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Predictive ability of Framingham risk score in Indian population - A retrospective study in a tertiary care hospital in patients with first acute coronary syndrome

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ABSTRACT

Background: Framingham risk score (FRS) is a widely recognized tool used by clinicians worldwide to determine and estimate the 10-year risk of manifesting clinical cardiovascular disease (CVD) of an individual and classify them into different risk categories on the basis of which necessary intervention can be taken. However, there is certain evidence questioning its predictive ability for risk stratification among ethnic Indian and Asian population. **Aims and Objectives:** In this study, we wanted to determine the predictive ability of FRS in the Indian population and to assess how the risk score is associated with certain variables which are not included in original FRS. **Materials and Methods:** It was a single institutional, retrospective, and observational study in patients with evidence (by ECG or Cardiac biomarker test -Preferably Troponin T) of diagnosis of acute myocardial infarction for first time. Eligible patients were assessed for their previous clinical records to calculate risk score as per FSR-coronary heart disease 2002. Predictive ability of FRS and association with different risk factors was tested for statistical significance. **Results:** The most of the study participants (63.8%) had low risk and only 4.8% of study population had high risk for developing CVD. Patients in the low risk group had significantly better high-density lipoprotein profile than other risk groups (P = 0.001). Mean systolic blood pressure was significantly higher in high-risk population (155 vs. 131 vs. 138 mm of Hg; P = 0.005). The left ventricular ejection fraction was significantly lower in high-risk group (39.2% vs. 53% vs. 52%, P = 0.008). Serum creatinine level was also significantly higher in high-risk group (P = 0.03). **Conclusion:** This clearly showed underestimation of FRS in prediction of CVDs in our study. Perhaps FRS needs a calibration and modified form with inclusion of other risk factors and parameters to determine and predict the future risk of development of CVD more accurately in Indian population.

Key words: Acute coronary syndrome; Framingham risk score; Indian population; Predictive ability

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INTRODUCTION

Cardiovascular disease (CVD) is the leading cause of death and disability worldwide encompassing a variety of conditions including – atherosclerotic vascular diseases such as coronary heart disease (CHD), cerebrovascular disease (CBVD), and peripheral arterial diseases.[1]

Gupta et al., reported that India alone is burdened with approximately 25% of cardiovascular (CV)-related deaths

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and would serve as a home to more than 50% of the patients with heart ailments worldwide within next 15 years leading to devastating socioeconomic consequences.[2,3]

Estimation of the risk of future CV events is an essential first step in the primary prevention of CVD. Such an estimate not only provides prognostically relevant information but more importantly provides the framework for selecting the nature and the intensity of the appropriate preventive therapy. Framingham risk score is a widely recognized tool used by clinicians worldwide to calculate 10-year CV risk in an individual and classify them for risk of coronary death or myocardial infarction (MI).[4] The Framingham CV risk score (FRS) has been utilized effectively to portend major CHD events across ethnic groups and races. South Asians (people originating from the Indian subcontinent) constitute almost a quarter of the world's population and have a high burden of CVD compared with other ethnic groups.[5]

A study from the United Kingdom showed that the South Asian population dwelling over there have a high risk of CVD mortality, but the risk prediction models appear to be inaccurate among them. In this study, the predictive capacity of the FINRISK and Framingham CV risk score (1991) prediction models was explored in the Newcastle Heart Project population, where 90% of South Asians were born in the Indian subcontinent. The study revealed that both the Framingham and FINRISK models gave similar results, mostly following expected patterns, but the SCORE model did not. National mortality data and modeled predictions agreed reasonably well for South Asians combined, and Bangladeshi and Pakistani men, but not for Indian men and Pakistani and Bangladeshi women. The varying rates show the limits of modeling and suggest that the potential gains from controlling major established risk factors could be substantial in South Asians and greater than in Europeans.[6] Consistent with this, numerous studies have shown that the risk assessment models developed for Western populations systematically underestimate risk in individuals of South Asian origin.[6]

Unfortunately, very little information is available to demonstrate how well this FCR scoring systems perform among resident Indians. As a result, the Indian physicians have to follow the same risk assessment models that are being used for Western populations. Thus, our study was aimed at finding whether the FCR score is holding true for the Indian perspective based on its predictive ability. This study also explored how the risk score is having correlation and association with certain variables like – total tri-glyceride (TG) level, serum creatinine, estimated glomerular filtration rate (eGFR), diastolic blood pressure, and different echocardiography parameters which are not included in original FRS.

