

Article

# PRESCRIPTION OF STATINS ACCORDING TO THE ASCVD ESTIMATOR AT PABLO ARTURO SUAREZ HOSPITAL, MARCH 2021 TO FEBRUARY 2022

## Prescripción de estatinas según el estimador ASCVD en el Hospital Pablo Arturo Suárez, marzo 2021 a febrero 2022

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**Receipt:** 2022-05-25  
**Acceptance:** 2022-08-16

### ABSTRACT

Worldwide, the leading cause of death is cardiovascular disease. The study details the prescription of statins at the Pablo Arturo Suarez Hospital in Ecuador between March 2021 and February 2022 following the ASCVD risk scale of the American College of Cardiology and the American Heart Association. There are 563 people in this cross-sectional and retrospective study: 70% women, 30% men, 93.30% mestizos, 48.10% diabetics, 62.30% hypertensives, and 18.70% smokers. 26.10% of all patients received statins, with simvastatin being the most common (96.60%). The mean cardiovascular risk in the general population was  $15.52 \pm 14.51\%$ , 44.99% of subjects had a risk lower than 7.50%, and 29% had a risk higher than 20%, with a statistically significant difference ( $p < 0.001$ ) according to sex. The study determined that 58.60% of the population received a statin or an inadequate dosage.

**Keywords:** Cardiovascular risk; Diabetes mellitus; Hypertension; Smoking; Statins.

## 1. Introduction

Cardiovascular diseases (CVD) can manifest as hypertension, acute myocardial infarctions, heart failure, or strokes. Cardiovascular disease is the leading cause of death worldwide, accounting for approximately 10% of deaths. Approximately 80% of early deaths due to heart disease and stroke are preventable. (Wong, et al., 2014).

CVDs cause the deaths of 17.7 million people each year, representing 31% of all deaths worldwide (WHO, 2017). Hypertension, being overweight, and obesity are the best-documented risk factors for cardiovascular disease; these conditions can manifest clinically as acute myocardial infarction or stroke over time (Bhatnagar, et al., 2016).

CVD accounts for 31% of deaths in Latin America and the Caribbean. Ischemic heart disease has a high death rate in all sub-regions, with the most significant rates in North America and the Caribbean. Unless preventive measures are implemented, it is anticipated that the number of deaths in the region attributable to CVD will grow by almost 60% between 2000 and 2020 (Barceló, 2006). In Ecuador, in 2014, 20% of early deaths were due to CVD and 8% to diabetes mellitus (DM) in men; on the other hand, in women, these pathologies were the cause of death in 21% and 12% of the cases, respectively. In women, the most frequent disease, with 36%, is cerebrovascular disease, and in men, 31% is a hypertensive disease (Grundey, et al., 2019; WHO, 2017).

The guidelines on the treatment of hypercholesterolemia published by the American College of Cardiology (ACC) and the American Heart Association (AHA) (Stone, et al., 2014) represent a change in approach to treatment toward a target level of low-density lipoprotein (LDL) (NCEP, 2002), towards an approach of global minimization of cardiovascular risk. No recent research has examined how cardiovascular risk and particular risk variables influence actual statin prescription in our region; thus, we sought to evaluate the associations between statin usage and cardiovascular risk.

## 2. Materials and methods

It is an analytical, cross-sectional, retrospective study carried out in the outpatient clinic of the internal medicine service of the Pablo Arturo Suarez Hospital in Ecuador. It was evaluated and approved by the bioethics subcommittee of the Pontifical Catholic University of Ecuador. The approval of the Pablo Arturo Suarez Hospital was obtained to review the medical records. Informed consent was not obtained since the patients were not directly questioned.

