The Puerto Rico Cardiovascular Risk-Estimation Study (PRCaRES): An Exploratory Assessment of New Patients in Physicians' Offices

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Objective: To determine the risk of developing coronary heart disease (CHD) in a cross-sectional sample of Puerto Rico residents through an analysis of the 10-year Framingham risk score.

Methods: An exploratory, retrospective, cross-sectional study of the medical records of patients 35 years or older who each visited the office of 1 of the 4 participating physicians on or after July 1, 2007.

Results: Data for 453 patients were extracted from the medical records, but 96 cases were excluded because of incomplete data or the patients' not fulfilling the inclusion criteria, thus yielding a total sample of 357 patients. The average patient age was 58 years old (±11.8); the majority (58%) was female. Eight of 10 patients were either overweight or obese. Eighty-five percent reported having at least 1 cardio-metabolic condition. Of these, 72.3% self-reported having hypertension; 38.4%, dyslipidemia; and 37.8%, diabetes. Many patients were not at goal for blood pressure or for lipid and glucose parameters nor were these patients taking any medication for these conditions. Nearly one-third of the participants had a 10% or greater 10-year risk of developing CHD. Compared with women, men were 3.3 times more likely to have a 10-year CHD risk of 10% or greater and 4.2 times more likely to have a risk of 20% or greater.

Conclusion: A substantial number of patients had risk factors for developing CHD and were not at goal for specific parameters. Larger scale epidemiological studies should be conducted to assess CHD risk in Puerto Rico so that public health initiatives to reduce this risk might be proposed. [*P R Health Sci J 2014;33:58-64*]

Key words: Puerto Rico, Cardiovascular Risk, Framingham, Metabolic Syndrome

Heart diseases are ranked first among the causes of death in Puerto Rico, accounting for 17.5% of all causes of death in 2009 (1). According to the National Vital Statistics Report of the Centers for Disease Control, 5,209 persons died in 2009 of diseases of the heart. This represents an age-adjusted mortality rate of 122 per 100,000 population. Furthermore, the Behavioral Risk Factor Surveillance System (BRFSS) indicates that 33% of Puerto Rico residents have been told they have high cholesterol or hypertension (2011 survey) and 12%, diabetes (2010 survey). In addition, the 2011 survey revealed that two-thirds of these individuals (71.1% of all males and 61.7% of all females) are either overweight or obese, both of which are risk factors for coronary heart disease (CHD) (2).

Cardiovascular diseases pose a burden on patients and on the health care system. A 2001 analysis of medical claims for cardiovascular conditions (coronary heart disease, hypertension, congestive heart failure, and cerebrovascular accidents and transient ischemia) revealed an overall prevalence of 13.5% for cardiovascular conditions (3). The prevalence was larger in the private sector (16%) than in the public sector (11.7%) and higher among female (14.2%) than among males (12.7%). In both the public and private sectors, the prevalence of cardiovascular disease increased with age.

The Framingham risk score (FRS) has been used extensively to assess the 10-year risk for developing CHD. CHD is defined as symptomatic ischemic heart disease, including myocardial infarction, stable or unstable angina, demonstrated myocardial ischemia by noninvasive testing, and history of coronary artery procedures (4). The Framingham risk prediction algorithm was incorporated into the Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel III, or ATP III) (4). This report states that a basic principle of prevention is

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that the intensity of risk-reduction therapy should be adjusted to a person's absolute risk. A review of other clinical trials conducted since the publication of the ATP III reinforced the recommendations of the report but proposed modifications in the treatment algorithm for LDL cholesterol (5).

Many people have a combination of risk factors that have been associated with the development of metabolic syndrome (MeS). MeS is recognized in the ATP III as a secondary target of risk-reduction therapy, the primary target for such therapy being LDL cholesterol. The ATP III, a diagnosis of MeS is made when 3 or more of the following risk determinants are present: abdominal obesity, a high level of triglycerides, a low HDL level, high blood pressure, and high fasting blood glucose (4). The overall prevalence of MeS in Puerto Rico has not been assessed. However, in the San Juan Metropolitan Area, it has been estimated by Gomez et al at 32% (6) and by Pérez et al at 43.4% (7). The prevalence has been found to be higher for men (45.3%) than for women (42.2%) and, in addition, higher for those in older age groups (58.2%, 70-79 years) than it is for those in younger age groups (12.8%, 21-29 years) (7).

