Risk of cardiovascular disease according to the Framingham score in patients with high blood pressure from Pillaro, Ecuador. 2017-2018

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Abstract

Introduction: Cardiovascular disease (CVD) is the main cause of morbidity and mortality worldwide. The use of the Framingham Risk Score is of great importance for predicting CVD risk.

Objective: To estimate the 10-year CVD risk in adult patients diagnosed high blood pressure (HBP) who visited the outpatient service of the San Miguelito de Pillaro Health Center, in Tungurahua, Ecuador, using the Framingham Risk Score (2008).

Materials and methods: Cross-sectional, observational, prospective and descriptive study conducted in 120 HBP patients aged 30 to 74 years who visited the outpatient service between January and October 2017. Data were obtained from the review of medical records, which were in turn updated during the execution of the study. The Framingham risk score was used to calculate the 10-year CVD risk. A descriptive analysis of the data was performed in Epi Info 7, using absolute frequencies and percentages.

Results: Of the 120 patients, 59.17% were women. Furthermore, 15% of the participants had been diagnosed with type 2 diabetes mellitus, 13.33% had a history of smoking, 47.50% had elevated systolic blood pressure, and 39.17% had hypercholesterolemia. CVD risk was low (≤ 1% Framingham score), intermediate (10-19%), and high (≥ 20%) in 15%, 29.16%, and 59.16% of participants, respectively. None of them had a very low CVD risk (≤1%).

Conclusion: The Framingham risk score was useful to estimate CVD risk in the study population treated in the primary health care setting. Consequently, more extensive use of this instrument in different health units is recommended to obtain better estimates of CVD risk and, as a result, achieve the implementation of health prevention and health care actions that improve the prognosis in the medium and long term, and thus the quality of life of these patients.

Keywords: Heart Disease Risk Factors; Cardiovascular Risk Score; High Blood Pressure; Primary Health Care (MeSH).

Resumen

Introducción. Las enfermedades cardiovasculares (ECV) son la principal causa de morbimortalidad a nivel mundial; el uso de la escala de Framingham es de gran importancia para predecir el riesgo de ECV.

Objetivo. Determinar el riesgo de ECV a 10 años en pacientes adultos con diagnóstico de hipertensión arterial (HTA) que asistieron al servicio de consulta externa del Centro de Salud de San Miguelito de Pillaro, Tungurahua, Ecuador, utilizando la escala de riesgo de Framingham (2008).

Materiales y métodos. Estudio transversal, observacional, prospectivo y descriptivo realizado en 120 pacientes con edades entre 30 y 74 años y con diagnóstico de HTA que asistieron al servicio de consulta externa entre enero y octubre de 2017. Los datos se obtuvieron a partir de la revisión de las historias clínicas, las cuales, a su vez, fueron actualizadas durante la ejecución del estudio. El riesgo de ECV a 10 años se determinó según el puntaje obtenido en la escala Framingham. Se realizó un análisis descriptivo de los datos en el programa Epi Info 7 utilizando frecuencias absolutas y porcentajes.

Resultados. De los 120 pacientes, 59.17% eran mujeres. Además, 15% de los participantes había sido diagnosticado con diabetes mellitus tipo 2, 13.33% tenía antecedentes de tabaquismo, 47.50% tenía tensión arterial sistólica elevada y 39.17% tenía hipercolesterolemia. El riesgo cardiovascular fue bajo (≤1% puntaje Framingham), intermedio (10-19%) y alto (≥20%) en 15%, 29.16% y 59.16% de los participantes, respectivamente. Ninguno tuvo riesgo muy bajo (≤1%).

Conclusión. La escala Framingham fue útil para estimar el riesgo cardiovascular de los participantes en el contexto de la atención primaria de salud, por lo que se recomienda un uso más amplio de este instrumento en las diferentes unidades de salud con el fin de obtener una mayor estimación del riesgo de ECV y así lograr la implementación de acciones de prevención y atención en salud que mejoren su pronóstico en el mediano y largo plazo, y, por tanto, la calidad de vida de estos pacientes.

