dressing on for at least 4 hours. After that, you can take off the dressing and put a band aide on the site. I will give you the band aide. The next morning you can take off the band aide. If you have any problems, please give me a call. I will give you written instructions and a form that talks about the medicines you will be receiving during the test before you leave today. Dr John Osborne is a cardiologist who will be in the office during the time of testing. He will read the pictures that will tell us if you have any problems with your heart. All of the staff members, Dr Osborne and I are all prepared and trained in emergency care, if a situation occurs. However, we do not anticipate any problems. The testing that we are doing are tests that are done everyday in his office without problems. We will have nearby all of the emergency equipment should it be needed. The radiation that you will be exposed to during the scanning of your heart is small. It is about the same amount that you would get in 1 year while living in the United States.

4.) CONSENT TO TESTING- I am going to give you a copy of the consent form and I will give you 10-15 minutes to review the form. If you have any questions at any time, please feel free to ask me. I will need your signature and consent before we move on to more information. If you wish to be in the study, sign the form. If you do not wish to be in the study, simply leave while others read the form. I will give you a $10 gift card at the door.

5.) DEMOGRAPHIC FORM- I will read the form to you and please circle or write your answer. If you have a question just raise your hand. I will collect the forms next as your blood pressure and heart rate is checked.

6.) VITAL SIGNS- As I mentioned before, I want to get your blood pressure and heart rate so that I will know how much medicine to give you. I will give you a form that has the specific amount of medicine that you need. I will give you a prescription that can be filled at any Wal-Mart for $4. I will give you the money to cover the cost of the medicine. My friends here who are nurse practitioners will help get your blood pressure & heart rate, but I will fill out the medication form before you leave.

7.) LOCATION OF THE STUDY- I will give you a map of where the testing site is in Grapevine, TX. On the day of the test, you will go to the Grapevine office at your designated time, which will be written on your instructions form that I will give you at the end of this meeting.

8.) TESTING DAY- On the day of testing, you will need to plan to stay at the testing site for about 2 hours. Remember to take your medicine 1 hour before your test time as noted on the form I will be giving you at the end of this meeting after I have checked your blood pressure and heart rate. Remember, if you had any problems with the first dose of the beta-blocker, I need to hear from you that day. If you would like, see

if someone can drive you to the testing center. When you arrive at the testing center, we will get your height and weight. We will also measure your waist with a measuring tape. With these numbers, we will calculate your body mass index (BMI), which will tell us if you are a normal weight or overweight. I will also have you do a urine pregnancy test to make sure that you are not pregnant. If the test is positive for pregnancy, you will not be able to be in the study and I will give you a $10 gift card. I will ask you to give me the name of your primary care physician so that I can send him your records of the test results, if you want me to. The nuclear technologist will start your IV in your arm. From that IV site, she will be able to get one small syringe of blood for testing. (I will have a syringe with me and show them.) Test #1 will check your cholesterol levels. The test is called a Cholestech. That is why the "Instructions Prior to Testing" form has instructions about eating. Test #2 will check your kidney function. The machine that we use for that is called an "iSTAT". Once this has been done, you will then be taken to the room that has the scanner. You will lie on the table on your back, with your arms over your head and a pillow beneath your knees for comfort. (Illustration to be provided.) You will lie on the table for about 10 minutes, but the actual scan is about 2 minutes. Before the scan begins, the IV will be connected to the machine that will give you the Iodine injection. However, before you get the injection, the machine will give you a "test dose" of normal saline or "salt water"…the amount is about the size of a tablespoon. We do this to make sure that the IV site is functioning correctly. If everything is working well, you will be given a squirt of Nitroglycerin under your tongue to help dilate the arteries of your heart. This may cause a minty taste in your mouth for a few seconds. This will allow us to get good pictures of the arteries of your heart. If your heart rate is not slow enough, we might have to give you another medicine in your IV called Lopressor. This can also cause lightheadedness and dizziness for a few seconds. If your heart rate is slow enough you will get an injection of "Omnipaque", which is the Iodine based solution, and more normal saline will go thru your IV in just 5.2 seconds. Most people do not feel anything when they are getting the infusion. After the scan, we will check your heart rate and blood pressure. When you heart rate is >60 beats per minute, or at baseline, and your systolic blood pressure> 100, or at baseline, we will discontinue the IV, put a dressing on it and give you a snack. As I mentioned before, you can take the dressing off 4 hours after the test and put a Band Aide on the site. I will provide you with the Band Aide. You can remove the Band Aide the next morning. Before you leave, Dr. Osborne will give you the results of your heart scan and I will tell you the results of your blood tests. If you wish, I will send the results to your primary care doctor for your records. If there are any abnormal testing results noted during your testing, we will discuss the results with you and also call your doctor to discuss the findings.

9.) GRATITUDE- You will be given a $25 gift card for your time and participation. If at any time you want to leave the study or you do not meet the inclusion criteria to be part of the study, you will be given a $10 gift card for your time.

REMEMBER….AT ANY TIME YOU CAN CALL ME. MY PHONE NUMBER IS POSTED ON THE FORMS THAT I AM GOING TO GIVE YOU.

