CONCORDANCE BETWEEN PROCAM AND FRAMINGHAM CARDIOVASCULAR RISK SCORES AMONG MEN RECEIVING HIV TREATMENT AT A NATIONAL HOSPITAL IN LIMA, PERU 2013

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ABSTRACT

Objectives. The aim of the study is to determine the concordance between the PROCAM (Prospective Cardiovascular Münster) and Framingham scales in patients receiving highly active antiretroviral therapy (HAART). ***Materials and methods.*** A cross sectional study was conducted in HIV-positive male population who use HAART in a national reference hospital located in Lima, Peru. To evaluate the concordance between the two scales the graphic method of Bland and Altman was used, for the evaluation of the correlation we used the Pearson coefficient and to measure the agreement we use the kappa coefficient. ***Results.*** 111 patients were enrolled, with an average age of 47.0 years.-The distribution of patients according to the risk was low, moderate and high, 81.2%, 13.6% and 5.4% respectively for PROCAM and 71.2%, 25.2% and 3.6% for Framingham. According to the graphic method of Bland and Altman, the concordance was adequate in low values and was lost as the risk score increased. Pearson's test found a strong correlation ($r=0.87$ and $p<0.05$) and the kappa coefficient was 0.56 ($p<0,001$). ***Conclusions.*** The agreement we found at low risk decreases as the risk increases. Strong correlation was found between the two scales. We recommend further studies in order to know which scale of cardiovascular risk is the most optimal scale for clinical practice among HIV population who receive HAART.

Key words: Risk assessment, HAART; Comparative study; Cardiovascular diseases (source: MeSH NLM).

INTRODUCTION

By 2012, the epidemic of human immunodeficiency virus (HIV) infection has resulted in 35.3 million infected people, with 2.3 million new cases worldwide [(1)]. The MINSA (Spanish acronym of Ministry of Health of Peru) reported 52,752 cases in Peru before February 2014, and 308 new cases, 124 of which are in Lima [(2)]. Antiretroviral therapy (ART) is a well-established treatment worldwide. In 2004, ART was specified in a ministerial decree for state healthcare institutions in Peru [(3)].

Multiple studies were carried out when ART was introduced, in order to determine its adverse effects. According to the Data Collection on Adverse Events of Anti-HIV Drugs (DAD) study (2003), protease inhibitors that are used along with nucleoside analog reverse-transcriptase inhibitors cause upregulation of a series of triglycerides and cholesterol and a decrease in the high-density lipoprotein cholesterol (HDL-c) level in patients treated with this regimen for four years [(4)]. At the Massachusetts General Hospital, USA, a relative risk of myocardial infarction of 1.75 was observed among HIV patients in comparison with patients who do not have

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HIV [5]. The HOPS study, conducted between 1992 and 2003, showed an increased incidence of myocardial infarctions after ART was introduced [6]. A study in Nigeria in 2013 found a link between ART and hypertension, obesity, and metabolic syndrome [7].

The presence of cardiovascular disease led to the use of tests that assess the risk of cardiovascular events, including the Framingham scale and PROCAM scale. The Framingham scale was developed in 2000, on the basis of the original Framingham study in the USA that followed 5209 males between 30 and 62 years of age on two occasions: in 1948 and 1971. The characteristics that were evaluated include age, total cholesterol, systolic blood pressure, tobacco use, and HDL-c; the Framingham scale is used in the majority of studies on HIV-positive patients. The PROCAM scale was developed in 2002, on the basis of the "Prospective Cardiovascular Münster" study in Germany that followed 5389 patients between 35 and 65 years of age between 1979 and 1985 [8,9]. The parameters that are tested include age, LDL-c, HDL-c, triglycerides, tobacco, diabetes, systolic blood pressure, and a family history of myocardial infarction in those younger than 60 years of age [8,9].

The Framingham scale has been recommended by many guides, such as the Adult AIDS Clinical Trial Group Cardiovascular Disease Focus Group (AACTG) [10] and the Pavia Consensus [11]. The latter indicated that every patient using ART requires cardiovascular risk stratification using the Framingham scale. On the other hand, some experts recommended using tests that include other parameters that are absent in the Framingham scale because this test can underestimate the cardiovascular risk [12]. For this reason, the present study also involves the PROCAM scale, which includes the level of triglycerides, the presence of diabetes mellitus, and the family history of myocardial infarction. It is worth emphasizing that hypertriglyceridemia (as measured only by PROCAM) and low HDL-c levels are clinical parameters that are generally altered in HIV-positive populations [13].