In spite of the availability of mortality and prevalence data, there is a lack of real-world, published information that would help in the understanding of the extent of cardiovascular risk among the general Puerto Rican population. Such information would be of importance to the establishing of primary prevention strategies that can be used by health care providers as well as to the developing of public health policy initiatives for the general population.

The main objective of this study was to determine the risks of developing CHD for the members of a sample population of patients in PR who had, for the first time, visited any 1 of 4 physicians participating in the study. Said risk was calculated using the Framingham 10-year–risk calculator, making use of those risk-score components that were available. Secondary objectives were as follows: 1) to determine the number of first-time patients who met the criteria for MeS or any of its components according to the NCEP ATP III guidelines; 2) to describe the age and gender characteristics of these patients according to 10-year CHD-risk stratification (>20%, 10-20%, and <10%) and to determine whether or not the MeS (or any of its components) is present; and 3) to determine the percentage of individuals not meeting the NCEP ATP III recommendations for blood lipids, blood pressure, or blood glucose.

Methods

Design

This was an exploratory, retrospective, cross-sectional study of a sample of patients who had, for the first time, visited the office of 1 of the 4 physicians (1 primary care physician and 3 specialists: 2 cardiologists and 1 endocrinologist) participating in the study. The rationale was to obtain a snapshot of the cardiovascular 10-year risk status of first-visit patients in this setting, with said "snapshot" being a picture of the general population's cardiovascular risk status.

Physician/Site selection

Physicians who had participated in past research studies, or who had expressed an interest in doing so, as well as those with ties to academic medical institutions were sought out; it was thought that these individuals would be highly likely to comply with the study's data-collection requirements in a timely manner and to participate in forums to discuss the study findings. In order to be able to make regional comparisons, physicians having the previous qualifications and whose offices were located in different parts of the island were chosen. Another important issue had to do with the patient populations of the prospective physicians: The patient volume needed to be high enough that data from patients whose first visits were in July 2007 or later would be adequate. In addition, the health insurance coverage of these patients needed to be varied (Medicare, private insurance, public insurance).

Participants

Being an exploratory study, the overall number of patients was limited. Using a standard sample size table and using published estimates of cardiovascular risk among Hispanics (35% in the United States [8]; no data available for Puerto Rico), we determined that a total sample size of at least 323 patients would allow us to obtain a 30% prevalence of high-risk individuals with a 95% level of confidence and a 5% level of precision. Sample sizes for published studies that have estimated cardiovascular risk vary widely, depending on whether they are large scale, epidemiological studies or exploratory, descriptive assessments. In terms of the latter type of study, a review of the literature revealed sample sizes that ranged from 50 to 815, with a mean of 306 patients (9-19). Cardiovascular-related studies conducted in Puerto Rico have used sample sizes ranging from 38 to 859, with a mean of 361 patients (20-23).

Based on the available evidence and the nature of this exploratory study, a total sample size of 500 was deemed appropriate. It is recognized that the prevalence of cardiovascular risk factors may not be exactly the same as it is for Hispanics in the United States and that for a lower prevalence of risk, a larger patient population might be required to gain the same degree of precision. In order to achieve this sample size, the records of 125 consecutive patients whose first visit occurred on or after July 1, 2007, were reviewed at each physician's office.

Inclusion/Exclusion criteria

Patients who were 35 years old or older at the beginning of data collection (July, 2007) were included. The FRS calculates risk taking into account a number of variables, one of which is age. The variables are themselves broken into ranges, and each

range is assigned a score. The individual scores are added up and the FRS determined. The age range in men of 35–39 years is scored at 0, which is why we started with that age. Only data for patients who were on their first visit to the participating physician during the study period were included in the analysis. The records for participating patients had to have recent laboratory values (either on the first visit or on the second visit if it occurred less than 3 months after the first visit) that included a lipid profile and a fasting glucose level. Patients under 35 years of age and pregnant women were excluded from the sample.

Study measures

The primary endpoint was 10-year risk for developing CHD as estimated using the FRS, and the secondary endpoint was the presence of MeS. Both were determined according to the NCEP ATP III guidelines (4). The FRS is a gender-specific measure based on an individual's current age, smoking status, total cholesterol, HDL cholesterol, blood pressure, and antihypertensive medication use. The number of points for each risk factor is assigned according to the laboratory values using specific tables (which as different for men and women). The total risk score is the sum of the points for each risk factor, which then is used to categorize the person's absolute 10-year risk.