APPENDIX M

ORIENTATION MEETING SPANISH

TU CORAZÓN Y MI PASIÓN

Manuscrito del encuentro orientación

1.) INTRODUCCION – Hola, mi nombre es Marygrace Hernandez Leveille y estoy una Enferma Medico de Cuida Critica trabajando en una oficina de cardiologuito con 20 años de experiencia como enferma. También estoy una estudiante de la Universidad de Texas a Arlington, trabajando en el titulo doctoral en enferma. Para graduar, necesito hacer un estudio en algo que tener interés. Tengo interés en las mujeres Hispanas y asuntos de corazón. Quiero investigador mujeres Hispanas y como desarrollar la enfermedad de corazón. No son muchos estudios de investigación sobre mujeres, y ya menos sobre las mujeres Hispanas. Tengo unos amigos aquí, quienes son enfermas médicos y me ayudan mas tarde del encuentro. Son #1, #2, #3, y #4. (Se introducen al grupo.)
2.) OBJECTO DEL ESTUDIO – Esto estudio investigará las mujeres entre las edades de 25-45 para determinar si las arterias del corazón son abiertos, que son los niveles de la colesterina y buscar el peso del cuerpo y medida de cintura. Quiero determinar si había relaciones entre los niveles de colesterina de mujeres y el peso y como abiertos son las arterías del corazón. Información del estudio nos ayuda aprender que otros estudios necesitará para aprovechar la salud del corazón de mujeres. Todos las medidas que proyectaré hacer son un parte rutina del evaluar la salud del corazón.
3.) REVISA DE INCLUSION/EXCLUSION CRITERIO – Para participar en el estudio, tiene que satisfacer alguno criterio. Como revista quiero que hablar del el papel que describe el estudio. Si esta embarazado o no ha tenido su ultimo menstruación no podía participar. Hará un prueba del embarazado orinal al día de la prueba para se hacer seguro que el prueba esta negativa. Si esta alérgico a un tipo de medicina que se llama "beta blockers" no estaría en el estudio porque se daremos esta medicina para ir más despacio la velocidad de corazón para la prueba. Si tiene asma y necesita tomar inhales diariamente, no estaría en el estudio porque el médica "beta blockers" podía hacerse ser asmático. Si esta alérgico a yodo (iodine), tinte radiografía, gambas, o mariscos no podía participar porque se dará un dosis de un inyección con yodo para que la machina podía sacar fotografías del corazón y veía tantas abiertas son las arterias de corazón. Si ha tenido mucho exposición de radiación o sesiones regular de radiación para un enfermedad que tenía, por su seguridad, pedirá que no participar en el estudio a causa de estará exponer a un dosis pequeño de radiación. Al día de la prueba, haré una prueba sanguínea para determinar si los riñones este funcionando bien. Si su nivel "creatine" es bastante alta, sobre 1.2, no estará en el estudio. El nivel creatine, me dice como funcionar los riñones. A causa de recibiría un inyección que tiene yodo, necesito hacer seguro que los riñones pueden filtrar el yodo por la cuerpo. Puede estar en el estudio si es "Hispánica", que significa que tiene familia/antepasados de México, Puerto Rico, Cuba, España, Las Ameritas Sur y Central el Republica Dominicana. Necesita ser entre las edades 25-45 y tiene menstruación regular. Miro a mujeres ante de menopausia "pre-menopausia." Si ha tenido un histerectomía y es entre las edades del 25-45, puede participar. Busco mujeres que puedan hablar y leer bien ingles para que leer la forma de consentimiento y poder comunicarnos bien. Quiero que responder bien a todos sus preguntas, si tenga algunas. Si no satisfecha el criterio, daré una tarjeta regalo de $10 para su tiempo, pero no pondrá participar en el estudio. Voy a esperar aquí por unos minutos si hay algunas que necesitar salir a causa de no satisfecha el criterio para el estudio… Hay algunos riesgos del estudio. Para que hace correctamente el examen del corazón, necesitará darse una medicina un beta blocker para ir más despacio de la velocidad del corazón, menos de 60 latidos del minuto. Compruebo la presión sanguínea y velocidad de corazón hoy, si proyecta a participar en el estudio y basando en la presión sanguínea y velocidad del corazón se dará la dosis apropiado de

la medicina que necesita. También tomará a la medicina la noche antes del estudio y la mañana del estudio. La medicina se va más despacio la velocidad de corazón y se baja la presión sanguínea. Si siente mareado o ligera de cascos sente o acoste para unos minutos. No conduces. Si la primero dosis de medicina se causa algunos problemas, llaméeme y no tomes el segundo dosis hasta que dándose más instrucciones. Los probabilidades de tiene problemas son pequeñas, pero es posible que tenga alguna mareado, ligera de cascos o nausea. Se daré una forma con todos de las instrucciones y una forma que describe los tipos diferentes de las medicaciones recibiera por el estudio. Cuando llega a la oficina se firmaré y uno de mis técnicos empieza un IV. Tiene un sitio de IV en el brazo para que dará una inyección que tiene yodo para las fotografías del corazón. ¿Alguien tiene un IV? Tenia un pellizco o pinchazo cuando el aguja entre el vena. Después del unos minutos el dolor desaparecía. No siente nada cuando examinara el corazón. Después del examen de corazón, se quita el IV y un apósito pequeño se pone. Se aplica presión al sitio por 5 minutos para hacer seguro que no haya sangría. Necesita tener el apósito por al menos de 4 horas. Después de este puede quitarse el apósito y se pone un band-aid al sitio. Se daré el band-aid. La próxima mañana puede quitarse el band-aid. Si tiene problemas, llámeme. Se daré instrucciones escritas y una forma que describe de las medicaciones se recibiría durante la prueba antes del salir hoy. El Dr. John Osborne es un cardiologiota quien estará en la oficina durante la prueba. El leerá las fotografías que nos mostrará si tenía algunos problemas del corazón. Todos los miembros del personal, el Dr. Osborne y yo estamos preparados y educados en cuida emergencia, si ocurría alguna situación. Pero no anticipa problemas. La prueba que hacemos son pruebas que se hacen cada día en esta ofician sin problemas. Tendremos todo el equipo emergencia muy circa si se necesite. La radiación que se expone durante el examen de corazón es muy pequeño. Es casi lo mismo cantidad que recibiría en 1 ano cuando viviendo en los Estados Unidos.

4.) CONSENTAMIENTO A LA PRUEBA – daré un copia del forma de consentimiento y se daré 10-15 minutos para examinaré la forma. Si tiene algunos problemas a cualquier tiempo, por favor me pregunta. Necesitará su firma y consentimiento andes de moverse a más información. Si quiere estar en el estudio, firme la forma. Si no quiere estar en el estudio, sencillamente salga cuando las otras lee la forma. Daré una tarjeta regla de $10 al puerto.
5.) FORMA DEMOGRAFICA – Leeré a se la forma y pro favor encierra o escribe su respuesta. Si tiene una pregunta, levante la mano. Coleccionará las formas próximas, cuando comprobado la presión sanguínea y velocidad de corazón.
6.) SIGNAS VITALES – Como dije antes quiero comprobar su presión sanguínea y velocidad del corazón para que saber la cantidad de medicina se daré. Daré una forma que describe la cantidad específicos de la medicina que necesita. Daré una prescripción que se puede llenar en cualquier Walmart pro $4. Daré el dinero para pagar por la medicina. Mis amigos aquí, quienes son enfermas medico, se ayudarán comprobar el presión sanguínea y velocidad del corazón, llenaré la forma medicina antes del sale.
7.) EL LUGAR DEL ESTUDIO – Daré un plano de la sitio de la prueba en Grapevine, TX. Al día de la prueba irá al la oficina en Grapevine al tiempo designado que estará escrito en la forma de instrucciones que se daré al fin del el encuentro.
8.) DÍA DE LA PRUEBA – Al día de prueba, proyectará que dar al sitio del la prueba por 2 horas. Recuerda tomar la medicina una hora antes del tiempo de prueba, como esta notado al forma que daré al fin del la encuentra después de comprobar el presión sanguínea y velocidad del corazón. Recuerda, si ha tenido algunas problemas con el dosis primero del beta blocker, necesito oír de su al mismo día. Si quiere, alguna persona pondría conducirse al sitio de la prueba. Cuando llega al sitio de la prueba, conseguiríamos su altura y peso. También mesuraremos la cintura con una cinta de mesurar. Con estas números, calcularemos su “body mass index” (BMI) (indexo del cuerpo masa), que nos dijéremos si esta del peso normal o sobrepeso. También se hará

