Ambiguity about Selection of Cardiovascular Risk Stratification Tools: Evidence from a North Indian Rural Population

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Abstract

Background: Several nonlaboratory based cardiovascular disease (CVD) risk scoring tools are available for resource-limited settings, but the performance of these tools remains to be established in Indian population. This study aimed to assess and compare the performance of the World Health Organization (WHO)/International Society for Hypertension (ISH) risk prediction chart and the Framingham Risk Score (FRS) calculator in an Indian setting. Materials and Methods: This cross-sectional study was carried out among 283 participants aged 30–74 years who attended screening camps in the rural area of Punjab from October to December 2015. Nonlaboratory-based WHO/ISH risk prediction chart for South-East Asia Region and FRS calculator was used to assess the 10-year risk of cardiovascular event. Chi-square test for trend and quadratic weighted kappa were used for analysis. Results: Of total participants, 67.1% were female. Mean age of the study participants was 52.1 (standard deviation ± 11.6) years. Using the WHO/ISH risk prediction chart, 11.3% and 4.9% of the participants were found to have high and very high risk, respectively, whereas, FRS calculator predicted high risk in 13.8% and very high risk in 12.0% for developing CVD in next 10 years. Agreement level between two risk prediction tools was good (67.8%). Conclusion: Although the good agreement was seen between WHO/ISH risk prediction chart and FRS calculator, the proportions of participants having a high and very high risk of CVD identified by these risk prediction tools are significantly different. In resource constraint setting like India, CVD risk prediction tools should be validated for local population by prospective cohort studies to ensure judicious use of resources.

Keywords: Cardiovascular diseases, health resources, primary care, risk

Introduction

Cardiovascular diseases (CVDs) are a major cause of disability and premature death worldwide and contribute substantially to the escalating cost of healthcare.[1] Of total 55.8 million global deaths estimated in 2015, 31% occurred due to CVD. Majority of these deaths occurred in low- and middle-income countries.[2] South Asia had the largest estimated increase (97.4%) in deaths from CVD between 1990 and 2013.[3]

As per the Global Burden of Disease (GBD) study (2010), age-standardized CVD death rate estimated in India was 272/100,000 population that was greater than the global estimates of 235/100,000 population.[4] Age-standardized burden of CVD in terms of DALYs in India were 3315–4228/100,000 in males and 2584–3438/100,000 in females.[5] It was estimated that CVD will be the largest cause of disability and death by 2020 in India.[6] In India’s epicemic of CVD, the causes of concerns are its accelerated buildup, the early age of disease-onset in the population, and the high case fatality ratio. Premature mortality regarding years of life lost because of CVD in India had increased by 59% from 1990 to 2010.[4]

Punjab, a North Indian state, has a comparatively higher prevalence of risk factors for CVD.[7,8] A recent Non-Communicable Diseases (NCDs) STEPS Survey in 18–69 years age group revealed prevalence of hypertension and diabetes to be 40.1% and 14.3%, respectively. Out of total sample, 11.3% of people consumed tobacco, and 15% consumed alcohol. Overweight (body mass index [BMI] = 25–29.9) and obesity (BMI ≥30) was present in 28.6% and 12.8% of

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the population, respectively.\textsuperscript{[7]} These risk factors can lead to higher risk of CVD like myocardial infarction, other heart disease, peripheral artery disease or stroke, if not managed appropriately.

The identification of people with high risk is crucial for prevention and control program, and clinical management of CVD. Considering its multifactorial causation, various risk scoring tools have been developed worldwide to predict CVD risk in the adult population. The Framingham Risk Score (FRS) calculator was developed from the data of the Framingham Study to assess CVD risk.\textsuperscript{[9]} Recently, the World Health Organization (WHO) in collaboration with the International Society for Hypertension (ISH) also developed regional risk prediction charts.\textsuperscript{[10]} Both these risk prediction tools recommended using nonlaboratory-based risk prediction methods for resource-limited settings where blood cholesterol measurement facility is not available. The Government of India recommended the use of WHO/ISH chart for South-East Asia Region, under National Programme for Prevention and Control of Diabetes, CVD, and Stroke (NPCDCS).\textsuperscript{[6]}

We did this study to assess and compare performance for 10-year cardiovascular risk using WHO/ISH risk prediction chart and FRS calculator among the participants enrolled in screening camps in an Indian setting.