Palabras clave: Enfermedades cardiovasculares; Hipertensión; Atención primaria de salud (DeCS).
Introduction

High blood pressure (HBP) is defined as blood pressure with systolic blood pressure (SBP) ≥140 mmHg or diastolic blood pressure (DBP) ≥90 mmHg. According to the World Health Organization (WHO), cardiovascular disease (CVD) is the leading cause of death worldwide: in 2016, ischemic heart disease and stroke caused about 15.2 million of all global deaths. However, in recent years, CVD mortality has declined markedly in North America, although changes in Latin America have not been so favorable.

In this regard, the WHO states that deaths related to heart disease and stroke are more frequent in low- and middle-income countries. In Ecuador, according to the 2018 Statistics on Live Births and Deaths, ischemic heart disease was the main cause of death in both men and women, accounting for 7 404 deaths. Most CVD can be prevented by addressing risk factors such as smoking, poor diets, overweight, and physical inactivity. Therefore, as stated by Zwaard et al., it is essential to people with high cardiovascular risk (CVR) be diagnosed and treated with medication and counseling to improve their lifestyle. Consequently, establishing CVR is of the utmost importance, and although there are different tools to measure it, Framingham equations are the most used method worldwide. They were developed more than 70 years ago in the context of the Framingham Heart Study (FHS), derive from an American Caucasian population and allow estimating the absolute risk for several CVD endpoints, including coronary disease and stroke.

Similarly, new scales for measuring CVR have been developed and validated based on the FHS. The most widely used are the traditional Framingham score, Framingham categories, new Framingham scales, multiple-risk-factor assessment equations from the American Heart Association and the American College of Cardiology, Joint British Societies CVD Risk Prediction Chart, New Zealand risk prediction tables, new Sheffield tables, Münster Heart Study PROCAM tables, Dundee Coronary Risk Disk, West of Scotland Cardiovascular Event Reduction Tool, and the SCORE Project.

The Framingham Risk Score (FRS) 2008 is a simple and common tool with external validity that has been assessed in different populations worldwide, so it is one of the most applicable methods for evaluating long-term (10-year) CVR around the globe. This score has the advantage of using simple and commonly available predictors such as age, sex, smoking, diagnosis of type 2 diabetes mellitus (DM2), blood pressure levels, presence of antihypertensive treatment, and total cholesterol (TC) and high-density lipoprotein cholesterol (HDL-C) levels. It should be noted that the estimate is currently thought to differ slightly within this model depending on the patient’s sex and the type of prevention (primary or secondary). Likewise, it is worth remembering that HBP is an important risk factor for developing CVD and therefore estimating CVR in patients with this condition is essential to avoid complications.

Since the FHS was originally designed for a Caucasian population between the ages of 30 and 70, there is still some controversy regarding the use of scores derived from it in other ethnic groups, especially in young patients, so validation is necessary. As a result, the FRS 2008 is regarded as a poor predictor of CVR in primary care in Ecuador.

In this scenario, the objective of this study was to determine the 10-year CVD risk in adult patients with a diagnosis of HBP who attended the outpatient service of the San Miguelito de Píllaro Health Center, Tungurahua, Ecuador, using the FRS 2008.

Materials and methods

Cross-sectional, observational, prospective and descriptive study. All adult patients (over 18 years of age) who attended the outpatient service of the Type A San Miguelito primary care health center between January and October 2017 with a diagnosis of HBP according to the 2018 ESC/ESH Guidelines for the management of arterial hypertension (n=146) were considered. Only patients aged between 30 and 74 years were included, as stipulated in the scale, so the final sample, which did not require a calculation, consisted of 120 individuals.

Data were collected between October 2 and December 22, 2017, by reviewing and updating the medical records of the 120 patients selected. The following data were obtained for each patient as established by the FRS 2008: age (being between 30 and 74 years, as this is the study population); sex (female/male); smoking history (yes/no); presence of antihypertensive treatment (yes/no); diagnosis of DM2 (yes/no); SBP levels (taken in the right arm with the patient sitting and resting for 5-10 minutes. Optimal: <120 mmHg, Normal: 120-129 mmHg, Normal-High: 130-139 mmHg, HBP 1: 140-159 mmHg, HBP 2: 160-179 mmHg and HBP 3: ≥180 mmHg), TC levels (normal <200 mg/dl, normal-high 200-239 mg/dl and high ≥240 mg/dl), and HDL-C levels (low <40 mg/dl, normal 40-59 mg/dl, and high ≥60 mg/dl).