un prueba del embarazado orinal para hacer seguro que no estas embarazado. Si la prueba esta positiva de embarazado, no estaría en el estudio y daría una tarjeta de regalo por $10. Se preguntaré a darme el nombre de su doctor de cuida primaria para que envío su historia de los resultados de la prueba, si me quiera. El técnico nuclear empezara el IV en el brazo. Del sitio de IV, pondrá coleccionar un pequeño jeringa de sangre para la prueba (tengo un jeringa con me y se mostraré). La prueba #1 comprobarán los niveles colesterina. La prueba se llama Cholestech. Por eso la forma de "instrucciones antes del prueba" tiene instrucciones de comer. La prueba #2 comprobará la función de los riñones. La machina que usamos se llama "iSTAT." Después de esto irá al cuarto en donde hay la machina del examen corazón. Se acostará a la espalda en la mesa con los brazos sobre la cabeza y una almohada debajo de los rodillos para comodidad (tener una ilustración). Se acostará a la mesa pro 10 minutos, pero el examen actual dura 2 minutos. Antes del examen el IV se juntará al maquina que se dará el inyección que tiene yodo. Pero, antes de recibir el inyección, la machina se dará un "dosis de prueba" de salina normal o "agua salado." La cantidad es casi la tañando de un cucharada. Haremos para hacer seguro que el sitio IV esta funcionando correctamente. Si, todo funciona bien, recibiría un chorro de nitroglicerina debajo del lengua para ayuda al dilate los arterías del corazón. Es posible de causar un sabor mente por unto segundos. Nos permitirá sacar fotografías bien de las arterias del corazón. Si la velocidad del corazón no esta bastante debajo, diese una otra medicina en el IV que se llama Lopressor. Puede causar mareado y ligera de cascos por unos segundos. Se el velocidad de corazón es bastante despacio recibiría un inyección de "Omnipaque," que es un solución que tiene yodo, y mas salina normal por su IV por 5.2 segundos. Muchos personas no siente nade cundo recibirá el inyección. Después del examen, comprobáramos la velocidad del corazón y presión sanguínea. Cuando el velocidad de corazón es
> 60 latidos del minuto, o a línea de base, y su presión sanguínea sistólica en > 100 o a línea de base, se quitaremos el IV, se pondremos un apósito, se daremos un bocado. Como dije antes, puede quitarse el apósito después de 4 horas y se pone un band-aid al sitio. Se daré el band-aid. Puede quitar el band-aid la próxima mañana. Antes de salir, el Dr. Osborne se dará los resaltos del examen del corazón y se dije los resultados de las pruebas de sanguínea. Si quiere, enviaré los resultados a su doctor de cuida primaria para su historia. Si hay resultados anormales de la prueba notado por la prueba, lo discutiremos y también llamaremos a su doctor para discutir los resultados.
9.) Se dará una tarjeta regalo de $25 para su tiempo y participación. Si a cualquier tiempo quiera dejar el estudio o no satisface el criterio del estudio, dará un tarjeta regalo de $10 para su tiempo.

RECUERDA…A CUALQUIER TIEMPO PUEDE LLAMARME. MI NUMERO DE TELEFONO ES EN LOS FORMAS QUE VOY A DARSE.

APPENDIX N

DEMOGRAPHIC FORM-ENGLISH

TU CORAZON Y MI PASION

Demographic Form

Please circle the best answer. If needed, please explain your answer on the line provided.

Date of last menstrual cycle:_____

Do you take medications for High Blood Pressure? YES NO DON'T KNOW
IF, "yes", name the medication:_____

Do you take medications for High Cholesterol? YES NO DON'T KNOW
IF, "yes", name the medication:_____

Do you smoke? YES NO DON'T KNOW
Have you ever smoked? IF, yes: How many cigarettes per day and for how long?
_____

IF, you have quit smoking, how long ago did you quit?
_____

Are you allergic to tape or latex? YES NO DON'T KNOW

Do you exercise? YES NO DON'T KNOW
IF, yes: how many times a week? _____
Do you have medical insurance? YES NO DON'T KNOW

Does your mother or father have (please circle)
Heart problems Heart attacks High Blood Pressure
High Cholesterol Diabetes

Do any of your brothers or sister have (please circle)
Heart problems Heart attacks High Blood Pressure
High Cholesterol Diabetes

APPENDIX O

DEMOGRAPHIC FORM- SPANISH VERSION

TU CORAZÓN Y MI PASIÓN

Forma Demográfico

Por favor encierra en un círculo la respuesta más correcta. Si es necesario, explique sus respuestas en las líneas debajo.

La fecha del último ciclo menstrual: _____

¿Toma medicaciones para presión sanguínea elevada? SÍ NO NO SÉ
SI, toma medicaciones, nómbrelas:_____

¿Toma medicaciones para colesterina elevada? SÍ NO NO SÉ
SI, toma medicaciones, nómbrelas: _____

¿Fuma?
¿Ha fumado en el pasado? SI, ha fumado: cuantas cigarrillos al día y para cuanto tiempo _____

¿SI, ha terminado de fumar, hasta que tiempo que terminé?
_____

¿Esta alérgico a cinta adhesiva o látex? SÍ NO NO SÉ

¿Haga ejercicios? SÍ NO NO SÉ
¿SI, haga ejercicios: cuantos tiempos a semana? _____
¿Tiene seguro medico? SÍ NO NO SÉ

Tiene su madre o padre (encierra en un círculo):
Problemas del corazón Ataques de corazón Presión sanguínea elevado
Colesterina elevado Diabetes

Tiene sus hermanos (encierra en un círculo):
Problemas del corazón Ataques de corazón Presión sanguínea elevado
Colesterina elevado Diabetes

APPENDIX P

MEDICATIONS ENGLISH

TU CORAZON Y MI PASION

Medications Used in the Study
PRE-TESTING (Corgard/ Nadolol)

- Corgard (Nadolol) is a type of medicine called a beta-blocker.
- If you know you are allergic to Beta Blockers, you will not be in the study.
- It is a pill that is swallowed. You will be given a form telling you how much to take and when.
- You will be taking Corgard (Nadolol) to slow your heart rate down. I would like your heart rate below 60. If your heart rate is already below 60, you will not have to take this medicine. I will check your heart rate to see how much medicine you will need.
- Corgard (Nadolol) can also decrease your blood pressure. I will check your blood pressure to see how much medicine you will need.
- When you take the medicine and if you become lightheaded or dizzy, lie down and raise your legs up on a pillow. Try to drink as much fluids as possible.
- If you start to have problems breathing, call Marygrace at 214-478-4597. You will not take the second dose of Corgard (Nadolol) the next day.