Aims and objectives

1. To determine the predictive ability and accuracy of Framingham risk score (FRS) in multi-ethnic Indian population.
2. To see how the risk score is having correlation & association with certain variables like-total triglyceride level, serum creatinine, estimated Glomerular filtration rate (eGFR), diastolic blood pressure and different echocardiography parameters which are not included in original FRS.

MATERIALS AND METHODS

It was a single institutional, retrospective, observational, and cross-sectional study in patients admitted in General Medicine or Cardiology ward which was done between January 2020 and May 2021.

Inclusion criteria

The following criteria were included in the study:

1. Any patient coming with symptoms of acute coronary syndrome (ACS) with proven evidence of diagnosis of Acute MI (AMI) by ECG or cardiac biomarkers test (preferably Troponin T)

The diagnosis of MI is based on the third universal definition of MI. As per this definition, a diagnosis of MI requires a rise and/or fall of cardiac biomarker values (preferably cardiac Troponin) with at least one value above the 99th percentile upper reference limit, along with either the symptoms of ischemia and/or new or presumed new significant ST-T changes or new left bundle branch block. The MI will be labeled as ST-segment elevation MI (STEMI) if the ECG revealed new ST elevation at the J point in two contiguous leads (≥0.1 MV in all leads other than leads V2–V3 and in case of leads V2–V3 ≥0.2 MV in men ≥40 years, ≥0.25 MV in men <40 years or ≥0.15 MV in women) or new onset left bundle branch block. If none of these ECG changes were present, then it was labeled as non-STEMI

2. Aged between 30 and 74 years
3. Patients who had recent lipid profile (i.e., within the past 6 months).

Exclusion criteria

Patients with prior history of stroke, cardiac arrest, Reynaud's disease, heart failure, peripheral vascular diseases, transient ischemic attack, pulmonary embolism, MI, coronary insufficiency, angina pectoris, and patients not having prior records of high-density lipoprotein (HDL) and serum cholesterol were excluded from the study.

Study technique

Based on the above mentioned inclusion and exclusion criteria, eligible patients were selected. Then, their lipid

profile (HDL, total serum TG, and serum cholesterol), renal function tests (Serum urea, creatinine, and eGFR), and echocardiogram report (Left ventricular ejection fraction [LVEF], left ventricular internal diameter [LVID], and left atrial internal diameter [LAID]) of 6 months back were reviewed and risk score was calculated as per FRS-CHDs 2002 to group them in high-, intermediate, and low-risk groups. After this association of FRS score with various conventional and unconventional risk factors was assessed for statistical significance. Approval for the study was taken from the Institutional Ethics Committee.

There is no source of financial grant or other funding.

Statistical analysis

Data were analyzed and compared according to appropriate statistical tests using SPSS v.20 software and Microsoft word-excel. Data were summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Unpaired proportions were compared by Chi-square test or Fisher's exact test, as appropriate. Any P<0.05 will be considered statistically significant.

RESULTS

Total 105 patients were analyzed in this study. Patients were divided into multiple risk groups according to FRS system. The most of the patients (63.8%) of the study had low risk and only 4.8% of study population had high risk for developing CVD (Table 1).

Mean age (66 years), minimum age (55 years), maximum age (71 years); all the age-related parameters were higher in high-risk group. The majority of study population (79%) comprises of male patients. About 80% of high risk, 87% of intermediate risk, and 74% of low-risk patients were male. Gender distribution was significantly different between the risk groups (P=0.0004). About 12% of low-risk patients were smoker in comparison to 75% of intermediate risk and 40% of high-risk group. Smoking habit differences among the risk groups were statistically significant (P<0.001) (Table 2).

Patients in the low-risk group had significantly better mean (±SD) HDL profile than intermediate and high-risk groups (45.7612±8.9088 mg/dl vs. 39.6364±8.6596 mg/dl vs. 37.0000±6.4807 mg/dl; P=0.001). In high-risk group, patients TG level was higher than low and intermediate risk group patients. The difference was not statistically significant (P=0.53). Mean total cholesterol (TC) level was also comparable in all the risk groups without any statistical significance (P=0.43) (Table 3).