It was not possible to conduct a 10-year follow-up for both tests in this study; this long-term approach should show whether there is concordance between these tests. If the concordance is found to be low, then more studies can be carried out to determine which test yields the more accurate diagnosis. If the concordance is found to be good, then a physician can use either of these tests because missing data such as diabetes mellitus, hypertriglyceridemia, and a family history of myocardial infarction would not alter the risk outcome after 10 years. According to the above rationale and because there are few studies of this type on this kind of population (and none in our country), it is worthwhile to compare the two tests on patients using ART.

The main objective of this study was to determine the concordance between the Framingham scale and PROCAM scale in male HIV-positive patients who receive ART at a national hospital in Lima, Peru. The secondary objectives were to explore the correlation between these tests, the global risk level in this population, and the lipid profile.

MATERIALS AND METHODS

DESIGN AND LOCATION OF THE STUDY

A cross-sectional and analytical design was used here to evaluate the concordance between these cardiovascular risk tests in an HIV-positive population receiving ART. HIV-positive patients that received ART between January and December 2013 were selected via out-patient consultations at the Infectious Diseases Service of the Hospital Nacional Edgardo Rebagliati Martins (HNERM, Spanish acronym).

STUDY POPULATION

The population included in the study corresponded to patients who were HIV positive and matched the following inclusion criteria: males receiving ART for a minimum of 1 year, between 35 and 65 years old, and attended an external HNERM consultation between the months of January and December 2013. Exclusion criteria were as follows: a history of angina pectoris determined by the Rose questionnaire, a history of myocardial infarction, cerebrovascular disease, or illnesses that alter the lipid profile such as hypothyroidism, nephrotic syndrome, cirrhosis, and pancreatitis.

VARIABLES

The main variables of the study were the risk percentages of the PROCAM and Framingham scales. They were both measured quantitatively and continuously (risk percentage of a cardiovascular event in 10 years) and categorically (low, under 10%; moderate, under 20%;

and high, greater or equal to 20%). The secondary variables were those included in these two tests (age, tobacco use, systolic blood pressure, a family history of myocardial infarction in those under 60 years of age, HDL and total cholesterol, and triglycerides), in addition to weight, height, and the body mass index. The "dyslipidemia" variable was assumed to mean elevation of total cholesterol ≥200 mg/dL, and/or LDL ≥160 mg/dL, and/or triglycerides ≥200 mg/dL according to ATP-III guidelines [14] and the American Association of Clinical Endocrinologists guidelines [15].

Concordance between the two tests was analyzed, meaning that we did not present exposure variables or response variables.

MEASUREMENT/DATA SOURCE

The participants were enrolled in an external consultation from the infectious disease service, after coordination with medical assistants. They had the first contact with the patients invited to participate in the study. The invitations were consecutive, that is, nonprobabilistic. After acceptance, the patients met with the researchers for data collection. The medical assistant was in charge of facilitating the retrieval of corresponding medical records in order to gather data from the laboratory.

A data collection instrument designed by the researchers was used; it contained the following variables: age, weight, a family history of myocardial infarction in those under 60 years of age, diabetes mellitus, tobacco use, and blood pressure, obtained through an interview, and LDL, HDL and total cholesterol, and triglycerides, from the clinical record, no more than three months prior to enrolling in the study. The data gathered were recorded in code to preserve personal information of the patients; these codes will also be given to the patients in order for them to receive their results at the end of the study.

Information regarding the ART was not gathered from every patient due to the constant variation in retroviral drugs due to external factors such as their availability.

The cardiovascular risk in each test was measured in accordance with the measurement tables for each of the tests. These tables were taken from PROCAM [8] and Framingham studies [9].

SAMPLE SIZE

The sample size was not measured for the Bland and Altman graphical method but was measured for an anticipated Pearson rho coefficient of +0.86. It is because this Pearson rho coefficient is the most commonly reported [16]. The assumption of the rho coefficient confidence interval of 0.10 units resulted in a minimum of 111 subjects for analysis. Considering a 20% rejection rate, 150 patients had to be invited. The PASS® software was used for the calculations.

STATISTICAL ANALYSIS

The Strata version 11 software for Windows was used for the statistical analysis, and Microsoft Excel 2010 was used for data entry. The Shapiro-Wilk test was used to assess the distribution of quantitative variables. These were presented as a mean and standard deviation or as a median and interquartile range in accordance with their distribution; qualitative variables were presented as percentages. The correlation was also determined using the Pearson correlation test to satisfy the secondary objective.