The FRS 2008 was applied to participants when they attended the outpatient clinic during the specified period (January-October 2017). The 10-year CVR was calculated using the 8 variables identified, with a score <10% considered as low risk, 10-20% as intermediate risk, and >20% as high risk.

Blood pressure was classified according to the guidelines for the prevention, detection, evaluation, and management of adult HBP in adults published by Whektron et al., while biochemical parameters, including CT and HDL-C, were measured using the colorimetric enzymatic method (CHOD-PAP).

CVR was calculated based on the following formula: RiskFactors = (ln(Age) * AgeFactor) + (ln(TotalChol) * TotalCholFactor) + (ln(HDLChol) * HDLCholFactor) + (ln(SysBP) * SysBPFactor) + Cig + DM - AvgRisk. The following constants were considered depending on the sex of the patient:

- For men: Age Factor: 3.06117, Total Chol Factor: 1.12370, HDL Chol Factor: -0.93263, Avg Risk: 23.9832 and Risk Period Factor: 0.88936.

Taking into account the scores obtained with the FRS 2008, the results were classified as follows: ≤1%: very...
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low risk, 2%-9%: low risk, 10%-19%: intermediate risk, and ≥20%: high risk.15,16

Statistical analysis

Data were entered into a database created in Microsoft Excel 2016 for subsequent descriptive analysis with the Epi Info 7 software using absolute frequencies and percentages.

Ethical considerations

The study took into consideration the ethical principles for medical research involving human subjects established by the Declaration of Helsinki17 and was approved on August 2, 2017, by the Bioethics and Research Involving Human Subjects Committee of the Universidad Regional Autónoma de los Andes by means of Minutes No. 23-08/2017_CBISH-UNIANDES. Also, the informed consent of each participant was obtained to collect the data.

Results

Table 1 summarizes the main findings obtained from the 120 patients who participated in the study. Among the most significant findings, it was noted that no patient was classified as very low risk and that those categorized as high risk were predominant in both sexes: 32 of the 71 women (45.07%) and 39 of the 49 men (79.59%). DM2 was present in 18 patients, representing 15% of the entire sample; of these, 15 were classified as high-risk.

Table 1. Cardiovascular risk determined for the study population according to the general data obtained from the Framingham 2008 risk score.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Overall cardiovascular risk</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Very low (%)</td>
</tr>
<tr>
<td>Total</td>
<td></td>
</tr>
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<td>30-34 years</td>
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<td>35-39 years</td>
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<td>Male</td>
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</tr>
<tr>
<td>Cigarette consumption</td>
<td></td>
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<tr>
<td>Yes</td>
<td>0</td>
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<tr>
<td>Antihypertensive treatment</td>
<td></td>
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<tr>
<td>Yes</td>
<td>0</td>
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<tr>
<td>No</td>
<td>0</td>
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<tr>
<td>Diabetes mellitus type 2</td>
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<td>Yes</td>
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<tr>
<td>No</td>
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<tr>
<td>Systolic blood pressure</td>
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<tr>
<td>Normal (120-129 mmHg)</td>
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<tr>
<td>Normal-High (130-139 mmHg)</td>
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<tr>
<td>HBP 1 (140 -159 mmHg)</td>
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<td>HBP 2 (160-179 mmHg)</td>
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<tr>
<td>HBP 3 (≥180 mmHg)</td>
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<tr>
<td>Total cholesterol</td>
<td></td>
</tr>
<tr>
<td>Normal (&lt;200 mg/dL)</td>
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<tr>
<td>Normal-high (200-239 mg/dL)</td>
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<tr>
<td>High (≥240 mg/dL)</td>
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<tr>
<td>High-density lipoprotein cholesterol (HDL)</td>
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<td>&lt;40 mg/dl</td>
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<tr>
<td>40-59 mg/dl</td>
<td>0</td>
</tr>
<tr>
<td>≥60 mg/dl</td>
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</tr>
</tbody>
</table>

HBP: high blood pressure.
Source: Own elaboration.
Regarding TC, 73 patients (60.83%) had normal levels (41 classified as high-risk), 27 (22.5%) had normal-high levels (15 classified as high-risk), and 20 (16.67%) had high levels (15 classified as high-risk).