If you have any questions please call Marygrace at 214-478-4597

DAY OF TESTING

- You will take Corgard (Nadolol) the morning of your test.
- Before any testing is done, I will check your blood to make sure your kidneys are working normally before you receive any x-ray dye. If they are not working normally according to the blood results, you will not be in the study.
- On the day of the test, you will get an intravenous plastic catheter in either arm so that you can get an injection of x-ray dye and fluid. This fluid is almost the same as drinking water. This dye will let us look at the arteries of your heart to see if there are any blockages. The name of the dye is Omnipaque® 350. The major ingredient in this dye is Iodine.
- Omnipaque® 350 is filtered through your kidneys and that is why we check your blood kidney levels before testing. Your body will get rid of the Omnipaque® 350 through your urine.
- If you know you are allergic to x-ray dye, you will not be in the study.
- If you know you are allergic to Iodine, shrimp or shellfish, you will not be in the study.
- If your heart rate is not below 60 at the time we are ready to do the heart scan, I will give you a medicine called Lopressor in your intravenous plastic catheter. Lopressor is also a beta-blocker that is used to slow the heart rate. Lopressor can be taken in pill form or intravenously. For this test, you will receive it through your intravenous catheter in your arm.
- Before the scanning of your heart starts, you will get one squirt of a medicine called NitroLingual under your tongue. This is a liquid form of Nitroglycerin which is the medicine given to people with chest pain. You will get this medicine because it helps dilate the arteries of your heart and we can get better pictures of the arteries to check for blockages.
- After the test, the small plastic catheter will be discontinued and a dressing will be applied. After 4 hours, you can take the dressing off.
- If you have any problems, please call Marygrace at 214-478-4597

APPENDIX Q

MEDICATIONS SPANISH

TU CORAZÓN Y MI PASIÓN

Los Medicaciones Usando en el Estudio
ANTES DE LA PRUEBA (Corgard/Nadolol)

- Corgard (Nadolol) es un tipo de medicina que se llama “beta blocker” (un bloque de beta).
- Si sabe que esta alérgico a “beta blockers, no serás en el estudio.
- Es una píldora que tragar. Se dará un forma que te diciendo cuantas de tomar y cuando.
- Tomará Corgard (Nadolol) para ir más despacio la velocidad de corazón. Quisiera que su velocidad del corazón será 60. Si el velocidad del corazón ya esta menos de 60 no necesitara tomar este medicina. Comprobar su velocidad del corazón para determinar cuanta medicina que necesitará.
- Corgard (Nadolol) puede reducir su presión sanguínea. Yo notará su presión sanguínea para determinar cuanta medicina que necesite.
- Si siente mareado o ligero de cascos, cuando toma la medicina, acostarse y levanta las piernas en una almohada. Bebe tantos fluidos que puedas.
- Si empieza tener problemas de respirar llame Marygrace a 214-478-4597. no tomara la segunda dosis de Corgard (Nadolol) el próximo día

Si tiene algunas preguntas pro favor llama a Marygrace a 214-478-4597

EL DIA DE LA PRUEBA

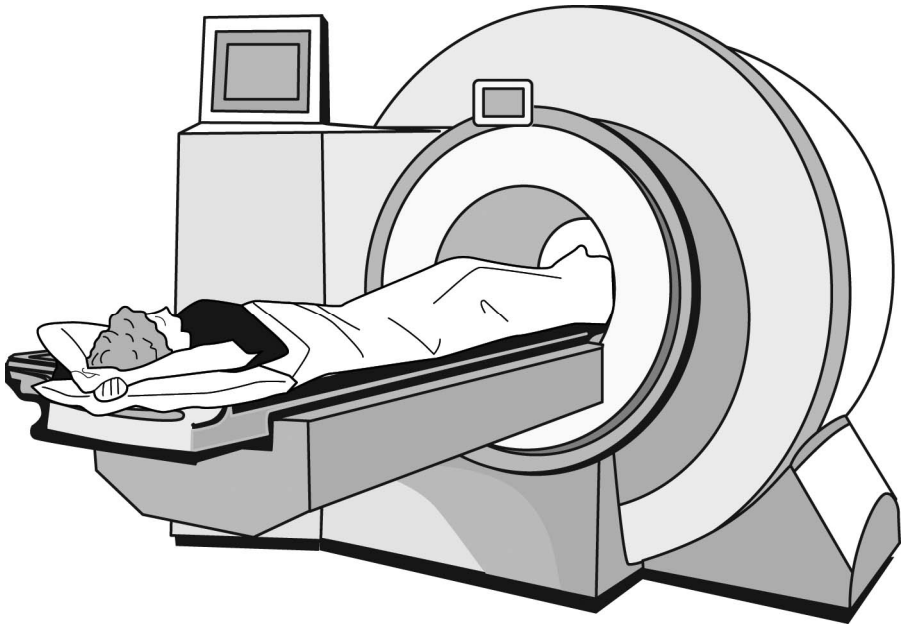
- Tomará Corgard (Nadolol) la mañana de la prueba.
- Antes de la prueba comprobaré su sangre para hacer seguro que los riñones están funcionando de normal, antes de recibir alguna tinte de radiografía. Si no están funcionando de normal (en los resultados sanguíneos) no estará en el estudio.
- El día de la prueba recibirá una catéter plástico intravenoso en uno brazo para tomar un inyección de tinte de radiografía y fluidos. Este fluido es casi lo mismo como agua bebido. El tinte nos ayuda ver los arterias del corazón para determinar si había algunas bloqueas. La tinta se llama Omnipaque® 350. El principal ingrediente en el tinte es yodo (Iodine).
- Omnipaque® 350 esta filtrado por los riñones, y por eso comprueba sus niveles de sangre riñones antes de la prueba. El cuerpo se quitará el Omnipaque® 350 por su orín.
- Si sabe que esta alérgico a tinte de radiografía, no estará en el estudio.
- Si sabe que esta alérgico a yodo (Iodine), gambas o mariscos, no estará en el estudio.
- Si la velocidad del corazón no es menos de 60 al tiempo que estamos listo para el examen de corazón, se daré una medicina en el catéter plástico intravenoso que se llama Lopressor. Lopressor también es un “beta blocker” usado para ir mas despacio el velocidad del corazón. Puede tomar Lopressor como píldora o por intravenoso. Para esta prueba, lo recibirá por el catéter intravenoso en el brazo.
- Antes de la empieza del prueba, recibirá un chorro de la medicina debajo del lengua que se llama NitroLingual. Esta es un forma liquida de Nitroglicerina, que es un medicina para personas con dolor del pecho. Recibirá la medicina porque ayuda con la dilación del los arterias del corazón y podemos tener fotografías mejores del arterias para comprobar si había bloqueas.
- Después de la prueba, se quitará la pequeña catéter plástico y se pondré un apósito. Después de 4 horas, se puede quitar el apósito.
- Si tiene algunas problemas, por favor llama a Marygrace a 214-478-4597