**Materials and Methods**

This population-based study with the cross-sectional design was carried out during October-December 2015. Screening camps for hypertension and diabetes were conducted in the rural area of district Fatehgarh Sahib of Punjab state (India) as a part of routine services provided by a tertiary health-care institution.

A sample size of 231 was estimated. For sample size estimation, the level of significance ($\alpha$) was taken as 0.05 and absolute precision as 4%. Prevalence (p) of high cardiovascular risk (>20%) in adults was assumed to be 10.8%, the value reported from a study conducted in Ahmedabad.\textsuperscript{[11]}

All persons aged 30–74 years who attended the screening camps in five villages were included in the study, after obtaining their informed written consent. Age group 30–74 years was chosen as FRS calculator is applicable for this age group.\textsuperscript{[12]} Those people who had a history of stroke, myocardial infarction or any other heart diseases (already diagnosed and self reported) were excluded from the study.

A pretested semi-structured pro forma was used to elicit demographic details, namely, age, sex, and other risk factors such as smoking status, presence or absence of diabetes and hypertension and treatment history of the participants.

Blood pressure was measured in sitting position on the right arm using Omran automatic blood pressure monitor, after 15 min of rest. Systolic and diastolic blood pressure was taken as the mean of two readings taken 5 min apart. Hypertension was defined as the study participants either having raised systolic or diastolic blood pressure ($\geq 140$ or $\geq 90$ mmHg, respectively) or taking treatment for hypertension.\textsuperscript{[6]} Capillary blood glucose was measured using Accu-Chek® Glucometer after minimum 8 h of fasting. A diabetic person was defined as someone taking insulin or oral hypoglycemic drug(s) or with fasting capillary plasma glucose level $\geq$126 mg/dl.\textsuperscript{[6,13]}

All current smokers and those who had quit smoking $<$1 year before the assessment were considered smokers for assessing cardiovascular risk.\textsuperscript{[6]} Height and weight were measured using Seca’s Stadiometer and digital weighing scale, respectively. Overweight and obesity were assessed by measuring BMI. For Indian population, BMI 18.5–22.9 k/m\textsuperscript{2} was taken as normal, 23–24.9 k/m\textsuperscript{2} was considered as overweight and $\geq$25 k/m\textsuperscript{2} was considered as obesity.\textsuperscript{[6]} Waist circumference (WC) was measured at the approximate midpoint between the lower margin of the last palpable rib and the top of the iliac crest. Hip circumference measurement was taken around the widest portion of the buttocks.\textsuperscript{[14]} Central obesity was defined as WC $\geq$90 cm for men and $\geq$80 cm for women or waist to hip ratio (WHR) $\geq$0.85 for women and $\geq$0.95 for men.\textsuperscript{[6]}

Nonlaboratory-based WHO/ISH risk prediction chart for South-East Asia Region (SEAR, Group D) was used to assess the 10-year risk of a fatal or nonfatal cardiovascular event. This chart provides approximate estimates of CVD risk in people who are not known to have established coronary heart disease, stroke, or other atherosclerotic disease. The CVD risk scoring is based on gender, age, systolic blood pressure, presence or absence of diabetes, and current smoking status. WHO/ISH risk prediction chart has five risk categories of $<$10%, 10%–20%, 20%–30%, and 30%–40% and $\geq$40%.\textsuperscript{[6]} For the management purpose, the risk categories of 30%–40% and $>$40% risk were combined as recommended in NPCDCS Guidelines.\textsuperscript{[6]}

Nonlaboratory-based FRS online calculator was used to calculate the risk prediction of the 10-year cardiovascular event based on gender, age, systolic blood pressure, presence or absence of diabetes, taking regular treatment for hypertension, and BMI.\textsuperscript{[12]} FRS calculator gives absolute score of CVD risk in percentage, hence it was further categorized as low risk ($<$10%), moderate risk (10%–20%), high risk (20%–30%), and very high risk ($\geq$30%) to compare it with WHO/ISH risk prediction chart. Participants were counseled for lifestyle modification, and pharmacological treatment was prescribed according to the Guidelines of NPCDCS.\textsuperscript{[6]}

Statistical analysis was performed using IBM SPSS Statistics for Windows, Version 24.0 (IBM Corp. Armonk, NY, USA). Qualitative data were presented as proportion and quantitative data as the mean and standard deviation (SD). To determine the difference between proportions, Chi-square test was used. To see agreement level between WHO/ISH risk prediction chart and FRS calculator, kappa statistics was applied. As data were arranged in ordinal categories and risk between various categories of CVD risk was not equal, the quadratic weighted kappa was used. Based on the value of kappa, agreement level
was poor (<0.20), fair (0.21–0.40), moderate (0.41–0.60), good (0.61–0.80), and very good (0.81–1.00). Ethical approval was taken from the Institute Ethics Committee. Unique identifiers were removed from the data before analyzing it to secure the confidentiality of the study participants.