In relation to HDL-C, 36 (30%) patients had levels <40 mg/dL (22 classified as high risk), 82 (68.33%) levels between 40 mg/dL and 59 mg/dL (49 classified as high risk), and only 2 had levels ≥60 mg/dL (one classified as low risk and the other, as intermediate risk).

As for SBP measurements, 12 (10%) patients had optimal values (4 classified as high-risk); 21 (17.5%), normal values (10 classified as high-risk); 30 (25%), normal-high values (17 classified as high-risk); 39 (32.50%), HBP 1 values (24 classified as high-risk); 13 (10.83%), HBP 2 values (11 classified as high risk); and 5 (4.16%), HBP 3 values (all classified as high risk).

About tobacco use, it was found that 15 (93.75%) of the 16 patients who had this habit were men.

With respect to age, it was noted that most participants classified as high-risk were elderly: 33 patients in the range 70-74 years and 24 in the range 65-69 years.

Finally, 99 (82.50%) of the 120 participants reported being on antihypertensive treatment, and 61 (61.62%) of them were classified as high-risk, 29 (29.29%) as intermediate-risk, and 9 (9.09%) as low-risk. Of the 21 (17.5%) who did not receive any treatment, 10 (47.62%) were classified as high risk, 6 (28.57%) as intermediate-risk, and 5 (23.81%) as low-risk.

**Discussion**

Each of the variables analyzed, the results of which are reported in Table 1, is discussed separately below.

**Sex**

In the present study, HBP was slightly more prevalent in women than in men (59.17% vs. 40.83%). This is consistent with the findings of Sánchez Seco Higuera et al., who found that 53.5% of women and 46.5% of men in a sample of 662 subjects over the age of 65 from Horche (Guadalajara, Spain) had high blood pressure. It should be noted that women have protective mechanisms against CVD, but they partially lose such protection when they reach menopause, making them more susceptible to developing this type of disease.

In spite of the above, it is noteworthy that the percentage of male participants classified as high-risk was significantly higher than that of females (79.59% vs. 45.02%), which may be influenced by tobacco use, as it was more frequent in males.

**Diabetes mellitus type 2**

The percentage of patients with DM2 found in the present study (15%) is considerably low, which coincides with an epidemiological study conducted in Japan, where approximately 20% of patients with high blood pressure had this disease. This is relevant because, according to research conducted in Ethiopia by Akalu & Belsti, a one-year increase in the duration of DM2 increases the likelihood of developing HBP by 16% (aOR: 1.16, 95%CI: 1.08-1.25).

**Smoking history**

The patients who reported smoking accounted for a small percentage of the study population (13.33%, n=16), although most of them (n=13) were classified as high-risk for CVD; therefore, it could be concluded that this habit, although rare, implies a higher CVR compared to non-smokers. However, in the study by Petermann et al., carried out in Chile, no association between these variables was identified in men, but it was found that the risk decreases in female smokers (OR: 0.67 95%CI: 0.52-0.86, p=0.002) and in former female smokers (OR: 0.77 95%CI: 0.60-0.99, p=0.040). This result contradicts most research in this matter, as few studies describe a decrease in blood pressure in smokers.

With respect to this variable, it should be noted that Akalu & Belsti assessed smoking in 378 patients with DM2 and a mean age of 56 years, finding that this population is 3.9 times more likely to develop HBP than those without this condition.

Similarly, Arboleda-Carvajal & García-Yanés, in a study of 249 people from a general population of the Amazon region of Morona Santiago (Ecuador), found that the main factor for CVR was smoking (48.6%), followed by overweight (40.2%) and low HDL-C (10.4%), which correlates with the findings of this research.

It is important to bear in mind that the present study did not evaluate the number of cigarettes smoked per day, but rather the presence or absence of consumption.

**High-density total and lipoprotein cholesterol**

Most (60.8%) of the participants had TC levels within the normal range and only a small percentage (16.6%) did not have an optimal result, which is similar to what has been reported by Sánchez Seco Higuera et al., who found that 23.3% of participants had hypercholesterolemia.