APPENDIX R

POSITION FOR SCANNING

TU CORAZÓN Y MI PASIÓN

Position for Scanning



APPENDIX S

CONSENT FOR STUDY ENGLISH

Consent form

Investigator: Marygrace Hernandez-Leveille, RN, MSN, ACNP-CS

You are invited to participate in a research study that will look at pre-menopausal Hispanic women and how heart disease is developed. Although this study will not benefit you directly, it will provide information that might determine if further studies need to be conducted to study Hispanic women and heart disease.

The study and its procedures have been approved by the appropriate people and review board at the University of Texas at Arlington. The study procedures involve no foreseeable risk or harm to you or your family. The procedures include (1) taking a medicine to slow your heart rate down, (2) having an intravenous needle placed in your arm to receive an injection and collect blood to check the functioning of your kidneys and your cholesterol level, (3) laying on your back, on a table for approximately 2-3 minutes, while you receive one squirt of medicine under your tongue and an injection in your arm so that your heart can be scanned, (4) if your heart rate is not below 60 beats per minute, you may receive a medication thru your IV to help slow the heart rate down, (5) having your heart rate and electrocardiogram continuously monitored during the heart scan, and (6)having your waist measured with a measuring tape.

Participation in this study will involve meeting with Marygrace to receive all of the information regarding the test and to receive a prescription for the free medication that you will need to take the night before the test and the morning of testing day. On the day of the test, you will arrive at 3801 William D. Tate, Suite 850 Grapevine, TX, 76051 at the scheduled time that you will be given. On the day of the test, you will anticipate spending approximately 2 hours, at the most, to complete the waist measurements, blood testing for cholesterol and kidney functioning, to start the intravenous port where you will receive contrast dye for the injection during the heart scan. You understand that the heart scan will take up to approximately 2 minutes and that you will need to lay flat on your back for the procedure. If you are pregnant, asthmatic, allergic to Beta Blockers, Iodine or shellfish, diabetic taking medications for diabetes and have an elevated kidney function test, you will not qualify for the study and you will not participate in the study.

At the orientation meeting and day of testing, you will be provided with small snacks and beverages. You will be provided with $25 cash at the completion of the study.

Your participation in this study is voluntary; you are under no obligation to participate. You have the right to withdraw from the study at any time.

Your name will not be revealed at any time. Your identity will not be revealed while the study is being conducted or when the study is reported or published. All information/data will be collected and entered into a secure computer database by Marygrace. The information will not be shared without your permission.

You are free to ask any questions about the study or procedures at any time. You can contact Marygrace at 214-478-4597 (cell) or 972-317-1506 (home) if you have further questions.

My supervising professor is Dr Carolyn Cason. Her address and phone number is included at the end of this form.

You may have a copy of the form to keep.

I have read this consent form and voluntarily consent to participate in this study.

_____

Participant's Signature

_____
Date

_____
Investigator's Signature

Marygrace Hernandez Leveille, MSN, RN, ACNP-CS
Nursing Doctoral Student
214-478-4597 (cell)
972-317-1506 (home)

Carolyn Cason, PhD, RN
Supervising Professor
University of Texas at Arlington
School of Nursing
Arlington, TX
817-272-2776

APPENDIX T

CONSENT FOR STUDY SPANISH

Forma del consentimiento

Investigadora: Marygrace Hernandez-Leveille, RN NSM, ACNP-CS

Esta invitado a participar en un estudio de investigación que enfocar en las mujeres Hispanas antes de menopausia y como se desarrollar el enfermedad de corazón. Aunque este estudio no se benéfica directamente, nos dará información que puede determinar si debería hacer mas estudios de mujeres Hispanas y la enfermedad de corazón.

El estudio y los procedimientos han sido aprobados por las personas necesarias y el tribunal de la revista de la universidad de Texas en Arlington. Anticipará que los procedimientos del estudio no presente ninguna riesgo o dolor a su o se familia. Los procedimientos incluye (1) tomando un medicina para ir mas despacio el velocidad de corazón (2) un aguja intravenoso en el brazo para recibir un inyección y para cumular sangre para determinar el función de los riñones y el nivel colesterina (3) se acostar en el espalda en una mesa por como 2-3 minutos, cuando recibir un chorro de medicina debajo del lengua y un inyección en el brazo para que podía examinar el corazón (4) si el velocidad de corazón no esta menos de 60 pulsaciones de minuto, recibiría un medicación por el IV para ayudar ir mas despacio el velocidad de corazón (5) el velocidad del corazón y electrocardiograma siempre observado durante el examen de corazón y (6) mesurar el cintura con un cinta de mesurar.

Participación en el estudio incluye un encuentro con Marygrace para recibir todo la información del prueba y un prescripción para la medicina libre que necesitará tomar el noche antes del prueba y la mañana de le prueba. El día de la prueba llegar a 3801 William D. Tate, Suite 850 Grapevine, TX 76051 al tempo que nos dará. El día de la prueba, pasará 2 horas al máximo para completar la medida de cintura, para la prueba de sangre por colesterina y función de riñones, para empezar el intravenoso puerto en donde recibirá el tinte del contrasto por el inyección durante el examen del corazón. Entiende que el examen del corazón dura 2 minutos y necesitará acostarse en la espalda para el procedimiento. Si esta embarazo, asmático, alérgico a Beta Blockers, yodo (Iodine), mariscos, diabético tomando medicaciones pro diabetes, o tiene una prueba de la función de los riñones elevada, no esta habilitado por el estudio, y no participará en el estudio.

Al encuentro de orientación y el día de la prueba se dará pequeñas comidas y bebidas si quiera. Se dará $25 en efectivo al fin del estudio.

Su participación en el estudio es voluntaria, no tiene ninguna obligación de participar. Tiene el derecho a dejar el estudio a cualquier tiempo.

Su nombre no se relevará de ningún tiempo. Tampoco su identidad no se relevará durante el estudio, ni cuando el estudio es reportado o publicado. Todo la información/datos se coleccionará y se pondré en el base de datos seguro computadora por Marygrace. La información no distribuirá sin su permisión. Esta libre de preguntar alguna pregunta del estudio o procedimientos a cualquier tiempo. Puede contactar Marygrace a 214-478-4597 (celular) o 972-317-1506 (casa) si tiene mas preguntas.