Participating physicians received a data-collection form and an orientation on how to extract the information from the medical record. Participating physicians were instructed to select the records of 125 patients whose first visit occurred on or after July 1, 2007. Data-collection forms were reviewed for completeness by the project manager. A form was considered to be complete if it contained the values necessary to estimate the FRS as well as the patient's demographic information.

The data-collection form included the following 3 sections: Patient Information (age, gender, weight, waist circumference, height, health insurance coverage, self-reported dietary restrictions, self-reported regular physical activity, and comorbid conditions), Clinical Parameters (total cholesterol, LDL, HDL, triglycerides, systolic and diastolic blood pressure, fasting blood glucose, and glycosylated hemoglobin), and Medication Therapy.

Analysis

An external contractor developed the database, entered the data, and performed the data analysis (under the supervision of the project manager). Ten-year cardiovascular risk was calculated for men and women according to the method delineated by the NHLBI (4). Patients were stratified according to risk level (>20%, 10-20%, and <10%) and to the presence of MeS and each of its components. Descriptive statistics were used to summarize patient demographics (e.g., age, weight), other Framingham score components, NCEP ATP III MetS components, morbidity, clinical characteristics, and medication use.

Institutional Review Board/ Ethical Review Committee

The PRCaRES protocol was reviewed and approved by the Ponce School of Medicine Institutional Review Board.

Results

Data for 453 patients were extracted from the medical records. Of the extracted cases, 96 were excluded because of incomplete data or because the patient represented did not fulfill the inclusion criteria; the total number of patients in the sample was, therefore, 357. Table 1 shows the characteristics of the patients whose records were reviewed for this study.

The self-reported level of regular physical activity was very low (13.7%), and 1 in 4 (28.4%) of the patients was perceived by the attending physician to be obese (Table 1). However, based on the calculated body mass index (BMI), which takes height and weight into account, 83% of the patients whose records included the data necessary for the estimation of BMI were either overweight (40%) or obese (43.3%). More females than males were overweight (53% vs. 47%) or obese (53.5% vs. 46.5%).

Eighty-five percent of the patients reported suffering from at least 1 cardio-metabolic condition: 72.3% self-reported having hypertension, 38.4%, dyslipidemia, and 37.8%, diabetes. One-third reported having at least 2 co-morbidities: 32% had hypertension and diabetes, 32% had hypertension and dyslipidemia, and 18.2% had diabetes and dyslipidemia. Nearly 1 in 5 (16.8%) reported having hypertension, diabetes, and dyslipidemia (Table 1).

Based on the number of self-reported conditions, it was not surprising that 75.4% of the patients (n = 269) were taking at least 1 medication. The average number of medications reported per patient was 2.1. More than half of the patients (54.1%) were on antihypertensives, while 22.1% were on antihyperglycemics, and 25.2% were on antihyperlipidemics. An interesting finding was that the proportion of patients who reported taking medications was much lower than the actual number of patients who reported having hypertension, dyslipidemia, diabetes, or some combination of any or all 3. More than half (51.3%) of the women and 46% of the men who self-reported having dyslipidemia were undergoing treatment, whereas 55.1% of the women and 59.1% of the men who self-reported having diabetes were undergoing treatment.

Table 2 shows the average laboratory values for lipid and glucose parameters and blood pressure as well as the proportion of patients who were at goal, according to the NCEP ATP III. A substantial number of patients were not at goal for most parameters. The number of patients with glycosylated hemoglobin (HbA1c) was low, most probably because this test is usually not done routinely during a physician's work-up.

Table 1. Sample Characteristics

Characteristic	Number of Patients	Percent
Gender		
Male	151	42.3
Female	206	57.7
Age Distribution		
35-44 years	57	16.0
45-54 years	87	24.4
55-64 years	89	24.9
65 years or older	124	34.7
Health insurance		
Yes	332	93
No	25	7
Dietary restriction		
Yes	104	29.1
No	253	70.9
Physically active		
Yes	49	13.7
No	308	86.3
Smoker		
Yes	47	13.2
No	310	86.8
Obese		
Yes	101	28.4
No	256	71.6
Congestive heart failure		
Yes	2	0.6
No/Not known	355	99.4
Diabetes		
Yes	135	37.8
No/Not known	222	62.2
Hypertension		
Yes	258	72.3
No/Not known	99	27.7
Dyslipidemia		
Yes	137	38.4
No/Not known	220	61.6
Previous stroke/TIA		
Yes	5	1.4
No/Not known	352	98.6
Peripheral vascular disease		
Yes	16	4.5
No/Not known	341	95.5
Renal disease needing dialysis		
Yes	2	0.6
No/Not known	355	99.4