Table 1: Distribution of patients according to risk group

Risk group	Frequency	Percentage
Low risk	67	63.8
Intermediate risk	33	31.4
High risk	5	4.8
Total	105	100

Table 2: Distribution of baseline characteristics in different risk group

Characteristics	Risk Group		
	Low Risk	Intermediate Risk	High Risk
Mean age (in years)	53.95±9.50	59.36±6.39	66.40±6
Gender			
Female	17	04	01
Male	50	29	04
Smoking			
Smoker	08	25	02
Non-smoker	59	08	03

Table 3: Comparison of lipid profile in different risk group

Lipid profile (In mg/dl)	Risk group			
	Low risk	Intermediate risk	High risk	P-value
Mean HDL	45.76	39.63	37	0.001
Mean tri-glyceride	163.95	148.45	179.81	0.53
Mean total cholesterol	154.59	143.81	150.8	0.43

Mean systolic blood pressure was significantly higher in high-risk population than low and intermediate risk group (155 vs. 131 vs. 138 mm of Hg; P=0.005). Mean Diastolic blood pressure was also higher in high-risk group, but the difference was not statistically significant (93 vs. 87 vs. 88 mm of Hg; P=0.18).

High-risk category had numerically highest percentage of diabetic patients among the three risk groups, but the difference was not significant (40% vs. 35.8% vs. 36.4%, P=0.98).

Mean serum urea and (e-GFR calculated by CKD-EPI formula) were comparable in all three risk groups (P=0.81 and 0.10). Mean serum creatinine was significantly higher in high-risk patients (P=0.03) (Table 4).

Among the cardiological parameters, LVEF was significantly lower in high-risk patients than other risk groups (P=0.008). Mean LVID and LAID were comparable between the risk groups (P=0.06 and 0.22) (Table 5).

The majority (35%) of the patients had double vessel disease among all the risk groups. 25% of all patients

Table 4: Comparison of renal function in different risk group

Renal function profile	Risk group			
	Low risk	Intermediate risk	High risk	P-value
Mean serum urea (In mg/dl)	30.14	31.72	32.2	0.81
Mean serum creatinine (In mg/dl)	1.14	1.20	1.40	0.03
Mean eGFR (CKD-EPI)	68.86	67.42	53.75	0.10

Table 5: Comparison of cardiac parameters in different risk group

Cardiac Profile	Risk Group			
	Low risk	Intermediate risk	High risk	P-value
Mean LVEF (%)	53.70	52.0	39.2	0.008
Mean LVID (cm^3)	46.58	49.00	49.6	0.06
Mean LAID (cm^3)	29.82	30.45	31.60	0.22

LVEF: Left ventricular ejection fraction, LVID: Left ventricular internal diameter, LAID: Left atrial internal diameter

had triple vessel disease and 80% of patients in high-risk category had triple vessel disease**.** The difference was statistically significant (P=0.03).

DISCUSSION

This retrospective study was done with 105 patients with obvious features of ACS admitted in various units of the medicine and cardiology department of a tertiary care hospital through a period between January 2020 and May 2021.

The World Health Organization has projected that CVD will become the greatest cause of morbidity and mortality in the world by coming years and it is expected that Indians would be the most affected among all ethnic populations.[7] Primary prevention in terms of risk stratification is pivotal to accurately determine and intervene early in the natural history of CVD. One goal in risk factor research is to move ever closer to the proximal direct causes of disease. A complementary goal is to improve prediction to identify individuals who are more likely to develop CVD and who therefore should be receiving more intensive interventions where possible. The focus is on maximizing the benefit/cost ratio of treatments.[8]

To this effect, the risk assessment defined by the Framingham Study researchers was a great leap forward.[4] These risk identifying researches led to the development of multiple other predictive CVD risk score calculators, such as the Munster Heart Study (PROCAM) Risk Score,[9] Sheffield Coronary Risk Tables, National Heart Foundation of New Zealand Guidelines, Dundee Coronary Risk Disc, and the SCORE project.[10]

In our study, we found that 67(63.8%) patients had low risk, 33(31.4%) patients had intermediate risk, and 5(4.8%) patients had high risk for the development of CHDs, as per Framingham risk score criteria, taking >20% as cutoff for a high-risk score. Hence, in our study, the Framingham model defined only 5% of the study population to be at high risk, which appeared to be an underestimation of the predictive ability of this tool in our patient population.