The universe was made up of the total number of individuals who attended the internal medicine outpatient clinic with diagnoses requiring the use of statins (diabetes mellitus II, high blood pressure, dyslipidemia) at the Pablo Arturo Suarez Hospital in Ecuador (8983, as documented by the institution's official record) during the period from March 2021 to February 2022. The selected sample was estimated using the formula for the study of proportions with a known population from the Epi Info program, including patients with diagnoses consistent with statin treatment. An estimate of 50% of patients at risk was taken as data, with a reliability level of 95%, and a 4% margin of error. The estimated sample size for this analysis was 563 patients. The patient's name was reserved throughout the research process, and the forms were coded with numbers for tabulation. Therefore, the identity of the patient was fully protected.

Sampling was done randomly using a random number program to avoid research bias. Subsequently, the medical records were reviewed, taking into account the following inclusion criteria: individuals of both sexes aged between 40 and 79 years, adults with no cardiovascular disease history (focusing on

primary and secondary prevention); and individuals with the following pathologies: diabetes mellitus II, high blood pressure, and dyslipidemia, and medical records that have all the data necessary to calculate cardiovascular risk. The exclusion criteria were: individuals under 40 years of age or beyond 79 years of age, adults with a history of cardiovascular disease (tertiary prevention), individuals with diseases that do not confer an increased cardiovascular risk: infectious and neurological; medical records that do not have all the data necessary to calculate cardiovascular risk, and adults seen on dates other than those stipulated for this study. All data were recorded in a structured form by the authors.

The information analysis was carried out in the statistical program SPSS in its version 23, guaranteeing the confidentiality of the information and respecting the patient's privacy. The qualitative variables were expressed in frequency and percentage in the univariate analysis, relating them to tables and odds ratio to establish their association. In contrast, the quantitative variables were expressed with a central tendency (mean) and deviation (standard deviation) measures.

In the bivariate analysis, the qualitative variables were analyzed using the chi-square test ( $\chi^2$ ) to determine their association and the Z test to calculate the differences between the proportions and the groups. The Student's t-test was utilized for the quantitative variables, with  $p < 0.05$  indicating statistical significance.

### 3. Results

Table 1 shows that 70% of the patients were female, with a mean age of  $60 \pm 11.01$  years, similar for both sexes. Systolic blood pressure had a mean of  $132.89 \pm 18.02$  mmHg, following similar behavior in men and women, while the mean diastolic blood pressure was  $77.37 \pm 10.69$  mmHg, being slightly higher in males with a mean of  $78.24 \pm 9.93$  mmHg. Total cholesterol levels had a mean of  $192.33 \pm 40.96$  mg/ dl, with a slightly higher figure in men of  $194.13 \pm 44.44$  mg/ dl; average cholesterol HDL was  $46.88 \pm 12.41$  mg/ dl, higher in women with a mean of  $47.95 \pm 12.63$  mg/dl, and finally, the mean LDL cholesterol was  $118.43 \pm 37.04$  mg/ dl, a value that was similar in both sexes.

**Table 1.**

General characteristics of patients studied at the Pablo Arturo Suarez Hospital.

	Sex					
	Male (n: 169)		Feminine (n: 394)		Total (n: 563)	
	Mean	SD	Mean	SD	Mean	SD
<b>Age</b>	60.41	11.50	60.04	10.81	60.15	11.01
<b>Systolic blood pressure</b>	132.77	17.95	132.95	18.07	132.89	18.02
<b>Diastolic blood pressure</b>	78.24	9.93	77.00	10.98	77.37	10.69
<b>Total cholesterol</b>	194.13	44.44	191.58	39.44	192.33	40.96
<b>HDL</b>	44.33	11.53	47.95	12.63	46.88	12.41
<b>LDL</b>	118.90	39.57	118.23	35.98	118.43	37.04

Source: Data collection form.

Prepared by: Llerena, et al. (2021).

Table 2 shows that the highest percentage of the patients studied were represented by the mestizo ethnic group, 93.30% (n: 525). When evaluating the patient's personal history, it was observed that 48.10% (n: 271) had a history of diabetes mellitus. Regarding tobacco use, 18.70% (n: 105) reported maintaining this habit, while 7.30% (n: 41) were ex-smokers. According to medication prescription: 62.30 % (n: 351) maintained treatment for arterial hypertension; while 26.10% (n: 147) received statins, with simvastatin, the most used with 96.60% (n: 142), followed by atorvastatin with 3.40% (n: 5).