Further analysis showed that a substantial number of patients who were not at goal for lipid levels, hypertension, or blood glucose levels were not being treated with medication therapy (see Table 3). Of particular concern is the percentage of patients not at goal for LDL cholesterol, with less than 1 in 5 receiving treatment. The highest proportion of patients receiving treatment was found in those who had high blood pressure and those who had abnormal levels of glycosylated hemoglobin.

As can be seen in both Figure 1 and Table 4, nearly one-third of the sample had a 10% or higher 10-year risk of developing CHD. Compared to women, men were 3.3 times more likely to have a CHD risk of 10% or higher and 4.2 times more likely to have a 20% or higher CHD risk. As expected, CHD risk was higher in the older age groups.

A secondary objective was to determine the number of first-visit patients who met the criteria for MeS or any of its components (according to the NCEP ATP III guidelines); however, this analysis was hampered by the lack of data from the medical charts. Only 20 patients had documented waist circumference values in their charts. Nevertheless, even without this value readily available, it was determined that 12% of the females and 23% of the males in the sample had MeS (data not shown). Almost 17% of the participants presented with 3 or more of the criteria that define MeS (waist circumference excluded).More females (28%) than males (16%) with reported values met none of the criteria for MeS.

Table 2. Laboratory values and percentage of patients at goal

Laboratory value	N	Mean ± SD	Percentage of patients at goal
Total cholesterol (TC)	357	187.1 ± 41.3 mg/dL	67.5%
Low-density lipoprotein (LDL) cholesterol	351	107.5 ± 36.2 mg/dL	42.5%
High-density lipoprotein (HDL) cholesterol	357	47.5 ± 13.7 mg/dL	49.6%
Triglycerides (TG)	356	146.3 ± 98.6 mg/dL	66.0%
Systolic blood pressure (SBP)	357	130.8 ± 17.8 mmHg	44.0%
Diastolic blood pressure (DBP)	357	79.5 ± 11.4 mmHg	75.1%
Fasting glucose (FG)	352	114.3 ± 41.9 mg/dL	67.3%
Glycosylated hemoglobin (HbA1c)	107	7.5 ± 1.7	56.1%

Goals: TC<200 mg/dL; LDL<100 mg/dL; HDL≥40 mg/dL for males and ≥50 mg/dL for females; TG<150 mg/dL; SBP<130mmHg; DBP<85 mmHg; FG<110 mg/dL; HbA1c≤7% (4).

Table 3. Percentage of patients not at goal and percentage who reported receiving medication treatment (by gender)

Laboratory Parameters	Male	% Treated	Female	% Treated
Total cholesterol ≥ 200mg/dL	24.5%	13.5%	38.3%	24.0%
LDL ≥ 100mg/dL	45.0%	11.8%	65.0%	19.4%
HDL<40/50mg/dL	54.0%	22.0%	49.5%	26.5%
TG ≥ 150mg/dL	37.7%	26.3%	31.1%	34.4%
SBP ≥ 130mmHg	65.0%	56.1%	49.5%	63.7%
DBP ≥ 85mmHg	33.1%	44.0%	18.9%	56.4%
FBG ≥ 110mg/dL	43.0%	44.6%	24.3%	48.0%
HbA1C>7%	16.6%	67.0%	11.1%	56.0%

TC = Total cholesterol; LDL = Low-density lipoprotein cholesterol; HDL = High-density lipoprotein cholesterol; TG = Triglycerides; SBP = Systolic blood pressure; DBP = Diastolic blood pressure; FG = Fasting glucose; HbA1c = Glycosylated hemoglobin. % Treated = the percentage of patients who reported being treated with a antihypertensive, a cholesterol-reducing drug, or an oral antihyperglycemic agent

Even though the presence of abdominal obesity has been found to be more highly correlated with the metabolic risk factors than an elevated BMI (4) is, some have argued that a BMI value over 30 kg/m2 may be used as a proxy for abdominal

obesity (24). If this value is used instead of abdominal obesity in this sample, the percentage of participants who would meet the criteria for MeS according to the NCEP would be 47.1% (n = 168). This is consistent with previous findings from a population-based study conducted in the San Juan metropolitan area, where the overall prevalence was found to be 43.3% (7). Nearly one-third of the females (35.4%) and two-thirds of the males (62.9%) would meet the criteria for MeS using BMI as a proxy for abdominal obesity. It is important to note that the ages of the members of the sample for the study conducted in San Juan range from 21 to 79 years, while the sample members in this study were 35 years and older.