La profesora superintendente es la Dr. Carolyn Cason. Su dirección y numero teléfono son incluidos al final del forma.

Puede tener una copia del este forma para guardar (tener).

He leyendo esta forma del consentimiento y voluntariamente da mi consentimiento a participar en este estudio.

_____

Firma del participante

_____
Fecha

_____
Firma de la investigadora

Marygrace Hernandez Leveille MSN, RN, ACNP-CS
Estudiante Doctoral de Enferma
214-478-4597 (cellular)
972-317-1506 (casa)

Carolyn Cason, PhD, RN
Profesora superintendente
La Universidad de Texas a Arlington
La escuela de enferma
Arlington, TX
817-272-2776

APPENDIX U

CTA CONSENT ENGLISH

CONSENT FOR CARDIOVASCULAR CT

I, _____ authorize Dr. _____ And/or such assistants as he/she may designate to administer and conduct a Cardiovascular CT scan. The purpose of this test is to evaluate my cardiovascular condition.

I understand that I will have an IV catheter inserted in my arm and IV contrast will be injected during the procedure. *I also understand that an IV medication may be injected to lower my heart rate for optimal imaging. My heart rate and electrocardiogram will be monitored continuously during the procedure.

I understand there are risks involved with this procedure. I also understand that I will be exposed to a small amount of radiation for a short period of time. Further, the facility in which the procedure is being administered is equipped to handle emergencies during the test and that personnel have been trained for emergency procedures. All risks and benefits have been fully explained to me and I voluntarily accept such risks associated with this test.

Patient Signature: _____ Date: _____

Witness: _____ Date: _____

*Only applies to the Cardiac CTA.

APPENDIX V

CTA CONSENT SPANISH

CONSENTIMIENTO PARA CT CARDIOVASCULAR

Yo _____authorizo Dr. _____
Y/o tales ayudantes cuando él/ella puede designar para administrar y conducir una exploración de CT cardiovascular. El objectivo de esta prueba es evaluar mi condición cardiovascular.

Entiendo que haré insertar un IV catéter en mi brazo e IV contraste será inyectado durante el procedimiento. También entiendo que una IV medicación puede ser inyectada para bajar mi precio de corazón para la representación óptima. Mi precio de corazón y electrocardiograma serán supervisados continuamente durante el procedimiento.

Entiendo que hay riesgos implicados con este procedimiento. También entiendo que seré expuesto a una pequeña cantidad de la radiación durante un período corto del tiempo. Adelante, la instalación en la cual el procedimiento está siendo administrado es equipada para manejar emergencias durante la prueba y aquel personal han sido entrenados para procedimientos de emergencia. Todos los riesgos y las ventajas de esta prueba me han sido totalmente explicados y voluntariamente acepto tales riesgos asociados con esta prueba.

FirmaPaciente:_____Fecha:_____

Testigo:_____Fecha:_____

APPENDIX W

INSTRUCTIONS PRIOR TO TESTING ENGLISH

TU CORAZON Y MI PASION

Instructions prior to testing

□ Do not eat breakfast if you have a morning test appointment.
□ Do not eat lunch if you have an afternoon test appointment, you may have a light breakfast.
□ Avoid caffeine the day of testing. You may have caffeine after the test.
□ Drink extra fluids the day before and the day of the test.
□ Take your Corgard (Nadolol) the evening before the test and morning of testing.
□ Please do not wear an under wire bra.

You are scheduled to have your testing completed:
Date:_____ Time:_____
Location: State of the Heart Cardiology
3801 William D. Tate, Suite 850
Grapevine, TX 76051
**See attached map

Corgard Dosage:_____mg evening before test

_____mg morning of the test

Thank you for participating in this study. Please notify me if I you have any questions.

Marygrace
214-478-4597 OR 972-317-1506

APPENDIX X

INSTRUCTIONS PRIOR TO TESTING SPANISH

TU CORAZÓN Y MI PASIÓN

Instrucciones para antes de la prueba

- No desayunas si tenga una cita para su prueba de la mañana.
- No almuerzas si tenga una cita para su prueba de la tarde, puede comer un desayuno ligero.
- Evita cafeína para el día de la prueba. Puede tomar cafeína después de la prueba.
- Bebe liquidas extras de día antes y el día de la prueba.
- Toma su Corgard (Nadolol) la noche antes de la prueba y la mañana de la prueba.
- Por favor no llevas un sostén de underwire.

Fecha: _____ Tiempo: _____
El lugar: State of the Heart Cardiology
3801 William D. Tate, Suite 850
Grapevine, TX 76051
**Ve el plano incluido.

Dosis de Corgard: _____ mg el noche antes del la prueba

_____ mg la mañana de la prueba

Gracias para su participación en el estudio. Por favor me nota si tienes algunas preguntas.

Marygrace
214-478-4597 o 972-317-1506

APPENDIX Y

CORGARD ADMINISTRATION

TU CORAZON Y MI PASION

Corgard administration

1. Corgard to be administered as follows:
    a. Systolic BP <120mmHG
       Resting HR < 60/minute
       No pre-medication
    b. Systolic BP<120mmHG
       Resting HR 60-75/minute
       Administer: Corgard 40 mg night prior to test
       Repeat Corgard 40 mg 1 (one) hour prior to scheduled testing
    c. Systolic BP <120mmHg
       HR >75/minute
       Specific orders from Investigator
    d. Systolic BP >120mmHg
       Resting HR < 60/minute
       No pre-medication
    e. Systolic BP >120mmHg
       Resting HR 60-75/minute
       Administer: Corgard 80mg night prior to test
       Repeat Corgard 80mg 1 (one) hour prior to scheduled testing
    f. Systolic BP >120mmHg
       Resting HR 75/minute
       Administer Corgard 120mg night prior to test
       Repeat Corgard 120mg 1 (one) hour prior to scheduled test

CORGARD Dosing						
Systolic BP	<120mmHG			>120mmHG		
Resting Pulse	<60	60-75	>75	<60	60-75	>75
Corgard Dose	None	40mg*	Decision per inves-tigator	None	80mg*	120mg*
* Medication to be administered night prior to scheduled test and 1 (one) hour prior to scheduled testing time.						

