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**ORIGINAL ARTICLE**

# Performance of the Framingham and SCORE cardiovascular risk prediction functions in a non-diabetic population of a Spanish health care centre: a validation study

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**Abstract**

*Objective.* To analyse the 10-year performance of the original Framingham coronary risk function and of the SCORE cardiovascular death risk function in a non-diabetic population of 40–65 years of age served by a Spanish healthcare centre. Also, to estimate the percentage of patients who are candidates for antihypertensive and lipid-lowering therapy. *Design.* Longitudinal, observational study of a retrospective cohort followed up for 10 years. *Setting.* Primary care health centre. *Patients.* A total of 608 non-diabetic patients of 40–65 years of age (mean 52.8 years, 56.7% women), without evidence of cardiovascular disease were studied. *Main outcome measures.* Coronary risk at 10 years from the time of their recruitment, using the tables based on the original Framingham function, and of their 10-year risk of fatal cardiovascular disease using the SCORE tables. *Results.* The actual incidence rates of coronary and fatal cardiovascular events were 7.9% and 1.5%, respectively. The original Framingham equation over-predicted risk by 64%, while SCORE function over-predicted risk by 40%, but the SCORE model performed better than the Framingham one for discrimination and calibration statistics. The original Framingham function classified 18.3% of the population as high risk and SCORE 9.2%. The proportions of patients who would be candidates for lipid-lowering therapy were 31.0% and 23.8% according to the original Framingham and SCORE functions, respectively, and 36.8% and 31.2% for antihypertensive therapy. *Conclusion.* The SCORE function showed better values than the original Framingham function for each of the discrimination and calibration statistics. The original Framingham function selected a greater percentage of candidates for antihypertensive and lipid-lowering therapy.

**Key Words:** *Antihypertensive treatment, cardiovascular risk functions, coronary risk, hypolipidemic treatment, SCORE risk chart*

Cardiovascular diseases are a health problem of the first order in the developed world. In Europe, they are the leading cause of death [1], their incidence is high [2], and they are a major source of disability and have a great impact on the costs of social and health care.

Cardiovascular risk is defined as the probability of presenting some cardiovascular disease within a specified period, usually 10 years. When the disease detected is ischaemic heart disease with its associated mortality and morbidity, one speaks of coronary risk. The risk of fatal cardiovascular disease is the probability of death from cardiovascular origin, whether coronary or not, including mortality from stroke, heart failure, or other cardiovascular causes.

The main utility of calculating cardiovascular risk is to aid in clinical decision-making by identifying high-risk patients in primary health care. These patients, together with those who already present arteriosclerosis, are those who would benefit most from drug therapy to reduce their cardiovascular morbidity and mortality.

In Spain, as elsewhere in Europe, the risk of coronary disease has been calculated on the basis of the Framingham function [3–7], even though this has been found to overestimate the risk in some populations [8–11]. For this reason, it is recom-

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There are two promising methods to assess cardiovascular risk: the Framingham risk score and the Systematic Coronary Risk Evaluation (SCORE).

- The SCORE function should be chosen over the original Framingham function to categorize the risk of cardiovascular disease in a Spanish population of 40–65 years of age.
- The original Framingham coronary risk table overestimates the coronary risk and selects a higher percentage of candidates for antihypertensive and lipid-lowering therapy than SCORE.



mended that the function should previously be calibrated for the population of the country in which it is to be used [8–14].

In this context, various systems have appeared to calculate cardiovascular risk in Spain, an example being the calibrated Framingham coronary risk tables (REGICOR) [15]. Also the SCORE (Systematic Coronary Risk Evaluation) tables [16] were recently published to estimate the risk of fatal cardiovascular disease. These are the tables currently recommended in European guidelines [17] and by the Spanish Interdisciplinary Committee for Cardiovascular Disease Prevention (CEIP) [18].

Given this background, the study was designed with the following objectives: (1) to assess the performance of the original Framingham coronary risk function [7] for predicting 10-year risk of coronary events in a non-diabetic population aged 40–65 years attended to in a healthcare centre and compare the performance with SCORE risk of cardiovascular death function [16]; and (2) to evaluate the prescription of lipid-lowering and antihypertensive drugs deriving from the use of those functions.