Table 4. CHD risk level by gender and age

Gender	Age Group	CHD Risk Level					
		Low (<10%)		Moderate to High (10 to 20%)		High (More than 20%)	
		n	%	n	%	n	%
Male	35-44 years old	31	52.5%	2	2.8%	0	0.0%
	45-54 years old	23	39.0%	9	12.7%	2	9.5%
	55-64 years old	5	8.5%	25	35.2%	4	19.0%
	65 years or older	0	0.0%	35	49.3%	15	71.4%
Total Male		*59*	*100.0%*	*71*	*100.0%*	*21*	*100.0%*
Female	35-44 years old	23	12.9%	0	0.0%	1	20.0%
	45-54 years old	52	29.2%	1	4.3%	0	0.0%
	55-64 years old	55	30.9%	0	0.0%	0	0.0%
	65 years or older	48	27.0%	22	95.7%	4	80.0%
Total Female		*178*	*100.0%*	*23*	*100.0%*	*5*	*100.0%*

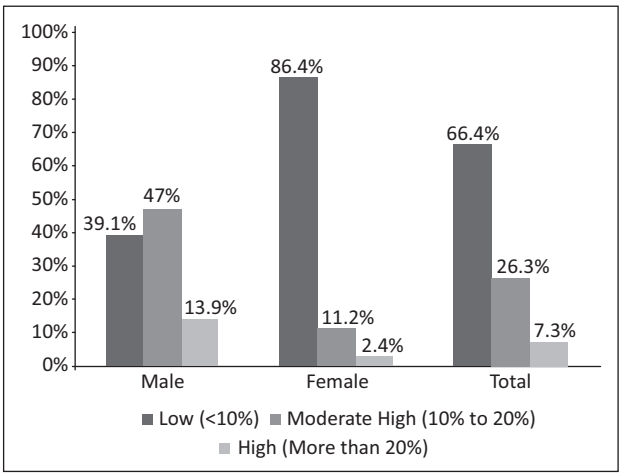

Figure 1. CHD risk-level distribution by gender

Discussion

The global burden of cardiovascular disease is considerable (25). Puerto Rico is no exception; every year more than 5,000 people (over 100 people per 100,000 population) die of heart disease (1). The results of the study described herein confirmed previous findings that indicate high prevalence of obesity, hypertension, diabetes, and dyslipidemia in Puerto Rico. Compared to the BRFSS, a larger percentage of patients whose data were included in this study were obese (41.4% vs. 26.2%), were hypertensive (73% vs. 32.7%), had diabetes (38.3% vs. 12.4%), or had dyslipidemia (39.6% vs. 34.3%) (2). The overall prevalence of MeS was lower than that previously found in San Juan (16.8% vs. 43.4%) (7), but this was greatly influenced by the lack of information regarding waist circumference in the medical records. If BMI were to be used as an indicator, the overall prevalence of MeS would be similar to that of previous studies. Since abdominal obesity has been found to be more highly correlated with the metabolic risk factors than an elevated BMI has, the results of this study highlight the need to document waist circumference as part of the standard medical history of new patients.

Therapeutic goal achievement is an important component in the management of chronic conditions such as hypertension, dyslipidemia, and diabetes. More than 60% of the patients were at goal for lipid, blood pressure, and blood glucose parameters, with the exception of LDL cholesterol and systolic blood pressure, for which components nearly 60% were not at goal. More importantly, a substantial number of patients who were not at goal also were not receiving medication treatment at the time of the first visit to the participating physicians. A few possible factors for these patients' not being at goal for specific parameters include poor lifestyle habits (poor dietary habits, lack of exercise), the lack of adherence to prescribed therapy, an inadequate medication regimen, and family history.