Regarding HDL-C levels, 30% of participants had results below the optimal value, 68.33% had normal values, and only 1.67% had optimal values, which is relevant because, according to a study performed in 35 patients with metabolic syndrome by Mendoza-Romo et al., individuals with optimal HDL-C values experience a significant beneficial change by lowering their blood pressure and therefore their CVR, whereas the latter increases in those with a decrease in HDL-C levels.

The measurement of these variables is of great importance because it is possible to establish adequate diets and nutritional recommendations focused on preventing possible cardiovascular events when determining CVR in patients using the FRS 2008.

**Antihypertensive therapy**

A large percentage of the participants in the sample analyzed were on antihypertensive treatment (82.5%). Of the 21 patients who reported not taking antihypertensive medication (17.5%), about half (47.61%; n=10) were classified as high-risk, which is concerning given that treatment is essential to avoid complications in these patients.

In this regard, Tang et al., in a cohort study of 2199 patients aged 65 years or older in Canada comparing adherence rates and associations with mortality using different adherence definitions and various methods...
of managing concurrent drug use, found that 24.1% to 90.5% and 71.2% to 92.7% of the patients were considered adhering when using fixed interval and prescription-based interval measurement possession ratios respectively, depending on how concurrent medications were handled. This situation shows a large fluctuation that is concerning because of the lack of homogenization in the level of awareness regarding treatment.

Likewise, Tan et al.,29 conducted a systematic review that evaluated the effectiveness of educational interventions to improve medication adherence in adult patients diagnosed with hypertension, hyperlipidemia, and/or diabetes, and concluded that health literacy is improved through health education, improving medication adherence as well.

**Age**

In the present study, the predominant age range was 70 to 74 years (n=42), in which high CVR prevailed (n=33), which was to be expected given the increased number of physiological changes associated with aging that could influence this aspect.

With respect to this variable, Akalu & Belsti21 found in their study that people over the age of 50 are more likely to have HBP, which can be attributed to the vascular changes that occur during aging and that trigger greater stiffness and thickening of the arteries. This is supported by different studies that report that the prevalence of HBP increases with age.21,30

**Systolic blood pressure**

When assessing SBP, it was found that in most participants the values were above 130 mmHg (72.49%), with a higher prevalence among older patients and in those who reported not being on antihypertensive treatment.

Based on the findings, it is confirmed that age is a factor of CVR, since SBP is more prevalent in patients over 60 years of age and is also associated with diseases such as stroke, cardiovascular disease, and increased mortality.21,30

**Overall cardiovascular risk in the study population**

When determining overall CVR according to the FRS 2008, in the present study most of the study population (59.17%) was classified as high risk; about a quarter (29.17%) was classified as moderate risk; and a small percentage (11.67%) was classified as low risk. These findings markedly differ from those found by De La Noval-Garcia et al.,22 who reported a low risk (<10% according to the WHO risk classification proposal) in 93.6% of participants in a study of 1,287 people (randomly selected) between 40 and 70 years in Havana, Cuba. It should be noted, however, that this difference is most likely due, on the one hand, to the fact that each study used a different tool for risk assessment (FRS 2008 vs. WHO classification proposal) and, on the other, to sampling differences in population size and type, since the present study included a specific sample (patients with HBP) that was 10 times smaller, whereas the study of Nova-Garcia et al.22 analyzed the general population.

Furthermore, the finding of the present study in terms of global CVR also differs from the results obtained by Muñoz-Gualan & Muñoz33 in a study carried out in 2015 in 80 apparently healthy military personnel of the 62nd Jungle Battalion “Zamora” (Ecuador), in which CVR was evaluated using the Framingham score, finding that 60% of the population was at low risk and 33.75% at moderate risk. The differences between the present study and the latter may be influenced by the physical fitness and systematic training that military participants received, which contributes to better overall health and, as a result, lower CVR.

It is also worth noting that the study by Giraldo-Trujillo et al.,34 carried out in 138 Colombian workers of both sexes, found that 28.6% of men were classified as low risk and 53.5% as medium risk with the Framingham-Grundy scale, which contrasts with the present study in that most participants were classified as high risk.