**Table 2.**

The ethnicity and personal background of Pablo Arturo Suarez Hospital patients.

		<b>Sex</b>					
		<b>Male (n: 169)</b>		<b>Feminine (n: 394)</b>		<b>Total (n: 563)</b>	
		<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>	<b>n</b>	<b>%</b>
<b>Ethnicity</b>	African American	10	5.90	26	6.60	36	6.40
	caucasian	0	0.00	2	0.50	2	0.40
	Mestizo	159	94.10	366	92.90	525	93.30
<b>DM</b>	Yes	74	43.80	197	50.00	271	48.10
	No	95	56.20	197	50.00	292	51.90
<b>Tobacco</b>	Yes	44	26.00	61	15.50	105	18.70
	No	110	65.10	307	77.90	417	74.10
	Former smoker	15	8.90	26	6.60	41	7.30
<b>HTN treatment</b>	Yes	94	55.60	257	65.20	351	62.30
	No	75	44.40	137	34.80	212	37.70
<b>Statins</b>	Yes	39	23.10	108	27.40	147	26.10
	No	130	76.90	286	72.60	416	73.90
<b>Statin type</b>	Simvastatin	38	97.40	104	96.30	142	96.60
	Atorvastatin	1	2.60	4	3.70	5	3.40
<b>ASA</b>	Yes	33	19.50	58	14.70	91	16.20
	No	136	80.50	336	85.30	472	83.80

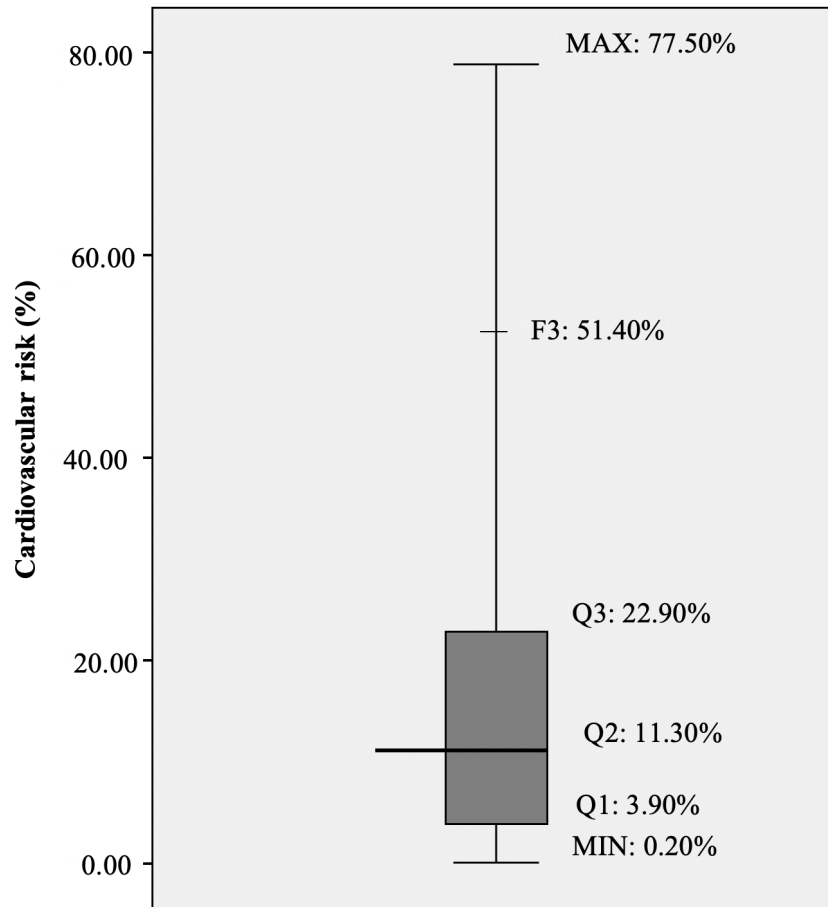
Source: Data collection form.