One-third of this first-time–visit sample of patients had a 10% or greater 10-year risk of developing CHD according to the FRS. Males accounted for a substantial number of these, as more than 60% of the participating males (compared to 13.6% of the females) had a moderately high or a high 10-year risk of developing CHD. Disparities in the different CHD risks between males and females have also been documented in other studies (8). CHD risk also increased with age, which is consistent with previous findings in the US (8).

This study has several limitations. Because of its exploratory nature, the sample size was limited. Data were extracted from the records of consecutive patients visiting the participating physicians' offices for the first time. Although we enrolled each patient on his or her first visit to the corresponding physician, we cannot assert that this was the first visit ever to that physician. Furthermore, the reasons for the visit were not available, and the sample may have been biased due to self-selection, as patients who visit physicians do so because they have been told they need to or because they feel ill. Furthermore, by including patients seen by an endocrinologist or a cardiologist, there is a selection bias in favor of a higher risk profile. Consequently, the sample was not necessarily representative of the Puerto Rico population.

The prediction scores produced using the FRS have been found to vary across ethnic groups (26). Therefore the scores may represent an over- or underestimation in terms of the risk of CHD in this population. We selected patients who were 35 years old or older and included patients who were over 79 years old in the cohort making up the 70- to 79-year-old age range, which inclusion may also have skewed the results. Furthermore, some of the data needed to estimate the risk score or to determine the presence of MeS (e.g., waist circumference) were unavailable, a lack which limited the usable information for some of the parameters. Finally, some data were self-reported by the patient (i.e., medical history) and so could not be validated.

Conclusions

This study confirms the findings of other studies that highlighted the risk of CHD in residents of Puerto Rico. A substantial number of first-visit patients whose records were reviewed had risk factors for developing CHD and were not at goal for specific parameters (e.g., LDL cholesterol, systolic blood pressure) that are used for the estimation of CHD using the FRS. In spite of not being at goal, a large percentage of patients of both genders were not receiving drug therapy to treat their conditions. Furthermore, a CHD risk and treatment gap was apparent between the male and female Puerto Rico residents included in the sample.

Larger scale epidemiological studies with sufficient statistical power are needed in order to generate definite conclusions that will help in assessing gaps in patient care—which gaps include those related to treatment with medications—and in proposing public health policy initiatives aimed at preventing CHD and its complications in the general population of Puerto Rico. A prospective study design that addresses patient awareness of estimated 10-year risk and actual calculated risk may prove useful for patient management. Furthermore, future research should assess newer risk factors that refine the prediction of CHD in our population (27) and determine the value of estimating this risk to guide clinical decision-making in practice so that patient outcomes might be benefitted.

Resumen

Objetivo: Conocer el riesgo de desarrollar enfermedad coronaria (CHD, por sus siglas en inglés) en una muestra transversal de personas residentes en Puerto Rico usando la escala de riesgo a 10 años de Framingham. Métodos: Estudio exploratorio, retrospectivo, transversal de expedientes médicos de pacientes de 35 años o más que visitaron las oficinas de 1 de 4 médicos participantes en o después del 1 de julio de 2007. Resultados: Se extrajeron datos de 453 pacientes de los expedientes médicos, pero 96 casos fueron excluidos debido a que sus datos estaban incompletos o por que no cumplían con los criterios de inclusión, para una muestra total de 357 pacientes. La edad promedio fue de 58 años (±11.8) y la mayoría (58%) eran mujeres. Ocho de diez pacientes estaban sobrepeso u obeso. Ochenta y cinco por ciento reportaron tener por lo menos una condición cardio-metabólica: 72.3% informó tener hipertensión, 38.4% dislipidemia y 37.8% diabetes. Muchos pacientes no estaban en meta de los parámetros de presión sanguínea, lípidos y glucosa y no estaban tomando medicamentos para estas condiciones. Casi una tercera parte tenía un riesgo a diez años de 10% o más de desarrollar CHD. En comparación con las mujeres, los hombres fueron 3.3 veces más propensos de tener un riesgo a diez años de desarrollar CHD de 10% o más y 4.2 veces más propensos de tener un riesgo de 20% o más. Conclusión: Un número sustancial de pacientes tenían factores de riesgo para desarrollar CHD y no estaban en meta de parámetros específicos. Estudios epidemiológicos en mayor escala son necesarios para determinar el riesgo de CHD en Puerto Rico y proponer iniciativas de política pública para reducir este riesgo.

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