## Material and methods

The design of this work was an observational longitudinal study of a retrospective cohort of patients ascribed to the "La Paz" healthcare centre in Badajoz, Spain. The follow-up period was 10 years. The cardiovascular events investigated were those included in the calculation of total coronary risk (angina and myocardial infarction, fatal and non-fatal) and fatal cardiovascular disease (cardiac death of coronary and non-coronary origin, death of cerebrovascular origin, and deaths from other cardiovascular causes). Acceptance as an event of cardiovascular origin required diagnostic confirmation by specialists or by the pertinent tests in the referral hospital. Similarly, the acceptance of a cardiovascular cause for death required confirmation in the hospital archives, inquiry in the Civil Registry Office to review the death certificate, and contact by telephone with relatives for confirmation of the event. The deaths from other causes were considered censoring events, such that only time to cardiovascular event or censoring is considered in the calculation of the time at risk.

For all the patients in the study, calculations were made of their coronary risk at 10 years from the time of their recruitment, using the tables based on the original Framingham [7] function, and of their 10-year risk of fatal cardiovascular disease using the SCORE tables [16].

The patients selected for the study were those attended to in the healthcare centre with ages in the range shared by both risk functions (i.e. between 40 and 65 years old), who had no known history of diabetes, ischaemic heart disease, or other cardiovascular disease, and with an anamnesis existing before 1 January 1995 of the variables necessary for the calculation of the two risk functions. Additional data recorded at the time of recruitment included: body mass index (BMI), triglycerides, low-density lipoprotein cholesterol (LDL cholesterol), consumption of lipid-lowering drugs, and consumption of antihypertensive drugs.

To assess calibration (i.e. the degree of similarity between predicted and observed risks), we calculated the predicted mean of coronary and fatal cardiovascular disease risks at 10 years and compared it with the observed occurrence of coronary or fatal cardiovascular events in the 10-year follow-up period. The Brier score was calculated as the average squared deviation between predicted and observed risks, and taken as a measure of accuracy. A lower value represents higher accuracy [19].

We calculated the area under the receiver operating characteristic curve (AUROC) statistic to assess discrimination (i.e. the ability of the risk-prediction model to differentiate between patients who experience a cardiovascular disease event during the study and those who do not); a value of 1 represents perfect discrimination.

The parameters used to analyse the validity of the different risk functions as screening tools for cardiovascular death and coronary risk were the sensitivity, specificity, positive and negative predictive values, and positive and negative likelihood ratios. The results are presented as overall summary estimates together with 95% confidence intervals.

The *diagnostic utility* of the functions was evaluated as the odds ratio [20], calculated as follows:

$$\text{Odds ratio} = \frac{(S \times E)}{[(1-S) \times (1-E)]}$$

where S is the sensitivity and E the specificity. An odds ratio greater than 20 is characteristic of useful diagnostic tests.

Patients were considered to be of high coronary risk if they scored ≥ 20% on the original Framingham table, and of high risk of fatal cardiovascular disease if their risk of cardiovascular death on the SCORE tables was ≥ 5%.

To estimate the percentage of patients who are candidates for drug therapy (antihypertensive or lipid-lowering), we applied the original European guidelines [18] and their Spanish translation and adaptation [21].

The data were processed and analysed using the program packages SPSS 12.0 and Epi Info 6.04.

## Results

The study included 608 patients between 40 and 65 years old with no history of diabetes, ischaemic heart disease, or other cardiovascular diseases. Table I lists the general characteristics of this population. The mean age was 52.8 years and the mean BMI 28.1 kg/m$^2$. Most were hypertensive (74.8%), 37.2% presented total cholesterol figures above 240 mg/dl, and 27.8% were smokers.

The actual incidence rates of coronary and fatal cardiovascular events were 7.9% and 1.5%, respectively. A total of 57 patients (41 men and 16 women) had at least one cardiovascular event during the follow-up of the cohort. There were 24 deaths: nine of cardiovascular origin (six coronary, one cerebrovascular, and two of other cardiovascular causes), and 15 non-cardiovascular (seven from cancers of different locations). Ischaemic heart disease predominated over cerebrovascular disease.

Table II gives discrimination and calibration performance data for original Framingham and SCORE functions. The Brier score, which is a measure of accuracy, was lower (that is, more accurate) for SCORE in men (0.0221) compared with the original Framingham (0.1200). Similarly, for women, the Brier score was lower for SCORE function (0.0079) compared with the original Framingham (0.0396). Original Framingham over-predicted risk by 64% while SCORE function over-predicted risk by 40%. When the analysis was performed in the 360 patients (200 women, 160 men) who were not under lipid-lowering or anti-hypertensive therapy at the beginning of the study, the discrimination and calibration parameters were similar to those obtained in the overall population, for either the original Framingham or the SCORE functions: the AUROC was 0.66 (0.54 to 0.77) or 0.87 (0.73 to 1.02), the Brier score was 0.0588 or 0.0056, and the predicted/observed risks ratio was 1.94 or 2.59, respectively.

