Original research

Ten-years cardiovascular disease risk among adults of a Sri Lankan community: Comparison of Framingham risk score and World Health Organization/International Society of Hypertension risk prediction charts.

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Abstract

Introduction
Cardiovascular disease (CVD) risk prediction plays a vital role in early detection of high-risk individuals. This study aimed to compare the risk of a cardiovascular event using the World Health Organization (WHO)/International Society of Hypertension (ISH) risk prediction charts and Framingham risk score (FRS).

Methods
A descriptive cross-sectional study was conducted among three hundred sixty six, 30 to 60 year old adults from Sabaragamuwa province, Sri Lanka. Participants were selected using a three-stage random sampling method, and the WHO STEPS wise approach was used to collect data. The ten-year risk was calculated using both methods and a risk ≥20 % was considered a high risk. Chi-square test was used to compare the calculated risk at a p-value of 0.05.

Results
Framingham risk score categorized 25.1% of the participants into the high-risk category, whereas it was 2% with the WHO risk prediction charts ($p<0.001$). Nearly 25% of the participants who were classified into the <10% risk category in WHO risk prediction charts were recognized as having high risk by the FRS. Moreover, 30.3% of the participants were classified as having 10-20% CVD risk by FRS, while WHO/ISH charts categorized them as <0% of CVD risk. The agreement between these two methods was very poor (k value= -0.002, p=0.950).

Conclusion
FRS identified a higher proportion of participants as having high risk compared to the WHO risk prediction charts. The discrepancy between these two methods is disturbing since none of these methods has been recalibrated for Sri Lanka.

Keywords: Framingham risk score, WHO/ISH risk prediction charts, Ten years cardiovascular risk, Sri Lanka

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Introduction

For the last few decades, the healthcare systems around the world have been experiencing a huge burden secondary to cardiovascular diseases (CVDs). The causes underlining many CVDs are rarely the result of one single risk factor but usually the end result of the combined effect of many risk factors [1]. This fact stresses the need to estimate CVD risk using all possible risk factors because either overestimation or underestimation of CVD risk results would occur if only one risk factor is considered. Therefore, various risk estimation methods have been developed over the last 50-odd years. The most commonly used methods are the Framingham Risk Score (FRS), Systematic Coronary Risk Evaluation (SCORE) and World Health Organization/ International Society of Hypertension (WHO/ISH) risk prediction charts.

FRS was first developed by Anderson et al. in 1990 based on the Framingham heart study [2]. It emphasized the potential importance of controlling multiple risk factors rather than focusing on one single risk factor [3]. It has helped to identify those at the highest risk for developing CVD [4]. Out of many risk prediction models, FRS is considered the best-known and most commonly used risk estimation method in many counties [5]. It assesses the relative importance of CVD risk factors and quantifies the absolute level of CVD risk of an individual patient. These risk factors can be easily obtained through the patient's history, physical examination and basic laboratory investigations. Ten-year risk for CVD is calculated as a percentage based on the percentage of risk; If the FRS is less than 10%, the risk is considered low, moderate if it is 10% to 19%, and high if it is 20% or higher [6].

WHO/ISH risk prediction charts have been developed by the WHO/ ISH using a modelling approach. These charts are designed to be used in low-and-middle-income countries where basic infrastructure facilities are not available, and the use of these charts is easy and inexpensive [7]. It indicates a 10-years risk of a major cardiovascular event in a person aged 40 to 79 years according to age, sex, blood pressure, smoking status, total blood cholesterol and presence or absence of diabetes mellitus. Based on these risk factors, individuals can be categorized as high risk, medium risk, or low risk for the upcoming ten years for CVD events. These charts have been used in different countries and regions and identified high-risk individuals for CVDs successfully [8]. Currently, Sri Lanka too is using these charts to calculate the 10-year CVD risk, and these charts have already been incorporated into the personal health record which is given by healthy lifestyle centres. Nevertheless, none of the previously conducted research in this field quantified the high-risk individuals towards CVDs by using 10-years CVD risk prediction, which it is considered prime in CVD prevention. Therefore, the objective of this study was to calculate the risk of a cardiovascular event using the FRS and WHO/ISH risk categories and to compare the calculated Framingham risk against the WHO/ISH risk categories used in Sri Lanka.