2. Patient is to hold medication prior to test if heart rate is <60/minute or systolic BP <120mmHg

**The investigator determines the Corgard dosing based on vital signs.

APPENDIX Z

PREGNANCY TESTING CONSENT ENGLISH

TU CORAZON Y MI PASION

Urine Pregnancy Testing

Utilizing the E.P.T. ® Urine Pregnancy Test Kit Instructions

1. The subject will void in a clean, dry container.
2. The investigator will complete the next steps:
3. Remove the test stick from the foil wrap and use the stick right away.
4. Remove the purple cap to expose the absorbent tip.
5. Hold the test stick by its thumb grip.
6. Keep the absorbent tip pointing downward.
7. Throughout the testing never hold the test stick with the absorbent tip pointing upward.
8. Dip the absorbent tip in the collected urine sample for 20 seconds only. After sampling, keep the absorbent tip pointing downward. Never hold the test stick with the absorbent pointing upward.
9. Place the test stick on a flat surface with the windows facing up for at least 2 minutes. You may notice a light blue color moving across the windows.
10. Wait 2 minutes to read the results. Be sure to read the result before 10 minutes has passed.
11. A blue line will appear in the square window as a control to show that the test has worked. If no blue line appears in the square window within 10 minutes, the test has not worked.
12. A (+) sign in the round window indicates a “pregnant” result. The lines that make up the sign can be different shades of blue and need not march the color illustrations.
13. A (-) sign in the round window indicates a “not pregnant” result.
14. The investigator will show the subject the results and review the results.
15. If the subject is pregnant, as indicated by the urine test, she will exit from the study with a $10 gift card.
16. If the subject is not pregnant, she will sign a form stating that she has reviewed the results and will continue on with the study, if she chooses to do so.
17. The results of the pregnancy test and the form will be kept under lock and key in room 508 in Pickard Hall at the University of Texas at Arlington.

I have reviewed my negative urine pregnancy test results and will voluntarily continue on with the study.

CTA# _____ Initials_____ Investigator initials_____ Date _____

APPENDIX AA

PREGNANCY TESTING CONSENT SPANISH

TU CORAZON Y MI PASION

Prueba de Embarazado Orinal

Instrucciones para Usando el E.P.T. ® Prueba del Embarazado Orinal

18. El sujeto orinará en un envase limpio y seco.
19. El investigador completará los pasos próximos:
20. Quitase la estaca de prueba de la envoltura hoja y úsalo inmediatamente.
21. Quitase la capa púrpura para exponer la punta absorbente.
22. Tiene la estaca de prueba por el agarro de pulgar.
23. Guarda la punta absorbente hacia abajo.
24. Para la prueba nunca tiene la estaca de prueba con la punta absorbente hacia arriba.
25. Sumerge la punta absorbente en el orín colección por solamente 20 segundos. Después del probador, guarda la punta absorbente hacia abajo. Nunca tiene la estaca de prueba con la punta absorbente hacia arriba.
26. Pone la estaca de prueba en una superficie llana con las ventanas hacia arriba por 2 minutos. Noticiaría un color de azul claro moviendo por las ventanas.
27. Espera 2 minutos para leer los resultados. Asegura a leer los resultados antes de los 10 minutos han pasado.
28. Una línea azul aparecerá en la ventana cuadra como un regulador de para asegurar si la prueba han funcionado. Si no aparecerá un línea azul en la ventana cuadra entre 10 minutos, la prueba no ha funcionando.
29. Un (+) signa en la ventana circular indicará un resulto de “embarazado.” Las líneas que forma la signa puede ser diferente matizas del azul y no necesita ser igual como los ilustraciones del color.
30. Un (-) signa en la ventana circular indicará un resultado de “no embarazado.”
31. El investigado mostrará al sujeto los resultados y examinará los resultados.
32. Si el sujeto está embarazado, como se indica la prueba orinal, se sale de estudio con una tarjeta regalo del $10.
33. Si el sujeto no está embarazado, firmará una forma que dice de ella ha examinado los resultado y continuará con el estudio, si quiere.
34. Los resultados de la prueba del embarazado y la forma guardará debajo de cerradura y llave en la cuadra 508 en Pickard Hall a la Universidad de Texas a Arlington.

He examinado mis resultados negativas de la prueba de embarazado orinal y continuaré voluntariamente con el estudio.

CTA# _____ Iniciales_____ Iniciales del investigador_____ Fecha _____

APPENDIX BB

BMI CALCULATION

TU CORAZON Y MI PASION

Body Mass Index (BMI) Calculation

http://www.nhlbisupport.com/bmi/bmicalc.htm

APPENDIX CC

HANDHELD iSTAT ® ANALYZER

TU CORAZON Y MI PASION

Handheld iSTAT ® Analyzer Instructions

1. Establish IV site per protocol with BD Vialon Saf-T- Intima catheter.
2. Aspirate 1cc of blood from secondary access port with 1cc syringe.
3. Place a few drops of blood onto the iSTAT Chem 8 ® cartridge.
4. Seal the cartridge and insert it into the handheld reader. The disposable cartridge is self-contained and requires no additional QC step.
5. In minutes, the results will appear on the screen of the iSTAT 1® analyzer.
6. Print results of blood chemistry and place on the “Data Collection Form”.

http://www.abbottpointofcare.com/istat/www/misc/popup/system-specs.htm

APPENDIX DD

eGFR CALCULATION

TU CORAZON Y MI PASION

Determination of Glomerular Filtration Rate

1. The CT tech will establish an IV site with the BD Vialon Saf-T-Intima catheter. From that site, 1cc of blood will be aspirated and an iSTAT will be completed.
2. The results of the creatinine level from the iSTAT will be entered into the eGFR calculator from the "http://davita.com/eGFR-calculator/" website by the CT tech.
3. The DaVita eGFR calculator will generate an eGFR.
4. If the eGFR is less than 30mL/min, the subject is excluded form the study.