The proportions of subjects included in the high-risk categories were 18.3% and 9.2% by the original Framingham and SCORE functions, respectively (Figure 1). More than 80% of them were male. The patients included in the SCORE high risk category were older, had higher systolic blood pressure values, and a greater percentage were smokers and used antihypertensive drugs. The patients identified as high risk by one risk function were also categorized as high risk by the other (Table III).

Table I. Baseline characteristics of the cohort studied.

| | Overall population (n = 608) | Men (n = 263) | Women (n = 345) | p |
|---|---|---|---|---|
| Age (years) | 52.8 (7.4) | 50.9 (7.6) | 54.2 (6.9) | < 0.001 |
| SBP (mm Hg) | 137.9 (20.1) | 136.2 (19.4) | 139.2 (20.5) | 0.074 |
| DBP (mm Hg) | 85.1 (11.2) | 85.3 (11.9) | 85.0 (10.6) | 0.643 |
| Arterial hypertension, n (%) | 455 (74.8%) | 191 (72.6%) | 264 (76.5%) | 0.272 |
| Total cholesterol (mg/dl) | 245.6 (41.2) | 244.2 (41.9) | 246.6 (40.6) | 0.377 |
| Total cholesterol: 240–279 mg/dl, n (%) | 226 (37.2%) | 91 (34.6%) | 135 (39.1%) | 0.252 |
| Total cholesterol > 279 mg/dl, n (%) | 109 (17.9%) | 48 (18.3%) | 61 (17.7%) | 0.856 |
| HDL cholesterol (mg/dl) | 52.1 (15.1) | 45.8 (12.7) | 56.8 (15.1) | < 0.001 |
| LDL cholesterol (mg/dl) | 167.9 (38.9) | 168.9 (39.5) | 167.2 (38.4) | 0.775 |
| Triglycerides (mg/dl) | 130.7 (81.0–156.5) | 155.4 (95.0–187.3) | 111.8 (73.8–135.0) | < 0.001 |
| BMI (kg/m2) | 28.1 (4.3) | 27.9 (3.6) | 28.3 (4.7) | 0.669 |
| Smokers, n (%) | 169 (27.8%) | 126 (47.9%) | 43 (12.5%) | < 0.001 |
| Ex-smokers < 1 year, n (%) | 25 (4.1%) | 21 (8.0%) | 4 (1.2%) | < 0.001 |
| Antihypertensive therapy, n (%) | 180 (29.6%) | 107 (31.0%) | 73 (27.8%) | 0.383 |
| Lipid-lowering therapy, n (%) | 112 (18.4%) | 48 (18.3%) | 64 (18.6%) | 0.925 |

Notes: Values are expressed as mean (standard deviation) or number of patients (percentage) in normal distributions, and as median (quartile 1–quartile 3) in non-normal distributions (triglycerides). SBP: systolic blood pressure. DBP: diastolic blood pressure. HDL-C: high density lipoprotein cholesterol. LDL-C: low density lipoprotein cholesterol. BMI: body mass index.

Table II. Discrimination, calibration, and validity statistics for predicted 10-year risk of cardiovascular disease by SCORE and original Framingham risk functions.

| | Original Framingham function | | | SCORE function | | |
|---|---|---|---|---|---|---|
| | Men | Women | Total | Men | Women | Total |
| AUROC | 0.61 (0.52–0.70) | 0.66 (0.49–0.82) | 0.70 (0.63–0.78) | 0.81 (0.66–0.95) | 0.91 (0.81–1.00) | 0.86 (0.77–0.96) |
| Brier score* | 0.1200 | 0.0396 | 0.0744 | 0.0221 | 0.0079 | 0.0140 |
| Predicted/observed risks ratio | 17.7%/13.3% (1.33) | 9.5%/3.8% (2.50) | 13.0%/7.9% (1.64) | 3.0%/2.3% (1.30) | 1.4%/0.9% (1.55) | 2.1%/1.5% (1.40) |
| Sensitivity | 51.4% (34.9–68.0) | 15.4% (0.0–35.0) | 41.7% (27.7–55.6) | 83.3% (53.5–100) | 33.3% (0.0–86.6) | 66.7% (35.9–97.5) |
| Specificity | 67.1% (61.0–73.2) | 95.2% (87.9–100) | 83.8% (80.7–86.8) | 84.1% (79.6–88.5) | 97.4% (95.7–99.1) | 91.7% (89.5–93.9) |
| PLR | 1.6 (1.1–2.3) | 3.2 (0.8–12.5) | 2.6 (1.8–3.8) | 5.2 (3.3–8.2) | 12.7 (2.7–77.1) | 8.0 (4.7–13.6) |
| NLR | 0.7 (0.5–1.0) | 0.9 (0.7–1.1) | 0.7 (0.6–0.9) | 0.2 (0.0–1.2) | 0.7 (0.3–1.5) | 0.4 (0.1–0.9) |
| Utility | 2.2 | 3.6 | 3.7 | 26.4 | 18.7 | 22.1 |