While there is some evidence that risk estimates based on Framingham data generalize well to other populations in the US and in Europe, many studies in the US and Europe have shown that Framingham risk factors overestimate the risk of CAD in Hispanics and Northern Europeans and some Asians (Japanese and Chinese).[11-13] A recent study on the Chinese and Danish cohort found the Framingham model overestimated the CAD risk.[14] There are also many studies which show underestimation of CAD risk by the Framingham model.[15]

In our study, the mean (mean±SD) age of patients in high-risk group was 66.4000±6.655 years, which was significantly higher than low (53.9552±9.5083) and intermediate risk (59.3636±6.3925) group patients (P<0.001).

It is important to recognize that the strongest predictor of CV risk in any risk equation is age. In actual Framingham CV study, almost all persons aged 70 and over are at >20% 10-year CV risk and almost nobody aged under 40 is at >20% 10-year CV risk.

However, in our study, the mean age in different risk groups varied between 54 and 66 years, which clearly showing that Indian population are prone to develop CADs at much lower age. If we further categorize all the patients in three major age groups, then we found that 70% of the population belong to <60 years of age.

Asian Indians, compared with other subpopulations, are at more risk for developing CAD and diabetes at a younger age (approximately 10 years earlier). Joshi et al., in their study, involving 15 medical centers in five South Asian countries said that the mean age for first AMI was lower in South Asian countries (53.0 years) than in other countries (58.8 years; P<0.001).

Our study had significantly higher number of male patients (77% vs. 23%, P=0.004). Although our study showed significantly higher number of CADs in males than, now-

a-days, the most of the Western studies reveal higher prevalence of CADs among females than males probably because of higher life expectancy and higher incidences of DM, hypertension, and hypercholesterolemia than males.[16] However, in Indian context, females have a less prevalence of CADs that may be due to their genetics, lower addiction rates, lack of having junk foods etc. as compared with males. This trend was reflected in our study.

However, also in our country due to certain social factors, females are given less importance for their health issues as compared to males, and this may lead to a major under-reporting of many diseases among them.

Michos et al., in their study showed that Framingham risk equation frequently classifies women as being low-risk, even in the presence of significant coronary artery calcium (CAC), which is a validated marker for the future CHD events among asymptomatic individuals. Determination of CAC may provide incremental value to FRE in identifying asymptomatic women who will benefit from targeted preventative measures.

Our study also revealed that 12% of low-risk patients were smoker in comparison to 75% of intermediate risk and 40% of high-risk group. This difference was statistically significant (P<0.001) reflecting the well-known contribution of smoking in development of CADs.

In our study, patients in the low-risk group had significantly better mean (±SD) HDL profile than intermediate and high-risk groups (45.761 mg/dl vs. 39.636 mg/dl vs. 37.00 mg/dl; P=0.001). HDL by its anti-inflammatory, anti-oxidant, and anti-apoptotic effect prevents atherosclerosis and subsequent development of CADs. Thus, patients with low levels of HDL are more prone to develop CAD and this was also seen in our study.

Jenkins et al., confirmed the correlation between HDL cholesterol (HDL-C) levels and CAD observed in epidemiological studies by performing coronary angiographies and found a significant association between HDL-C levels and the severity of atherosclerosis.[17] A recent meta-analysis, including 302.430 subjects from 68 long-term prospective studies, supported the importance of HDL-C measurement in the risk assessment for CAD.[18]

In our study, although both the TC and the TG level showed a positive correlation with the risk group, both of them were not statistically significant.

There was a mixed type of picture found in different studies related to association of total serum cholesterol and TG and the risk of development of ACS. Kumar et al., observed significantly higher TC and TG levels in AMI patients.[19]

Mean systolic blood pressure was significantly higher in high-risk population than low and intermediate risk group (155 vs. 131 vs. 138 mm of Hg; P=0.005). Mean diastolic blood pressure was also higher in high-risk group, but the difference was not statistically significant (93 vs. 87 vs. 88 mm of Hg; P=0.18).

