Indian Heart Journal 73 (2021) 353–358

Contents lists available at ScienceDirect

Indian Heart Journal

journal homepage: www.elsevier.com/locate/ihj

Comparison of original and modified Q risk 2 risk score with Framingham risk score - An Indian perspective

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ARTICLE INFO

Article history:
Received 16 June 2020
Received in revised form
9 December 2020
Accepted 14 January 2021
Available online 19 January 2021

Keywords:
Q risk 2
Framingham risk score
Smokeless tobacco
Cardiovascular disease
Primary prevention

ABSTRACT

Objective: No study among Indian population has proposed modification of existing cardiovascular disease (CVD) risk scores or novel risk scores as risk estimation using conventional risk calculators can't be generalized because of epidemiological differences.

Material and methods: A single center observational study was performed at a tertiary care center among participants having no evidence of CVD. Prevalence of various cardiac risk factors were analysed and 10-year risk was estimated using Framingham risk score (FRS), Q risk 2 score calculator (QRISK2) and Modified Q risk 2 (mQRISK2) which included smokeless tobacco consumption. QRISK2 and mQRISK2 were compared with FRS and participant's eligibility for statin therapy as primary preventive measure was assessed.

Results: Total of 4045 participants were enrolled from August 2016 to July 2019. 3520(87%) had no history of smoking in their lifetime while smokeless tobacco consumption was seen in 1153(28.5%), diabetes in 422(10.4%), hypertension in 1096(27.1%), obesity in 2035(50.3%), and family history of CVD in 353(8.7%) participants. High risk participants were found to be 826(20.4%), 627(15.5%), and 509(12.6%) by using FRS, mQRISK2 and QRISK2, whereas those eligible for statin therapy were maximum by mQRISK2 among 1323(32.7%) participants compared to QRISK2 (n = 1191; 29.4%) and FRS (n = 826; 20.4%) model. Krippendorff's alpha for mQRISK2 was in better agreement with body mass index (BMI) and lipid FRS CVD scoring system as compared to QRISK2 risk model.

Conclusion: CVD risk stratification based on smokeless tobacco use is first of its kind from this part of world and should be part of CV risk assessment.

1. Introduction

Burden of cardiovascular disease (CVD) in India is huge, the age-standardized death rate due to CVD being 272 per 100,000 population compared to the global average of 235 per 100,000 population.[1] Its presentation and progression is also quite different from western population as it presents a decade earlier among Indians and have more case fatality rate.[2–5] This can be attributed to difference in prevalence of traditional risk factors as well as different impact on risk of CVD by same traditional risk factors among Indian population.[6] INTERHEART and INTERSTROKE study have demonstrated that more than 86% of CVD was attributable to nine key risk factors (diabetes, hypertension, smoking, lipids, obesity, diet, physical activity, alcohol consumption and psychosocial factors).[7,8] Identification of risk factors and estimation of future risk of atherosclerotic cardiovascular events play an important role in primary prevention of cardiovascular risk. Multiple cardiovascular risk scoring models derived from epidemiological data of specific population groups are available for use, but they can't be accurately extrapolated because of the differences in their prevalence and each factor having different impact altogether. Contrary to smoking

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https://doi.org/10.1016/j.ihj.2021.01.016

which is a part of all risk assessment tools, smokeless tobacco is a common method of tobacco consumption in Indian population which is however not taken into consideration in any models of risk assessment.[9] The best known and unarguably most widely adopted model globally for risk assessment is Framingham Risk Score (FRS).[6,10] QRISK2 developed by Collins et al, a British risk assessment tool, has been seen to underpredict the risk among South Asians population.[11,12] Moreover, regional modification of risk assessment tools considering prevalence of those risk factors may yield better outcome as compared to the original tool. This study was designed to find the prevalence of different risk factors, risk of cardiovascular diseases among study participants, eligibility for statin therapy as primary preventive measure and comparison of FRS with QRISK2 and its modification with respect to use of smokeless tobacco as it is quite prevalent in India.