The main objective was to determine the concordance between the two tests; the Bland and Altman graphical model was used for this purpose. This is a graphical method for estimating the concordance between repeated measurements on the same individual. This concordance is represented by the average of two measurements in comparison with their absolute difference in a scatter plot. The graph contains a central line that represents the average difference and two horizontal margins that are the concordance limits. If, on the whole, the measurements of values are stable and follow a normal pattern, 95% of the values will be concordant [17]. The Pearson rho coefficient was also used to determine the correlation, and the agreement was calculated using the tests categorized by the κ coefficient.

ETHICAL CONSIDERATIONS

This study's protocol was approved by the ethics committee of the Universidad Peruana de Ciencias Aplicadas and by the HNERM Training Committee. Written informed consent was obtained because the study dealt with a potentially vulnerable population.

RESULTS

Because the treating physician was the person applying inclusion criteria, he/she did not have access to the number of people tested for eligibility. Nonetheless, there were 134 eligible people confirmed, 23 of whom

were excluded (13 for not meeting the "age" criterion, 4 for having started ART in the past 12 months, and 6 for the lack of a complete laboratory profile). In the end, 111 eligible patients were analyzed in the study (Figure 1).

A description of numerical and categorical variables used in the two tests is shown in the figure. It is worth highlighting the data with the greatest implications. In relation to numerical variables, the median age was 47 years; the average BMI, triglycerides, and cholesterol were 25.4 kg/m^2, 265.0 mg/dL, and 231.8 mg/dL, respectively. As for categorical variables, the most remarkable were tobacco use, present in 20 patients (18%), and the "low" PROCAM and "low" Framingham results, corresponding to 90 (81.2%) and 79 patients (71.2%), respectively. No missing data were observed for any variable of interest in the study population. The main characteristics of the participants in the study are shown in Table 1.

Finally, the absolute frequency of dyslipidemia was 85 patients (76.6%). Of these, 81.2% showed total cholesterol of ≥200 mg/dL, 69.4% triglyceride cholesterol ≥200 mg/dL, and 44.7% LDL-c ≥160 mg/dL. These criteria were detected in 20.7% of the study population.

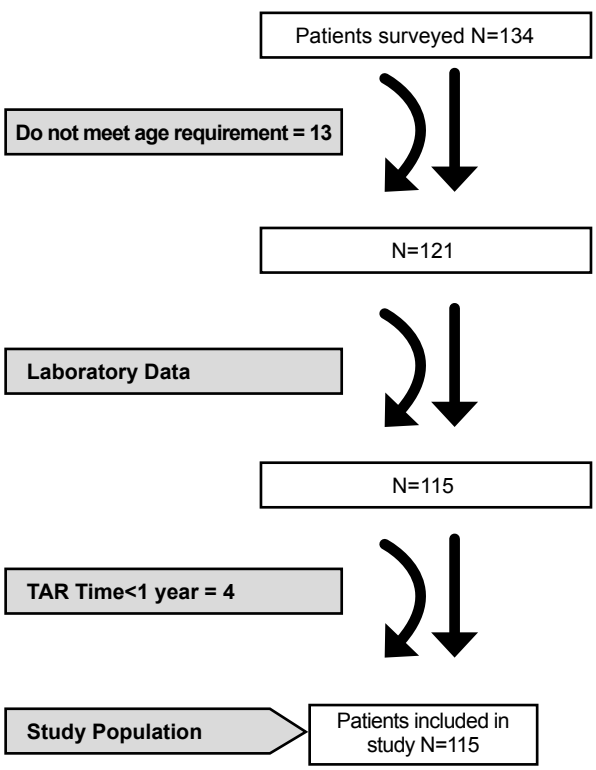


Figure 1. The flow chart of participant selection

Table 1. General Characteristics of the study population (n = 111)