Methodology

Study design, participants and settings

A descriptive cross-sectional study was conducted involving 366 adults aged 30 to 60 years from Sabaragamuwa province of Sri Lanka. Sabaragamuwa province is located in the southwest region of the island, and 9% (1,928,655) of the Sri Lankan population lives in it [9]. It includes two administrative districts, and each district is divided into divisional secretary areas. Each divisional secretary area is further divided in to Grama Niladhari (GN) divisions for administrative easiness.

Three-stage random sampling method was used to select the sample from the defined population. First, one divisional secretariat division was selected from each district by using a random number generator. Then 10% of GN divisions were randomly selected from each selected divisional secretariat division. Sampling within the selected GN divisions was done as the third stage. The sampling frame was the electoral lists available at the selected GN divisions. All Sri Lankans above 18 years are registered in the electoral list of the GN division in which the person lives. During the registration, it is mandatory to record name, national identity card number, address, and sex according to the household. The present study used the electoral register prepared for the year 2018 as the sampling frame. Participants who were critically ill, pregnant, and mentally unfit were excluded.

Data collection

WHO STEP-wise approach was used to collect data. In STEP 1 interviewer-administered questionnaire was used to collect data on demographic variables (age, sex, years of education, educational qualifications, occupation, monthly income), smoking status and history of hypertension, diabetes millets and

dyslipidemia. In STEP 2, blood pressure was measured using the same digital blood pressure monitor for all the participants. Three blood pressure measurements were taken with a three-minute resting period in between each measurement. Mean of the second and third readings was taken as the final blood pressure value. Hypertension was defined as systolic blood pressure ≥140 mmHg and/or diastolic blood pressure ≥90 mmHg and/or currently taking antihypertensive medications [10, 11].

STEP 3 involved drawing blood samples for laboratory analysis. The participants were asked to fast overnight for 12 hours and all the analyses were performed at the same laboratory. Fasting blood sugar, total cholesterol, low density lipoprotein (LDL) and high-density lipoprotein (HDL) were measured. National Cholesterol Education Programme-Adult Treatment Panel III (NCEP-ATP III) Guidelines were used to categorize cholesterol levels in this study [12]. High total cholesterol level was defined as > 200 mg/dL and/or taking lipid-lowering medications, low HDL was defined as <45 mg/dL in men and <55 mg/dL in women, high LDL was defined as >130 mg/dL [13, 14]. According to the WHO diagnostic criteria for diabetes, fasting blood glucose (FBG) level >126 mg/dL and/or currently taking anti-diabetic drugs was considered as diabetic [15].

Data analysis

To calculate the Framingham risk, age, sex, systolic blood pressure, known diabetic, serum TC and HDL-cholesterol values, antihypertensive therapy and current smoking status were used [5, 16]. The 10-year risk of CVD was classified as <10%, 10%-20%, 20%-30%, 30%-40% or >40%. Age, sex, blood pressure, current smoking status, total cholesterol and presence or absence of diabetes mellitus were used to calculate the CVD risk according to the WHO/ISH risk estimation charts [8]. Similar to Framingham risk estimation 10-year risk was categorized in to five groups as <10%, 10% to 20%, 20%-30%, 30%-40% or >40%. risk scores > 20% were considered as high risk in both categories.

Data were analyzed for frequency of distribution, proportion and percentages for categorical variables and mean ± SD median and IQR for continuous variables. Chi-square test was used to assess the association between two risk estimation methods and the agreement between those methods was assessed using Cohen's kappa coefficient with 95% confidence intervals.

Ethics approval

Ethical approval was obtained from the Ethics Review Committee of the Faculty of Medicine, University of Peradeniya, Sri Lanka. Informed written consent was obtained from all individual participants included in the study.

Results

This study involved 366 participants with a participation rate of 87.1%. The mean age was 45.2 years (SD = 8.8), and 31.7% (n=116) of them were men.

Prevalence of CVD risk factors

The prevalence of hypertension was 27 % (n=99) with 23.8% (n=87) having raised systolic blood pressure and 14.2% (n=52) having raised diastolic blood pressure. Overall prevalence of high total cholesterol was 39.9% (n=146) with high low-density lipoproteins and low high-density lipoprotein accounting for 37.7% (n=138) and 29% (n=106) of prevalence respectively. Of all the respondents 9% (n=33) were estimated to be diabetic while 13.1% (n=48) had impaired blood glucose level.