Notes: AUROC = Area under the receiver operating characteristic curve. PLR = positive likelihood ratio. NLR = negative likelihood ratio. *A lower score indicates better accuracy of risk estimates.

Following the practical guidelines of the SCORE report [18,24] would mean that 31.0% and 23.8% of the patients according to the original Framingham and SCORE functions, respectively, would be candidates for therapy with lipid-lowering drugs ($p < 0.01$), and 36.8% and 31.2% (no significant difference) for therapy with antihypertensive drugs (Table IV).

## Discussion

Both the original Framingham and SCORE functions overestimated the risk of cardiovascular disease in our cohort. The SCORE performed better than the original Framingham function for discrimination and calibration statistics in our cohort, although both overestimated the actual risk (see Table II). The original Framingham risk function [7] overestimated coronary risk by 64% (by 33% in men, and by 150% in women). The SCORE function also over-predicted the population's risk of cardiovascular death by 40%. Applying the SCORE project guidelines [16,17,21], 31.0% and 23.8% of the patients would be candidates for lipid-lowering drug therapy according to the risk classification made with the original Framingham and SCORE functions, respectively. With respect to antihypertensive treatment, the respective analogous percentages would be 36.8% and 31.2% of the patients as candidates for antihypertensive therapy.

The main utility of calculating cardiovascular risk is to aid in clinical decision-making by identifying high-risk patients in primary health care who could benefit from lipid-lowering or anti-hypertensive therapy. Our study evaluated the performance of two important cardiovascular disease risk equations in a cohort of patients from general practice during a 10-year follow-up period, with the conclusion that the SCORE model provides a more accurate prediction than the Framingham one. Similar results were obtained in the group of 360 patients without lipid-lowering or anti-hypertensive therapy. However, this study has clear limitations. The population was not randomly selected, but needed to have a clinical history available that included the information necessary for the calculations of cardiovascular risk with the different functions analysed. Given this context, one can understand the greater prevalence and mean values of the risk factors in our cohort. Nonetheless, these aspects in no way interfere with the comparability of the different risk functions, even though this type of patient selection might limit the external validity of the study. Furthermore, the long latency between risk acquisition and disease development, and trends in lifestyle changes are reasons why evaluations need to be of long duration: even a 10-year study period may be too short to detect changes in

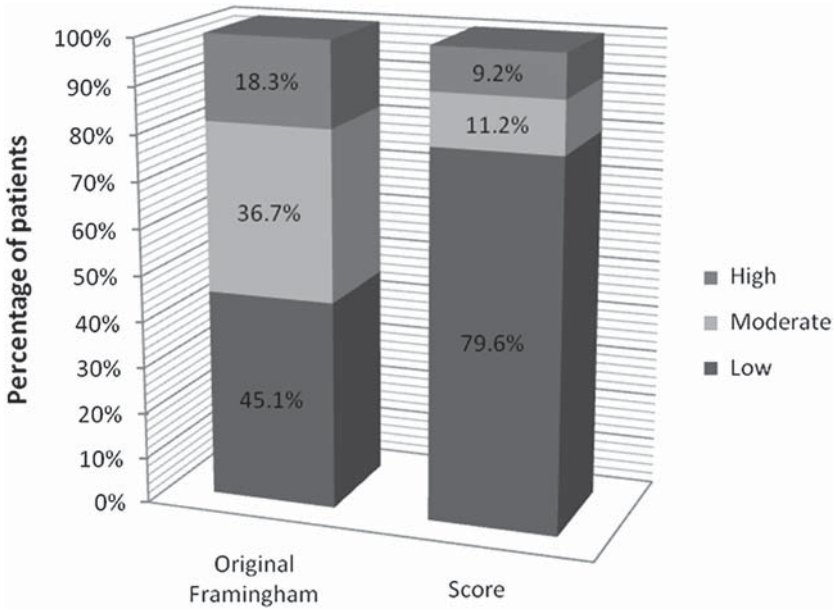


Figure 1. Risk category distribution of the population according to the original Framingham and SCORE risk functions.

cardiovascular mortality and morbidity, especially in small populations [22,23].