## RESULTS

A total of 283 persons participated in the study; 67.1% were female. Mean age of study participants was 52.1 (SD ± 11.6) years. Mean systolic and diastolic blood pressure were 143 (SD ± 19.9) mmHg and 84.3 (SD ± 10.4) mmHg, respectively. Mean BMI of the study participants was 24.3 ± 5.3 kg/m² (Males: 23.7 ± 4.7 kg/m²; Females: 24.6 ± 5.6 kg/m²). Smoking was significantly more prevalent among males (P < 0.001). Diabetes, hypertension, and generalized obesity did not vary significantly with gender. Central obesity was present in more than 85% of the study participants as measured by WC and WHR [Table 1].

Table 2 presented CVD risk of the study participants using CVD risk prediction tools – WHO/ISH chart and FRS calculator, respectively. WHO/ISH chart predicted almost similar risk of developing CVD in both males and females (P > 0.05). While FRS calculator predicted that CVD risk of >20% was significantly lower in females as compared to males (females - 15.3%, males - 47.3%; P < 0.001). Median Framingham CVD risk score in our study was 10.3 (Interquartile Range = 15.4).

Agreement level between WHO/ISH risk prediction chart and FRS calculator for cardiovascular risk assessment was good as measured using quadratic weighted kappa (k = 0.678, 95% confidence interval = [0.597–0.758]) [Table 3].

## DISCUSSION

We found two commonly used risk prediction tools, namely, WHO/ISH risk prediction chart and FRS calculator, reveal the different proportion of persons in high and very high-risk categories of CVD, in spite of having good agreement level. Hence, this is a challenging situation in medical practice to predict the CVD risk and initiate a timely intervention to prevent morbidity and mortality.

The study reported a higher prevalence of CVD risk factors than NCDs STEPS Survey and DLHS-4 Survey in rural Punjab. It could be attributed to following three characteristics of our study: first, possible preferential voluntary participation of persons with higher CVD risk factors in the screening camps; second, relatively higher age group (30 years and above) as compared to 18 years and above in STEPS and DLHS-4 Survey; and third, use of lowered BMI cutoffs for Asian populations in our study for categorizing overweight and obesity as compared to Global BMI criteria in STEPS and DLHS-4 Survey.

Using WHO/ISH risk prediction chart, we found 33.2% of participants has ≥10% predicted the risk of CVD, whereas Bansal et al. reported this as 44.4%. Reason for higher prevalence in their study may be due to higher age group (≥40 years) and outpatient department based recruitment of the study participants. In our study, as calculated by FRS calculator 25.1% of participants had a moderate risk and 25.8% had a high or very high risk of developing CVD in next 10 years. Parikh et al. in a community-based study found 11.7% of participants had an intermediate risk (10%–20%) and 10.6% had a high risk (≥20%) of developing CVD in next 10 years by using Framingham Heart Study model based nonlaboratory predictors. Although the

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**Table 1: Distribution of risk factors for cardiovascular disease among the study participants (n=283)**

| Risk factors | Male (n=93), % | Female (n=190), % | Total (n=283), % | P* |
|--------------|----------------|-------------------|-----------------|-----|
| Smoking      | 16 (17.2)      | 03 (1.6)          | 19 (6.7)        | <0.001 |
| Diabetes     | 16 (17.2)      | 38 (20.0)         | 54 (19.1)       | 0.5  |
| Hypertension | 71 (76.3)      | 132 (69.5)        | 203 (71.7)      | 0.2  |
| Obesity      | 35 (37.6)      | 81 (42.6)         | 116 (41.0)      | 0.8  |
| Overweight   | 13 (14.0)      | 21 (11.1)         | 34 (12.0)       |      |
| Raised WC    | 79 (84.9)      | 163 (85.8)        | 242 (85.5)      | 0.8  |
| Raised WHR   | 74 (79.6)      | 179 (94.2)        | 253 (89.4)      | <0.001 |

*Chi-square test; †Raised WC (male >90 cm; female >80 cm); ‡Raised WHR (male >0.95; female >0.85). WC: Waist circumference, WHR: Waist: hip ratio