Prepared by: Llerena, et al. (2021).

Figure 1 shows that the mean cardiovascular risk in the general population was 15.52%, the minimum value was 0.20%, and the maximum value was 77.50%. In addition, 31.40% of the patients (n: 177) maintained a risk greater than 3.90 and less than 11.30% between the first and second quartiles. Figure 2 shows that men had an average cardiovascular risk of 20.31%, while women had an average of 13.46%.

**Figure 1.**

General population cardiovascular risk according to the ASCVD scale.

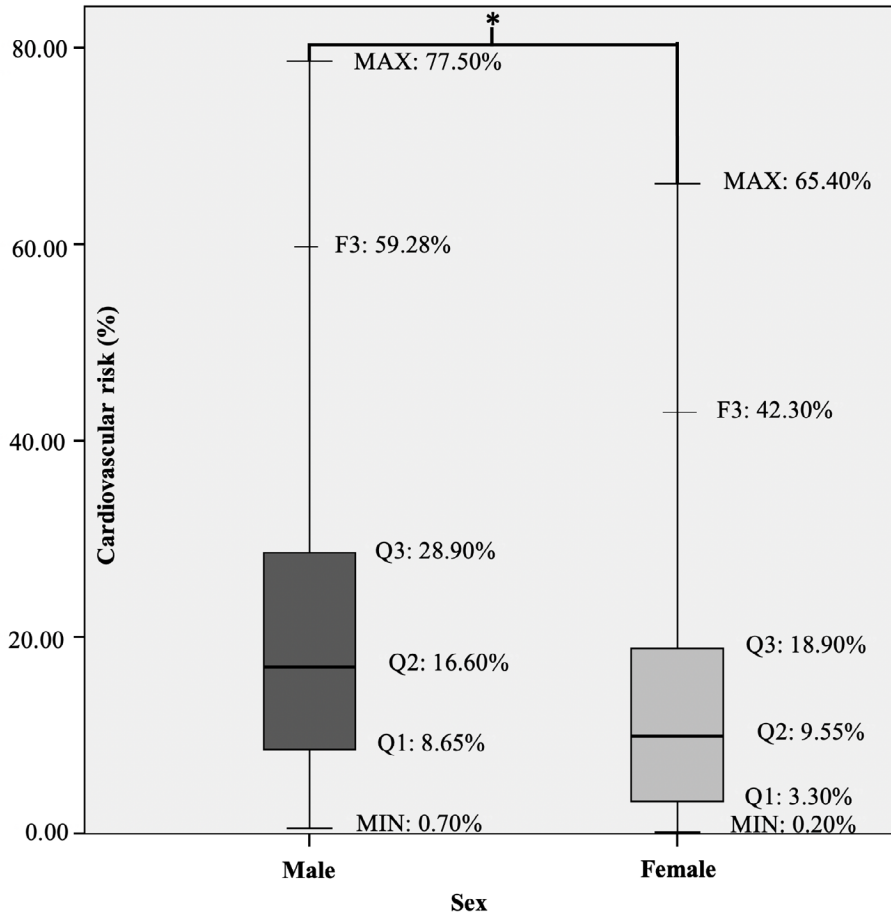


		<b>n</b>	<b>%</b>
Cardiovascular risk	<7.50%	253	44.90
	7.50-20%	147	26.10
	>20%	163	29.00

Source: Data collection form.

Prepared by: Llerena, et al. (2021).

**Figure 2.**  
Cardiovascular risk according to the ASCVD scale by gender.



	Male		Female		
	Mean	SD	Mean	SD	Student's t
Cardiovascular risk	20.31	15.93	13.46	13.36	<0.001*

Source: Data collection form.

Prepared by: Llerena, et al. (2021).