Whether or not a patient is categorized as of high risk could have important therapeutic implications. Therefore, the fact that both the SCORE and the original Framingham function overestimated the actual risk is relevant for practising GPs. Over-prediction would inevitably lead to a disproportionate number of people being targeted for treatment, affecting healthcare resources and potentially exposing patients to unnecessary treatment. Similarly, any systematic under-prediction of risk could potentially deny patients much needed treatment.

Since in our study the SCORE provides better values than the original Framingham function, we conclude that the former should be chosen over the latter to categorize the risk of cardiovascular disease in a Spanish population of 40 to 65 years of age. In addition it must be borne in mind that the SCORE function has recently been calibrated in Spain [24]. The REGICOR function was also recently calibrated and validated [25] with the prevalence of cardiovascular

Table III. Characteristics of patients identified as of high risk by any of the two functions.

| | High risk by original Framingham (n = 111) | High risk by score (n = 56) |
|---|---|---|
| Age (years) | 56.2 (6.6) | 60.5 (4.1) |
| SBP (mm Hg) | 150.3 (19.2) | 158.4 (22.2) |
| DBP (mm Hg) | 90.4 (10.3) | 90.7 (11.6) |
| Total cholesterol (mg/dl) | 256.0 (40.3) | 261.4 (55.9) |
| HDL cholesterol (mg/dl) | 40.6 (10.6) | 47.1 (11.6) |
| LDL cholesterol (mg/dl) | 186.0 (40.1) | 186.1 (55.9) |
| Triglycerides (mg/dl) | 178.2 (106.0–221.3) | 156.1 (98.0–203.0) |
| BMI (kg/m2) | 28.8 (4.1) | 27.9 (3.9) |
| Smokers, n (%) | 65 (58.6%) | 39 (69.6%) |
| Ex-smokers < 1 year, n (%) | 14 (12.6%) | 1 (1.8%) |
| Arterial hypertension, n (%) | 106 (95.5%) | 52 (92.9%) |
| Antihypertensive therapy, n (%) | 48 (43.2%) | 30(53.6%) |
| Lipid-lowering therapy, n (%) | 29 (26.1%) | 18 (32.1%) |
| Coronary risk by original Framingham | 27.7% (6.8%) | 28.3% (9.6%) |
| Cardiovascular risk by SCORE | 5.3% (3.7%) | 8.5% (3.1%) |
| Men, n (%) | 93 (83.8%) | 46 (82.1%) |
| Women, n (%) | 18 (16.2%) | 10 (17.9%) |

Notes: Values are expressed as mean (standard deviation) or number of patients (percentage) in normal distributions, and as median (quartile 1–quartile 3) in non-normal distributions (triglycerides). SBP: systolic blood pressure. DBP: diastolic blood pressure. HDL-C: high density lipoprotein cholesterol. LDL-C: low density lipoprotein cholesterol. BMI: body mass index.

Table IV. Patients in the total population identified as candidates for drug therapy (lipid-lowering or antihypertensive) according to the recommendations of the SCORE guidelines, with the risk estimated by the original Framingham and SCORE functions.

| | | Total (n = 608) | Men (n = 263) | Women (n = 345) |
|---|---|---|---|---|
| Lipid-lowering therapy | Original Framingham, n (%) | 189 (31.0%) | 114 (43.3%) | 75 (21.7%) |
| | SCORE, n (%) | 145 (23.8%) | 75 (28.5%) | 70 (20.3%) |
| | p-value | < 0.01 | < 0.001 | 0.833 |
| Anti-hypertensive therapy | Original Framingham, n (%) | 224 (36.8%) | 110 (41.8%) | 114 (33.0%) |
| | SCORE n (%) | 190 (31.2%) | 81 (30.8%) | 109 (31.6%) |
| | p-value | 0.07 | < 0.01 | 0.919 |

risk factors in a Spanish region. These findings are further evidence of the need for an adjustment, calibration, and validation of the risk functions on large populations representative of each country´s reality such as that recently reported for the United Kingdom [26–28]. This adapted tool will help primary care practitioners to decide and to face another important challenge: to support decision-making by providing meaningful, understandable, and acceptable information to patients [29]. Finally, the general practitioner should not forget that there is a strong need for less fragmentation and more holistic thinking if we want effective cardiovascular prevention [30].



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***Conflicts of interest:*** None

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