APPENDIX EE

PROCEDURE FOR CTA TESTING

TU CORAZON Y MI PASION

Procedure for Computed Tomography Angiography of the Coronary Arteries

1. Informed consent completed and signed by subject.
2. Investigator reviewed and completed pre-procedure form and inclusion/exclusion criteria met.
3. Reaffirm with subject that the Corgard has been taken as directed.
4. In the lab room, the subject will have a patent IV established with either an 18 gauge or 20 gauge BD Vialon Saf-T-Intima catheter in either arm. The trained CT tech will establish the IV site and patency. The size of the catheter used will depend on the size of veins and at the discretion of the CT tech. The CT tech has 8 years of testing and starting IVs.
5. From the established IV site, 1 cc of blood will be drawn from the BD Vialon Saf-T-Intima catheter port and an "iSTAT" and a Cholestech will be computed to establish normal kidney function via BUN/creatinine testing and lipid panel testing.
6. The results of the "iSTAT" will be logged in the lab Log Book for compliance issues of the testing site. No identifying subject information will be documented.
7. A subject will have a creatinine level of 1.2 mg/dL or less in order to proceed with CTA testing.
8. If applicable, the subject will remove under wire bras before testing. The subject will lie on the table of the Philips Brilliance ™ 64 slice CT scanner. A pillow under the head and knees will be placed for comfort measures. The patient will have her arms over her head resting on the pillow.
9. The patent BD Vialon Saf-T-Intima catheter will be securely attached to the Medrad Stellant™ device, by the CT tech, for dual injection of Normal Saline and Omnipaque® 350 per standard protocol programmed in the Philips Extended Brilliance™ Workspace.
10. If the heart rate is not below 60 beats per minute, Lopressor 5mg will slowly be given intravenously.
11. During the scanning procedure, the blood pressure and heart rate will be monitored by the Philips M3 ™ M3046A device. The trained CT tech, Marygrace, a trained cardiology nurse practitioner and a cardiologist will observe the procedure.
12. The first view obtained is a "Scout" which is a non-contrast computed tomographic scan of the chest using the Philips Brilliance ™ 64 slice CT scanner with attention to the heart, great vessels and coronary arteries. The Philips Brilliance ™ 64 slice CT scanner will automatically say "Breath in and hold your breath". This is a 5.2-second phase. The scanner will then tell the subject to "Relax".
13. Prior to injection, the Philips Brilliance ™ 64 slice CT scanner will give a 5cc test dose of Normal Saline to assess for patency of the IV site.
14. After IV patency has been established, one squirt of NitroLingual Spray will be administered sublingually if the systolic blood pressure is greater than 110. Do not administer sublingual spray if the systolic blood pressure is less than 110.
15. Approximately 12-15 seconds after the NitroLingual Spray, multiple high resolution 64 slice computed tomography images of the heart and adjacent vascular structures will be obtained using 0.625 collimation with a slice thickness of 1.0 mm in the axial plane with 0.2 pitch with 400ms gantry rotation using 512-acquisition matrix. A rapid intravenous infusion of 100cc of non-ionic radiopaque contrast media (iohexol 75%; Omnipaque ®-350) will be administered during a single breath held followed immediately with a 40cc saline infusion to optimize contrast density.
16. Electrocardiographic retrospective gating will be used with a rate-related gating protocol to minimize motion artifact. Unedited axial images will be processed with the Philips Extended Brilliance ™ Workspace and displayed using two-dimensional and

three-dimensional images in the axial, sagittal, and coronal planes will be reviewed. Left ventricular function and wall motion will be assessed in the long and short axes and ejection fraction will be calculated using the Simpsons Rule Technique programmed in the Philips Brilliance ™ 64 slice CT scanner.

17. Once the scan has been completed, the subject will then be assisted to the sitting position. If the blood pressure is greater than 100 systolic or at baseline, and the heart rate is greater than 60 beats per minute or at baseline, the subject will then be able to stand from the table.
18. The BD Vialon Saf-T-Intima catheter will then be discontinued and immediate pressure will be applied to the IV site until all bleeding has stopped and hemostasis is achieved. A pressure dressing of gauze and wrap will be applied for security. The subject will sent home with a secure pressure dressing. The subject will maintain the pressure dressing for 4 hours after the procedure and then the dressing can be taken off and discarded by the subject.

APPENDIX FF

INSTRUCTIONS AFTER TESTING ENGLISH

TU CORAZON Y MI PASION

Instructions AFTER Testing

After testing is completed, you will leave our office with a small dressing to the intravenous site. If you notice any bleeding, please apply pressure to the dressing for at least 15 minutes and call me. You may take the dressing off 4 hours after the testing has been completed and replace it with a band aide. The next morning you can take off the band aide. You may have a small bruise in the area but it should go away in 3-7 days. If the area is sore or tender to touch, take Ibuprofen/Advil 200mg (if you are not allergic to it) and call me for further instructions.

At the end of the visit, you will get a copy of your results of your cholesterol levels, kidney functions testing and Dr Osborne will talk to you about the results of the scan of your heart. If you would like, I will mail your results to your doctor.

If at any time before or after the test you have questions, PLEASE call me.

Thank you for participating in this study.

Marygrace
214-478-4597
972-317-1506

APPENDIX GG

INSTRUCTIONS AFTER TESTING SPANISH

TU CORAZÓN Y MI PASIÓN

Instrucciones para DESPUÉS de la prueba

Al final de la prueba, salga de la oficina con un apósito pequeño en el lugar intravenoso. Si nota alguna hemorragia, da presión al apósito por 15 minutos y llámeme. Cuatro horas después del fin de la prueba, pueda quitar el apósito y substituirlo con un Band-Aid. La mañana próxima pueda quitar el Band-Aid. Es posible que tenga una pequeña abolladura en el lugar intravenoso, pero debe desparecer en 3-7 días. Si el lugar es doloroso o tierna al tocar, toma Ibuprofen/Advil 200mg (si no lo esta alérgico) y llámame para mas instrucciones.

Al fin de la cita, recibirá una copia de los resultados de sus niveles colesterina, la prueba de la función de los riñones, y el Doctor Osborne te hablaré de los resultados del examen del corazón. Si quiere, enviraré sus resultados a su doctor.

Si tienes preguntas al cualquier tiempo antes o después de la prueba, POR FAVOR llámame.

Gracias para su participación en este estudio.

Marygrace
214-478-4597
972-317-1506

APPENDIX HH

LINKAGE LOG

Linkage Log (Confidential)

CTA #	NAME (LAST,FIRST)_____	SEND INFO TO PCP?	PRIMARY CARE PHYSICIAN'S NAME

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BIOGRAPHICAL INFORMATION

Marygrace Hernandez-Leveille was born, raised and educated in Texas. She went to St. Austin's Catholic School in Austin, TX from kindergarten to the 8th grade and then attended Austin High School for 4 years. She completed her Bachelors of Science in Nursing degree at Hardin-Simmons University in 1976. She had the wonderful opportunity of traveling throughout the United States as a traveling registered nurse for 8 years. During her travels, she worked as an intensive care nurse in various cities such as Las Vegas, Washington, D.C., Philadelphia, Baltimore, Los Angeles, San Antonio and Tampa. After having a great rewarding life of traveling and having fun, she decided it was time to return home to Dallas, TX and return to school to pursue an advanced nursing degree. She attended the University of Texas at Arlington and completed her Masters in Nursing in 1999. She graduated as an Acute Care Nurse Practitioner and went back to her first love: cardiology. Since graduation, she has been employed in the cardiology setting. Again, she received another calling for higher education. In 2003, she entered the first nursing doctoral cohort at the University of Texas at Arlington. Her interests grew into the field of research and teaching while maintaining her love and passion for cardiology and Hispanic women.