Table 3 studied those patients who received the indication to take statins, showing that 96.60% (n: 142) received simvastatin (68.70% received 20 mg daily, and 27.90% received 40 mg daily); to a lesser extent, 3.4% (n: 5) received atorvastatin, with “0.70% (n: 1) receiving 20mg and 2.70% (n:4) receiving 40mg.” It is noteworthy that this type of statin at these doses is considered moderate-intensity by previously published theoretical references. Those with a prescription for the same received only this degree of intensity.

**Table 3.**

Type and dosage of statins prescribed to Pablo Arturo Suarez Hospital patients.

		Statin dose					
		20mg		40mg		Total	
		n	%	n	%	n	%
<b>Statins</b>	Simvastatin	101	68.70	41	27.90	142	96.60
	Atorvastatin	1	0.70	4	2.70	5	3.40
	Total	102	69.40	45	30.60	147	100.00

Source: Data collection form.

Prepared by: Llerena, et al. (2021).

Table 4 shows the cardiovascular risk calculator's recommendations regarding statin use, showing that 26.10% (n: 147) were prescribed treatment during outpatient control. Regarding the recommendations, it was stated that 24% (n: 135), according to their cardiovascular risk, required a statin of moderate-intensity; however, only 6.40% received it (n: 36).

**Table 4.**

Prescription of statins in accordance with the ASCVD risk scale for cardiovascular disease.

		Statin treatment						$\chi^2$ (p)
		Yes		No		Total		
		n	%	n	%	n	%	
<b>ACC/AHA Recommendation</b>	Moderate intensity statins	36	6.40	99	17.60	135	24.00	11.69 ( $<0.009$ )
	Moderate to high intensity statins	23	4.10	92	16.30	115	20.40	
	High intensity statins	59	10.50	110	19.50	169	30.00	
	No indication for use of statins	29	5.20	115	20.40	144	25.60	
	Total	147	26.10	416	73.90	563	100.00	

Source: Data collection form.

Prepared by: Llerena, et al. (2021).

In addition, 20.40% (n: 115) received the recommendation of moderate-to-high-intensity statins, of which only 4.10% (n: 23) received it. Of those who required a high-intensity statin (30% (n: 169)), 10.50% (n: 59) received treatment; however, it was of moderate intensity. In reference to those without indication of statins (25.60% (n: 144)), 5.20% (n: 29) did receive treatment during their outpatient control.

In conclusion, 58.60% (n: 330) of the patients did not have enough statin prescriptions, which included 53.40% (n: 301) of patients who needed it at different doses but did not receive it and 5.20% (n: 29) who did receive treatment when they did not need it.



## 4. Discussion

In the evaluation of the results, it was observed that the highest proportion of patients belonged to the mestizo ethnic group (93.30% (n: 525)), followed by the Afro-American ethnic group (6.40% (n: 36)). In different analyses, ethnicity has been described as a cardiovascular risk factor, as in the case of Gasevic et al., who carried out a meta-analysis that included 110 studies, obtaining a result that Afro-American ethnicity is more prone to arterial hypertension, diabetes mellitus, and obesity than the other ethnic groups (Gasevic, et al., 2015).

Diabetes mellitus has been studied as a cardiovascular risk factor in numerous investigations and has been proposed as an independent factor; even though the individual only has this pathology and lacks the rest of the factors, it will continue to increase on its own cardiovascular risk. In the analysis conducted by Rawshani et al., it was determined that among “patients with type 2 DM, the hazard ratio for AMI was 0.84 (95% CI 0.75 to 0.93), and the hazard ratio for stroke was 0.95 (95% CI 0.84 to 1.07).” Similarly, the probability of hospitalization for heart failure was consistently higher in diabetic patients than in controls, 1.45 (95% CI 1.34 to 1.57). In addition, it was shown that maintaining glycated hemoglobin (HbA1c) higher than the average value was the most significant predictor of coronary events, and smoking was the strongest predictor of death (Rawshani, et al., 2018).