This clearly showed a strong association between SBP and the development CADs. Higher the SBP, higher is the risk. Although DBP is not showing any statistically significant correlation for ACS occurrence, we assume that larger sample size could clearly prove any correlation, if any, in Indian population. In patients with established CAD, the effect of blood pressure lowering *per se* is beneficial.

Considering diabetes mellitus (DM) as one of the important risk factors for CADs, we found in our study that 36.19% of the population have DM and the occurrence of DM does not show any statistical significance among various risk groups.

In India Gupta et al., in their Jaipur Heart Watch-2 prospective study found a high prevalence of DM in patients with CADs along with other conventional risk factors.[20] Knowing the fact that DM plays a very significant role for premature development of CVDs and is its alarming increment rate in Indian population, we conclude that probably the small sample size in our study is unable to create a statistically significant picture.

Apart from checking the validity of FRS in risk prediction and association of different conventional risk factors with CADs, in our study, we also tried to find whether creatinine, urea, and eGFR (e-GFR calculated by CKD-EPI formula) that are showing any association and correlation with different risk groups of our study population. Although mean serum urea and eGFR were comparable in all three risk groups (P=0.81 and 0.10), high creatinine and lower eGFR were associated more with high-risk population. Mean serum creatinine was significantly higher in high-risk patients among all the risk groups (P=0.03).

Nishimura et al., in their study showed that predictive score including CKD as a coronary risk factor for the Japanese population was more accurate for predicting CHD than the original Framingham risk scores in terms of the C-statics and net reclassification improvement.[21]

In this study, we found as the risk increased the LVEF decrease substantially. LVEF was significantly lower in high-risk (39.2% vs. 59% vs. 53%; P=0.008) patients than other risk groups.

Ching et al., aimed to evaluate the relationship between the Framingham risk score (FRS) and LVDD by conducting a cross-sectional study among 359 hypertensive patients. However, there was no correlation between both mean FRS and LVDD.

Other parameters like LVIDs and size of LA showed an increment in their value as the risk score increases but these were not statistically significant. Since in our study, all the population had a cardiac event, that is, ACS (in this case), we further took our step forward to find the number of major coronary vessels got involved which were revealed through coronary angiography in different risk groups and try to establish any correlation, if any, that exist with FRS.

In our study, we found that 80% of high-risk patients developed triple-vessel disease, and it is statistically significant. As per our best knowledge, till date, there is no study done to evaluate the correlation between FRS and angiographic findings. Still from our study, it can be said that the FRS can play a very important tool for the prediction and correlation of number of coronary vessels diseased in high-risk category and we can manage this kind of patients in a more efficient manner to prevent the events and consequently further complications.

Hence, depending solely on FRS to predict CVD risk in Indian population and guiding treatment on the basis of that might not be that wise decision. It is evident that there is a need for population specific risk estimations because major chunk of our population belongs to low socio-economic status where different other factors play a crucial role other than the conventional risk factors.

Limitations of the study

In spite of every sincere effort, this study has some limitations:

1. The sample size was very small. hence, the study findings have to be interpreted with caution
2. The study was done in a single center so cannot be extrapolated on entire population
3. The study was carried out in a tertiary care hospital, so hospital bias cannot be ruled out.

CONCLUSION

The widely accepted tool for prediction of the future CADs/CVDs, the Framingham CV risk score (FRS) for CHD is unable to put our study population in proper risk category for their CADs/CVDs. We found 5% of our patients belong to high risk group, although rest all presented with their first ACS without prior history of CVDs. This clearly showing under-estimation of FRS in prediction of CADs in our study. Perhaps FRS needs a calibration and modified form with inclusion of other risk factors and parameters to determine and predict the future risk of development of ACS/CVD more accurately in Indian population.

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SD- Concept and design of the study and preparation of the first draft of manuscript; **LB-** Data collection and statistical analysis and reviewed the manuscript; **TM-** Concept and coordination and prepared the manuscript; **KB-** Literature review, interpretation of results, reviewed the manuscript; and **SKP-** Did the literature review, intellectual contribution, and final editing of the manuscript.

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