Distribution of the CVD risk factors

The distribution of the CVD risk factors used in both risk estimation methods are showed in the table 1.

Table 1: Mean, median and interquartile range of blood pressure, fasting blood sugar, total cholesterol, HDL cholesterol and LDL cholesterol (n=347)

Variable	Mean (SD)	Median	Interquartile range
SBP*	128.8 mmHg (18.2)	125	114 - 138
DBP**	79.7 mmHg (10.3)	79	72 - 86
FBS***	99.2 mg/dl (34.8)	90.0	83.7 – 97.4
TC#	192.4 mg/dl (36.9)	192.3	169.1- 215.5
HDL##	46.3 mg/dl (10.6)	44.6	39.0 – 52.3
LDL###	121.3 mg/dl (33.0)	122.4	101.6 – 143.5

*Systolic blood pressure **Diastolic blood pressure ***Fasting blood sugar
#Total Cholesterol ##High density lipoprotein ###Low density lipoprotein

Ten-year CVD risk according to FRS and WHO/ISH risk prediction charts

According to the FRS categorization less than half (43.4%) of the study population was categorized in to <10% of 10-year CVD risk category. According to WHO/ISH risk prediction charts majority (97.3%) of the study population were categorized into <10% of the 10-year CVD risk category (Table 2).

Table 2: Ten-year CVD risk according to FRS and WHO/ISH risk prediction charts.

10-year risk	FRS	WHO/ISH charts
	N (%)	N (%)
<10 %	159 (43.4)	356 (97.3)
10-20%	112 (30.6)	2 (0.5)
20-30 %	62 (16.9)	5 (1.4)
30-40 %	25 (6.8)	1 (0.3)
≥40 %	8 (2.2)	2 (0.5)
Total	**366**	**366**

FRS identified a higher number of participants with high CVD risk (risk score ≥20%) than WHO/ISH risk prediction charts and the difference was statistically significant (Table 3).

Table 3: Ten-year dichotomized CVD risk according to FRS and WHO/ISH risk prediction charts

10-year risk	FRS	WHO/ISH charts
	N (%)	N (%)
< 20%	271 (74.0)	358 (97.8)
≥20%	95 (26.0)	8 (2.2)
Total	**366**	**366**
	$\chi 2$ P=<0.001	

Table 4 shows the ability of each risk estimation method to categorize the study participants into different risk categories. Both methods identified 41.5% (n=152) of the sample as having <10% CVD risk. Surprisingly, 25% of the participants who were classified in to <10% risk category in WHO/ISH charts were recognized as having high risk (≥20%) by FRS. Moreover, 30.3% (n=111) of participants were classified as having 10-20% CVD risk by FRS, while WHO/ISH charts categorized them as <10% of CVD risk. None of the participants in risk categories of 20-30%, 30-40% and >40% were recognized as having such risk by both methods (Table 4).

Table 4: Comparison of WHO/ISH and FRS in their ability to categorize the participants into different risk categories

WHO/ISH Charts (%)	FRS (%)				
	<10	**10-19**	**20-29**	**30-39**	**≥40**
<10	152	111	61	24	8
10 -< 20	2	0	0	0	0
20 - <30	3	1	0	1	0
30 - <40	1	0	0	0	0
≥40	1	0	1	0	0

The percentage of agreement between FRS and WHO/ISH risk prediction charts

To identify the degree of agreement between these two risk estimation methods, the kappa value was calculated (Table 5). It was -0.002 (p=0.950). This finding shows a significant discrepancy between these two methods [17].