In this order of ideas, smoking has become one of the emerging risk factors in recent years since both smokers and ex-smokers have a considerable increase in cardiovascular risk. Cho et al.’s study demonstrated that diabetic patients who smoked had a greater risk of CVD and death than diabetic patients who did not smoke (Cho, et al., 2018).

Similarly, hypertension has been one of the most studied cardiovascular risk factors; in the present study, 62.30% (n: 351) of the patients suffered from this disease and were undergoing treatment. This finding contrasts with what was observed in a cardiovascular risk analysis carried out by Trinade et al., in which 23.03% had a history of AHT, which was statistically significantly associated with DM, increased abdominal circumference, high BMI, and dyslipidemia (Radovanovic, et al., 2014).

Regarding statins, their protective effect on cardiovascular diseases has been documented. The study by Ramos et al., which consists of a meta-analysis of 46,864 patients with a mean age of 77 years and a mean follow-up of 5.6 years, demonstrates that its effect remains contentious. This study concluded that the positive effects of statins on cardiovascular diseases were not observed in non-diabetic individuals. At the same time, those with DM showed a crucial protective effect and a decrease in all-cause mortality, an effect that was substantially reduced after 85 years of age. It has disappeared in nonagenarians (Ramos, et al., 2018). Only 26.10% (n: 147) of the patients had a statin prescription in the present report. Treatment with acetylsalicylic acid has been studied over the years, and its prescription has been modified for it to behave as a protective factor for CVD. In research by Cadopano and colleagues, in which 15 studies that met rigorous evaluation criteria were systematically evaluated, it was determined that only 1 of these was able to identify that aspirin has significant efficacy in reducing blood pressure, coronary events; this was due to studying death from CVD caused by AMI and stroke in this analysis (Capodanno & Angiolillo, 2016).

When evaluating cardiovascular risk in the study population, it was observed that the mean was  $15.52 \pm 14.51\%$  and that 44.90% (n: 253) of the patients presented a risk of less than 10%. In contrast to the data are given in research by Gangadhar et al., which indicated that 70% of patients had a cardiovascular risk of more than 10%, these findings suggest that only 30% of patients had a cardiovascular risk of 10% or more (Ghorpade, et al., 2015). Meanwhile, according to an investigation carried out by Azevedo and colleagues, it was determined that 41.67% of the population had a low



cardiovascular risk, a finding that shows a result similar to that presented in this report (Azevedo, et al., 2018). When evaluating the mean cardiovascular risk according to gender, it was observed that men had a higher mean than women (20.31 versus 13.46), a statistically significant figure. This finding is compared to what was observed in Azevedo et al. It has been reported that men have a higher cardiovascular risk than women (Azevedo, et al., 2018).

It is crucial to mention that the ACC/AHA ASCVD risk calculator was utilized to determine cardiovascular risk. Other calculators were created for the same purpose, but not all have the right features. For example, Acevedo et al. conducted an analysis in which they concluded that the ACC/AHA ASCVD method is better than the Framingham evaluation system because it is capable of predicting cardiovascular mortality in low-risk populations, something that was demonstrated when performing a mortality evaluation with a mean follow-up of 7 years (Acevedo, et al., 2017). Regarding the use of statins and the recommendations of the ACC/AHA, it was shown that the most significant proportion of the individuals evaluated did not receive an adequate prescription. This fact is relevant because, as previously mentioned, statins have protective effects concerning cardiovascular risk as long as they are used appropriately and in the population that needs it. Herttua et al. (2016) found that statins in patients with moderate to high cardiovascular risk were low, concluding that individuals with hypercholesterolemia and hypertension who do not take statins or antihypertensive medication have a significantly higher risk of fatal stroke (Herttua, et al., 2016) compared to the ACC/AHA guidelines.

The general characteristics of the patients studied were slightly homogeneous because no significant differences were observed according to sex. Similarly, it was observed that the prevalence of DM was 48.10%, treatment for AHT 62.30%, smoking habit 18.70%, use of statins 26.10%, and use of acid acetylsalicylic 16.20%. The risk estimate in 10 years of CVD was  $15.52 \pm 14.51$ , being higher in the male sex, and the risk lower than 7.50% predominated in 44.90% (n: 253) of the patients.