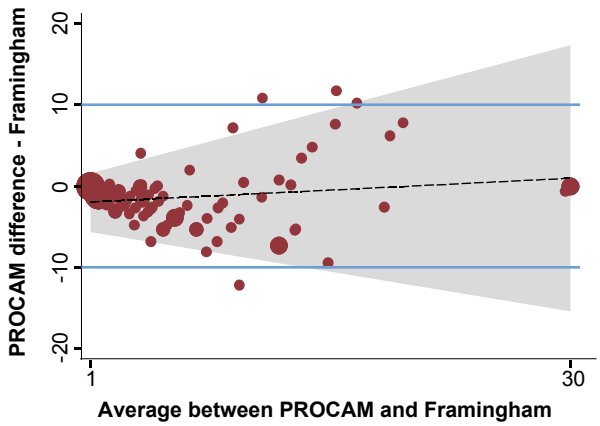
Characteristics	n	Measure of dispersion/
Measure of dispersion/**	47	RIC: 43 – 53
Weight (kg)*	73.8	DE: 10.62
Height (m)*	1.69	DE: 0.08
Body mass index (kg/m^2)*	25.39	DE: 3.90
Systolic blood pressure(mmHg)*	120.52	DE: 13.83
Diastolic blood pressure (mmHg)*	79.6	DE: 9.40
Tobacco use***	20	18%
*Diabetes mellitus****	2	1.8%
Dyslipidemia***	85	76.6%
Family history of myocardial infarction***	12	10.8%
Low-density lipoproteins (mg/dL)*	136.9	DE: 46.8
High-density lipoproteins (mg/dL)*	47.2	DE: 18.9
Triglycerides (mg/dL)*	265.0	DE: 213.8
Cholesterol (mg/dL)*	231.8	DE: 107.8
Hypertriglyceridemia***	59	53.2%
Hypercholesterolemia***	69	62.2%
Low PROCAM***	90	81.2%
Moderate PROCAM***	15	13.6%
High PROCAM***	6	5.41%
Low Framingham***	79	71.2%
Moderate Framingham***	28	25.2%
High Framingham***	4	3.6%

*Average; **Median; ***absolute and relative frequency. IQR: Interquartile range. SD: Standard deviation

Using the Bland and Altman graphical method, we found that the concordance between low levels of cardiovascular risk decreases as cardiovascular risk increases (Figure 2). The κ coefficient was 0.56 ($p < 0.001$; 95% IC: 0.41–0.71). The Pearson correlation coefficient between the results of these two tests was 0.87 ($p < 0.001$; Figure 3).

The distribution of risk according to each score is shown in Table 1. In contrast, a total risk value was 7.2% (standard deviation [SD] 6.4%) for Framingham and 5.9% (SD 7.1%) for PROCAM.

Judging by the distribution of risks according to each test (Table 2), 85.6% of the patients categorized as "low-risk" by PROCAM were also "low-risk" according to the Framingham scale; 50.0% of the patients categorized as "high-risk" by PROCAM were also "high-risk" in the



Dotted line: mean difference.
Blue lines indicate the limits of concordance (± 2 averages)

Figure 2. The Bland and Altman graphical method for determination of concordance between the scores of the PROCAM (Prospective Cardiovascular Münster) scale and Framingham scale.

Framingham scale; the rest were at a moderate risk. There were four "high-risk" patients according to the Framingham score; PROCAM categorized three of these as "high-risk" and one as "moderate-risk."

DISCUSSION

The concordance between the Framingham scale and PROCAM scale that we observed in this study according to the Bland and Altman graphical evaluation is acceptable for low values and decreases as the risk score increases. These results are in agreement with a study conducted in Spain on a population without HIV [16] where it was reported that the concordance decreases as the risk decreases in accordance with the tests. Likewise, PROCAM overestimates the high risks and underestimates the low risks [16] according to the graphical evidence from the Bland and Altman method, in line with our findings. It must be emphasized that our study seems to be the first to use the Bland and Altman graphical method in populations receiving ART.

The determined κ coefficient, despite being significant ($p < 0.001$), had a value of 0.56, which corresponds to moderate concordance. This result is similar to that reported in a study carried out in Brazil [18] and another one in Spain [19], with $\kappa = 0.65$ and $\kappa = 0.36$, respectively. The κ coefficient was determined by obtaining the numeric value for estimation of the concordance, making it easier to evaluate, in comparison with the Bland and Altman method, which shows only graphical results, but these results are prioritized because the κ formula can assess tests only qualitatively.

Our results show that the two tests are not sufficiently concordant to be used nondifferentially or to replace each other. Nonetheless, it is not known which test yields the most accurate risk assessment because to answer this question, a follow-up of the population is required for 10 years as well as a bigger sample size. It should be stressed that the lowest concordance is observed in high-risk groups, but this is the population that requires the highest predictive precision for therapeutic measurements.

We believe that the incomplete concordance that we observed between the two tests as well as the greater risk determined by the PROCAM scale can be explained by the inclusion of triglyceride variables, the family history of myocardial infarction, and total overall population risk in the area where each test was developed.