**Table 2: Comparison of cardiovascular risk assessed by two different tools (n=283)**

| Cardiovascular risk categories | Low risk, n (%) | Moderate risk, n (%) | High risk, n (%) | Very high risk, n (%) | P* |
|-------------------------------|----------------|---------------------|----------------|-----------------------|-----|
| WHO/ISH risk prediction chart |                |                     |                |                       |     |
| Male (n=93)                   | 59 (63.4)      | 18 (19.4)           | 10 (10.8)      | 06 (6.5)              | 0.7 |
| Female (n=190)                | 130 (68.4)     | 30 (15.8)           | 22 (11.6)      | 08 (4.2)              |     |
| Total (n=283)                 | 189 (66.8)     | 48 (17.0)           | 32 (11.3)      | 14 (4.9)              |     |
| Framingham risk score calculator |                |                     |                |                       |     |
| Male (n=93)                   | 27 (29.0)      | 22 (23.7)           | 22 (23.7)      | 22 (23.7)             | <0.001 |
| Female (n=190)                | 112 (58.9)     | 49 (25.8)           | 17 (8.9)       | 12 (6.3)              |     |
| Total (n=283)                 | 139 (49.1)     | 71 (25.1)           | 39 (13.8)      | 34 (12.0)             |     |

*Chi square for trend. WHO: World Health Organization, ISH: International Society for Hypertension
same risk prediction tool was used in both studies, the proportion of individuals at high risk is greater in our study. It could be explained by volunteer bias due to screening camps-based sample selection, the participation of higher age group in our study, and more prevalent risk factors of CVD in Punjab.[23] Kanjilal et al. also assessed CVD risk in participants with a strong family history of CVD by using Laboratory-based Framingham Score Chart and reported that 14.9% were at intermediate risk (10%-20%) and 5.3% were at high risk (≥20%) for CVD in the next 10 years. However, the mean age of participants was lower and the tool employed was based on laboratory; which may lower the proportion of high-risk participants.[19]

In our study, both CVD risk prediction tools identified different proportions of individuals in various risk categories (P < 0.001). WHO/ISH risk chart predicted only 5% of participants with ≥30% risk of CVD in next 10 years while FRS calculator identified 12% of participants with ≥30% risk. The difference documented in the Malaysian study was akin to our study findings.[20]

Our study shows good agreement (67.8%) level between the two tools. Still, it is far away from maximum attainable agreement for CVD risk. Mchugh recommended 80% agreement as the minimum acceptable agreement in healthcare research.[21] Remaining 32% is a significant proportion which will be categorized in to different CVD risk categories by these two tools and will create uncertainty about initiation of intervention.

In developing countries like India where the health-care delivery system is not robust and time to reach a health facility in case of a cardiovascular event is high, the prevention and management of CVDs are of paramount importance. Unfavorably, two most widely used risk prediction tools to categorize individuals at high risk of CVD leaving physicians in doubt about the selection of a tool, particularly in remote areas and low resource primary care settings.

WHO/ISH risk prediction charts are, notwithstanding, derived by statistical models using extrapolated data about the prevalence of risk factors for CVD from the GBD study; these risk prediction charts have not been systematically validated for their accuracy and validity in prospective studies.[19] FRS although widely used and has good discrimination in most populations (including those from outside the United States).[22] However, it is not validated in Indian Population. Both under- or over-estimation of CVD is detrimental as it may defeat the benefit by eliminating those who need treatment or put them under disadvantage regarding mental trauma for being at risk of the disease. It will also waste meager resources for screening and management of at-risk individuals. Therefore, large population-based studies are required to validate these prediction tools to improve their utility for clinical practice and policy planners and program managers in India.

**Conclusion**

The findings of our study provide evidence that despite having good agreement level between these two risk stratification tools, the proportion of high-risk individuals identified by them is different. Their use would be dismal to prevention and control efforts for CVDs if the accurate proportion of high-risk individuals is not identified. In resource constraint settings like India, validation of the cardiovascular risk prediction tools by prospective cohort studies may be pragmatic to ensure judicious use of resources.

**Limitations**

This study has few limitations. This was a cross-sectional study conducted on the participants attending screening camps held for hypertension and diabetes. It may lead to selection bias and limit the generalizability of the results. However, it does not affect the validity of the study for comparison of both tools for cardiovascular risk assessment.

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**Conflicts of interest**

There are no conflicts of interest.

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