It is also noteworthy that, compared with the studies described above, the overall CVR was significantly higher in the present study, which may be due to the fact that these studies were performed in populations different from the FHS (Caucasians aged between 30 and 60 years). This heightens debates over the FRS 2008’s utility in different ethnic groups, particularly among young patients.30,35

On the other hand, in a study carried out in 2014 with 208 women between 35 and 74 years old from Havana, Rodríguez-Blanco et al.,35 found that the most frequent factors of overall CVR were smoking (44.71%) and SBP≥140 mmHg (28.36%),36 results that differ from those of the present research.

In general, the findings of this study are consistent with those reported in the literature; however, even though the population analyzed here presents with a large number of risk factors, they are not the ones that predispose it to high CVR, but rather the association of some of them in the same patient. In addition, the changes that the body goes through over time, both structural and functional, predispose to the development of CVD,10 indicating the importance of taking preventive measures and conducting a comprehensive follow-up of patients.

**Final remarks**

In 2018, the ESC/ESH guidelines recommended using the SCORE scale in European and North American populations to assess CVR in patients without known CVD with a 10-year risk estimate, for which it is important to know the hypertension-mediated organ damage.13 Thus, the stratification of CVR according to this tool can help detect patients who require timely comprehensive management, eliminating the predictors of death. This is considered a substantial contribution to Ecuador’s national primary health care program.

It is essential to bear in mind that although CVR prediction equations are widely accepted, there is evidence showing that they cannot be applied directly to all populations; therefore, defining the most suitable model to use in the Ecuadorian population is a priority. To this end, the study by Muñoz et al.,37 in which external validation of the Framingham and PROCAM models was performed in 1,013 Colombian patients aged 30 to 74 years and free of cardiovascular events at the time of enrollment to the cohort (1984 to 1996), can be used as a guide. In that study, the authors concluded that the FRS 2008 should be used with caution in low- and
intermediate-risk Colombian populations with no previous history of CVD because it overestimated the risk and demonstrated a low capacity for discrimination between low- and high-risk patients.

Similarly, it should be noted that in Ecuador, the Ministry of Public Health recommended using the Globorisk tool to assess CVR in the country because it was developed in a multi-ethnic population, Latin Americans (Mexico) being representative; it allows calculation without laboratory values, makes an estimate for 11 countries, and is free of charge. However, the FRS 2008 calibrated by Muñoz et al. continues to be used since it has been widely disseminated in recent years, the health personnel is familiar with its use, and has been endorsed by 2 consensuses of the Colombian Society of Cardiology, as reported by Muñoz et al. This model should be calibrated for use in the Ecuadorian population with local epidemiological data, which would pave the way for future studies determining the most appropriate scale for usage in the country.

Limitations

One of the limitations of this study is that different age ranges, the standardization approach, and the lack of cross-validation of laboratory tests make it difficult to compare the results obtained with those of other studies of similar characteristics in the absence of standardization.

Another limitation is that it is unknown whether the FRS 2008 is the most suitable instrument for estimating the CVR in Ecuador since the epidemiological characteristics of Ecuadorians are different from those of Americans, the population for which this instrument was designed, and absolute CVD mortality is higher in the USA.

Finally, while FRS 2008 is a valuable tool for predicting CVD risk, it has numerous limitations that must be noted before applying its results, such as the fact that it is an estimation algorithm rather than a medical examination. In addition, the original cohort did not include a young population, making it an inaccurate tool in this age group, and, finally, it does not include other possible factors of CVR.

Moreover, the cross-sectional nature of the present study makes it difficult to better address the direction of causality between variables, so it is suggested to conduct additional studies by delving into the relational and explanatory levels of research within the CVR line of research.

Conclusions

The FRS 2008 proved to be a useful tool for estimating CVR in primary health care in the study population. Therefore, a wider use of this tool is recommended in the different health units of Ecuador in order to obtain a better estimate of CVD risk, which will allow for the implementation of prevention and health care actions to improve prognosis in the medium and long term, and, consequently, the quality of life of these patients.

Conflicts of interest

None stated by the authors.

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