The Pearson correlation was found to be 0.87 ($p < 0.001$) meaning "strong correlation." This result is similar to that presented by Álvarez *et al*. with the Pearson coefficient of 0.86 [16]. The positive correlation in both studies can be attributed to the negligible differences in the variables assessed by both tests. Although the correlation does not allow us to demonstrate concordance, it was used in

Table 2. Distribution of patients according to cardiovascular-risk tests PROCAM (Prospective Cardiovascular Münster) and Framingham scale

		Framingham			Total (%)
		Low-risk (%)	Moderate-risk (%)	High-risk (%)	
PROCAM	Low-risk (%)	77 (85.6)	13 (14.4)	0 (0)	90 (100)
	Moderate-risk (%)	2 (13.3)	12 (80)	1 (6.7)	15 (100)
	High-risk (%)	0 (0)	3 (50)	3 (50)	6 (100)
	Total(%)	79 (71.2)	28 (25,2)	4 (3.6)	111 (100)

this study to attain the secondary objective. We believe that these findings show the discrepancy between the output of the Pearson method and the Bland and Altman graphical analysis. The Pearson coefficient also enables comparison of our findings with the results of other studies because it is the most widely used method.

We found that for a greater risk, the PROCAM scale overestimates the results in comparison with the Framingham scale; in other words, the Framingham scale undervalues the results in comparison with PROCAM (Figure 2).

In studies conducted in Brazil, Spain, and Australia and in the DAD analysis (Law MG *et al*.) [16, 18–21] as well as in this study, the majority of patients (>45%) were classified into the low-risk group. The risk pattern here, as in other studies, has a pyramidal distribution, forming the basis of the low-risk group, followed by the moderate, and high-risk groups.

The prevalence of moderate and high risk according to the Framingham scale was 21.4%, much greater than the 9% in a report on the DAD study by Law *et al*. [20] and lower than the 29.1% in a local study in Australia, i.e., Hadigan C. *et al*., who also worked with an HIV-positive population receiving ART [21]. The literature backing up this difference was not found; this phenomenon can be attributed to racial factors and/or an insufficient sample size.

As much as 76.6% of the study population had dyslipidemia, which is greater than the 42% reported in the national study by Villegas *et al*. [22]. The relative frequency of hypertriglyceridemia was 53.2%: greater than the 28% reported in the study by Villegas *et al*., and similar to the 52% in a study in Arequipa [23]. A French study showed 28% prevalence of hypertriglyceridemia (lower than the 53.2% found here) [24]. Villegas in Peru, and Mulligan K. and Worm S.W. in the USA, confirmed the susceptibility of patients receiving ART to the alteration of the lipid profile, regardless of the cultural and temporal factors [13,22,25]. We can speculate that these discrepancies can be attributed to the differences in diet between the geographic areas, variation in cut-off points for defining hypertriglyceridemia and hypercholesterolemia in different studies, or to the male-only analysis in the present study.

In 2013, the American College of Cardiology (ACC), in cooperation with the American Heart Association (AHA) published the "Guideline on the Assessment of Cardiovascular Risk" [26] and the "Guideline on the Treatment of Blood Cholesterol to Reduce Atherosclerotic Cardiovascular Risk in Adults: A Report of the American College of Cardiology/American Heart Association Task Force on Practice Guidelines" [27]. These guidelines promote the "ASCVD-Risk" scale, which was not used due to the absence of the "triglyceride" variable. In addition, because these guidelines appeared only recently, the empirical data are scarce so far.

Our study has certain limitations, such as the applicability of risk estimates to the different populations analyzed here because any cardiovascular-risk-scoring system must first be evaluated thoroughly before incorporation into clinical practice and requires updating on the basis of the changing trends in risk factors. There is also a selection bias because the sample was selected in accordance with the order of patients cited who matched the inclusion criteria and agreed to participate; we consider this bias to be minimal because the order of consultation is not affected by any demographic, clinical, or therapeutic variables of the disease. Furthermore, the study does not include women because the PROCAM scale is applicable only to men. Another limitation is the number of patients in the high-risk group, because if it is small, it results in a great error. Finally, the proportion of patients with dyslipidemia here is not necessarily representative because of the limited sample size.

We can conclude that the concordance between low risks decreases as the risk increases. The PROCAM scale classifies more patients into the high-risk group as compared to the Framingham scale. In addition, a strong correlation and consistent agreement were observed between the two cardiovascular risk tests.

A validation study is recommended for both tests at a local level, that is, to contrast the risks estimated by these tests with the cardiovascular events that occur within the subsequent 10 years. Likewise, in similar studies conducted in the future, we recommend to include variables such as treatment and its relation with dyslipidemia (hyperlipidemia, hypertriglyceridemia, or hypercholesterolemia) as well as analysis of other variables such at the CD4+ T lymphocyte counts and the proportion of patients with detectable viral load because these parameters can indicate upregulation of triglycerides or a decrease in HDL concentration. Finally, there should be frequent comprehensive evaluation of the patients receiving ART in our environment via assessment of their cardiovascular risk by means of either of these two tests.

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