Table 5: Agreement between FRS and WHO/ISH risk prediction charts

		FRS (%)		
		<20	**≥20**	**Total**
WHO/ISH Charts	***<20%***			
	Count	265	93	358
	Expected count	265.1	92.9	358
	≥20%			
	Count	6	2	8
	Expected count	5.9	2.1	8
	Total			
	Count	271	95	366
	Expected count	271.0	95.0	366.0
Measure of agreement	**Value**	**SE**	**Approx T[b]**	**Approx sig**
	-0.002	0.025	-0.062	0.950

Discussion

According to the FRS categorization, one-fourth of the study population (25.1%) were categorized in to ≥20% of 10-year CVD risk category, while it was only 2% according to the WHO/ISH risk estimation charts. FRS could identify a greater number of participants with high CVD risk (risk score ≥20%) compared to WHO/ISH risk prediction charts and the difference was statistically significant. Although the present study used the WHO/ISH charts with actual total cholesterol level to estimate the 10-year CVD risk, it predicted a lesser number of participants as high risk compared to FRS. This is detrimental to the prevention and control of CVDs if high-risk individuals are under-identified because this would lead to higher rates of under-treatment and subsequently more complications.

In most of the studies done in other countries, FRS predicted a higher risk than WHO/ISH risk prediction charts similar to the present study. Several studies reported FRS as the most useful tool for 10-year CVD risk prediction compared to other risk prediction models such as ACC/AHA Atherosclerotic CVD (ASCVD) risk score, QRISK2, Joint British Society calculator-3 (JBS3) and Systematic Coronary Risk Evaluation (SCORE)[18]. The reason for this difference might be that FRS uses several additional outcomes compared to other risk scores. Among these different CVD risk prediction methods WHO/ISH risk prediction charts estimated a lesser number of participants with high risk for CVDs. On the other hand, several studies reported that FRS overestimate the CVD risk compared to other risk prediction models [19-22]. Therefore, the discrepancy between these two methods is disturbing since none of these methods has been validated for Sri Lanka.

Similar to the present study finding, a multicentric study done in 2011 using WHO/ISH risk estimation charts reported 2.2% of ≥20% of 10-year CVD risk in Sri Lanka [23]. Nevertheless, another similar study done in an urban community in Sri Lanka using WHO/ISH risk prediction charts found 8.2% of the participants with ≥20% risk whereas the present study captured mostly a rural population [24]. No studies comparing FRS with WHO/ISH charts were found in Sri Lanka.

Another noteworthy finding of the present study was the proportion of high blood pressure among the participants categorized in the high-risk category (≥20% risk) was significantly higher in FRS (50.6%) compared to WHO/ISH risk estimation charts (14.3%). Similarly, the other CVD risk factors, including high total cholesterol, high LDL and low HDL were more prevalent in the FRS high-risk group compared to WHO/ISH risk estimation chart high-risk group.

Therefore, it is interesting to explore further reasons as to why a lesser proportion of participants presented CVD risk factors though they are categorized as high risk according to the WHO/ISH risk prediction charts. This finding emphasizes the importance of further studies on the CVD risk estimation capacities in between these two different models. The appropriateness of the study design to achieve the objective of this study was increased by choosing a well-defined population and conducting the study in a representative sample from Sabaragamuwa province in Sri Lanka. Three-stage random sampling method used in this study gave the same chance for each adult aged 30-60 years in Sabaragamuwa province to be selected for the study. Since the electoral list which had been used as the sampling frame was the most updated version, the selection bias of this study was minimized. Furthermore, routine calibration of each instrument ensured accurate results. Calibration was done as soon as the equipment was purchased and then routinely at weekly intervals. Measurements were recorded and checked for accuracy each time. This also ensured the quality of measurement recorded by each piece of equipment. Moreover, all blood samples were collected by a registered nurse and other well-experienced phlebotomists. WHO guideline on best practices in phlebotomy was followed in the drawing and transportation of the blood samples. To ensure the quality of blood samples, serum separation was done just after the blood collection using a portable centrifuge machine, and all samples were transported to the laboratory within 4 hours of data collection. All blood samples were packed in a rack to avoid breakage during transportation.

Limitations of the study

Since it took only a snapshot of the population, if another timeframe is chosen differing results may be possible. Furthermore, though the male-to-female ratio in Sabaragamuwa province is 1: 1, this study captured a ratio of 1:2.1. Because of that, limitations could occur when the findings are projected to the total population.

Conclusion

FRS identified a higher proportion of participants as having a high CVD risk compared to the WHO/ISH risk prediction charts. There is a significant discrepancy between these two methods. Therefore, recalibration of each method for Sri Lanka is recommended, otherwise we may be missing a large proportion of those who are at high risk for cardiovascular diseases with the use of WHO risk prediction charts alone.

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