## 5. Ethical aspects

The Bioethics Committee of the Pablo Arturo Suarez Hospital in Ecuador approved the development of the study, as indicated by document number MSP-CZ9-HPASGEHO-20-0240-O. Furthermore, the researchers guarantee the confidentiality of the information obtained by reviewing the medical records and agree to use the material only for academic purposes.

## 6. Conflict of interest

None

## 7. Declaration

None

## 8. Disclosure

None

## 9. Funding

None

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## RESUMEN

A nivel mundial, la principal causa de muerte es la enfermedad cardiovascular. El estudio detalla la prescripción de estatinas en el Hospital Pablo Arturo Suárez de Ecuador entre marzo de 2021 y febrero de 2022, siguiendo la escala de riesgo ASCVD del Colegio Americano de Cardiología y la Asociación Americana del Corazón. Son 563 personas en este estudio transversal y retrospectivo: 70% mujeres, 30% hombres, 93.30% mestizos, 48.10% diabéticos, 62.30% hipertensos y 18.70% fumadores. El 26.10% de los pacientes recibía estatinas, siendo la simvastatina la más frecuente (96.60%). El riesgo cardiovascular medio en la población general fue de  $15.52 \pm 14.51\%$ , el 44.99% de los sujetos tenía un riesgo inferior al 7.50%, y el 29% tenía un riesgo superior al 20%, con una diferencia estadísticamente significativa ( $p < 0.001$ ) según el sexo. El estudio determinó que el 58.60% de la población recibía una estatina o una dosis inadecuada.

**Palabras clave:** Riesgo cardiovascular; Diabetes mellitus; Hipertensión; Tabaquismo; Estatinas.

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## List of abbreviations

**AACVPR:** American Association for Cardiovascular and Pulmonary Rehabilitation

**AAPA:** American Academy of Physician Assistants

**ABC:** Association of Black Cardiologists

**ABI:** Ankle brachial index

**ACC:** American College of Cardiology

**ACPM:** American College of Preventive Medicine

**ACS:** Acute coronary syndrome

**ADA:** American Diabetes Association

**AGS:** American Geriatrics Society

**AHA:** American Heart Association

**AHT:** Arterial hypertension

**AMI:** Acute myocardial infarction

**APhA:** American Pharmacists Association

**Apo:** Apolipoprotein

**ASA:** Acetylsalicylic acid

**ASCVD:** Atherosclerotic cardiovascular disease risk estimator

**ASPC:** American Society of Preventive Cardiology

**BMI:** Body Mass Index

**CAC:** Coronary Artery Calcium Score

**CETP:** Cholesteryl Ester Transfer Protein

**CI:** Confidence interval

**CKD:** Rheumatic heart disease

**CTT:** Cholesterol Treatment Analysis

**CVA:** Cerebrovascular accident

**CVD:** Cardiovascular disease

**CVR:** Cardiovascular risk

**DM:** Diabetes mellitus

**E:** Number of CVD events prevented per 100 people treated over 10 years

**F:** Outlier

**FFA:** Free fatty acids

**GFR:** Glomerular Filtration Rate

**HF:** Heart failure

**IDB:** Every 12 hours

**IDL:** Intermediate Density Lipoproteins

**LASO:** Latin American Obesity Studies Consortium

**LDL:** Low Density Lipoprotein

**LpL:** Lipoprotein lipase

**n:** LDL decrease in mmol /L

**NHANES:** United States National Health and Nutrition Examination Surveys

**NLA:** National Association created for the study of lipids

**NNT:** Number of people needed to treat

**PAD:** Peripheral arterial disease

**PCNA:** Preventive Cardiovascular Nurses Association

**Q:** Quartile

**SD:** Standard deviations

**TG:** Triglycerides

**TIA:** Transient Ischemic Attack

**TRL:** Triacylglyceride -rich lipoproteins

**USA:** United States of America