2. Material and methods-

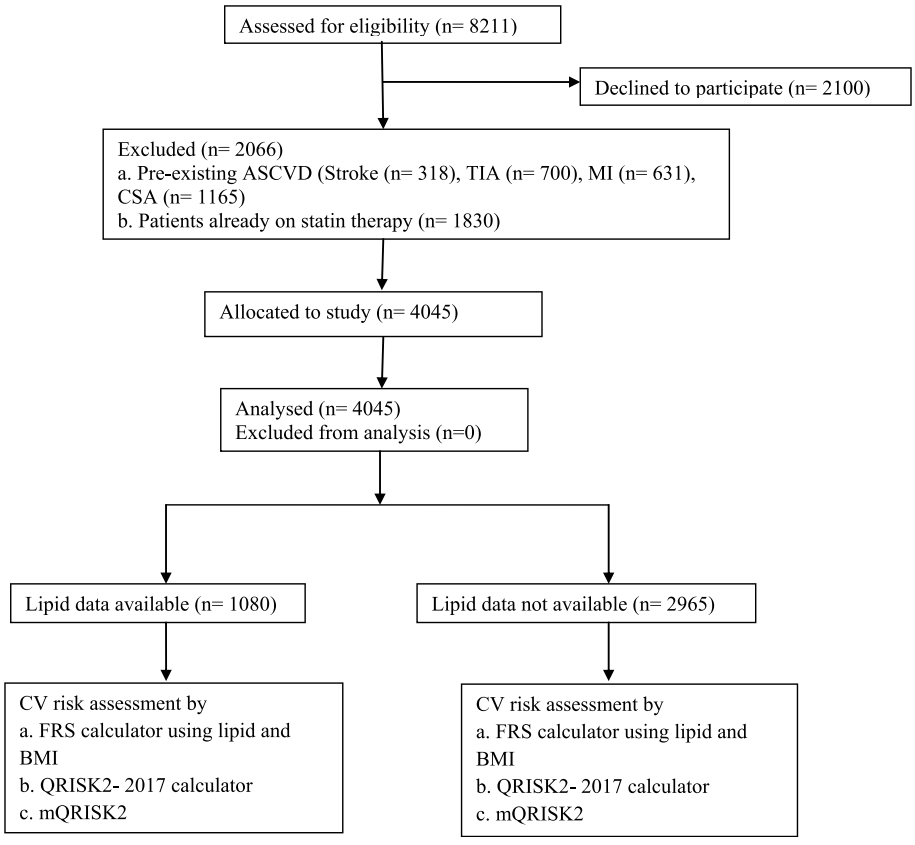
2.1. Methodology

This was a single center cross sectional study performed at a tertiary care center from August 2016 to July 2019. The subject recruitment process is outlined in Table 1. Inclusion criteria were subjects of age 25–85 years who had visited hospital along with patients who were admitted under cardiology department for various indications. Exclusion criteria were subjects with (a). pre-existing atherosclerotic cardiovascular disease (stroke, transient ischemic attack, myocardial infarction and angina) and (b). those receiving statin therapy for various indications. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964 and later revisions. Informed consent was obtained from all participants for being included in the study.

Race and ethnicity were self-reported and recorded. All participants underwent clinical history and physical examination which included height, weight, blood pressure and detailed cardiovascular examination for any obvious cardiac disease. Blood sample was collected from all participants fasting blood sugar, lipid profile, and renal function test. Blood pressure was measured in right arm in supine position using mercury sphygmomanometer. Hypertension was defined according to criteria laid down by Joint National Committee (JNC) as systolic blood pressure $\geq$ 140 mm Hg or diastolic blood pressure $\geq$ 90 mm Hg or previous history of hypertension or history of use of anti hypertensive medicines.[13]

Diabetes mellitus was defined as per the American Diabetes Association 2018 definition as fasting blood sugar $\geq$126 mg/dl and/or post prandial blood sugar $\geq$200 mg/dl. Participants who were already diagnosed as diabetes mellitus or on any antidiabetic medication or having detected RBS>200 mg/dl at the time of diagnosis were also classified as diabetes mellitus.[14] Family history was defined as positive if participants had a mother, father, brother or sister who has had a heart attack or 'angina' under the age of 60. The e-GFR (estimated glomerular filtration rate) was calculated from MDRD (Modification of Diet in Renal Disease) study equation and Chronic kidney disease stage 4 or 5 (CKD) was defined as e-GFR <30 ml/min.[15] Atrial fibrillation was defined as irregularly irregular pulse on examination and electrocardiogram with absence of P

Table 1
Flow chart showing subject recruitment process and cardiovascular risk assessment protocol (n = 4045).



wave. Rheumatoid arthritis was diagnosed as per history from participants about previous diagnosis or treatment for the same.

Dyslipidemia was defined as per National Cholesterol Education Program (NCEP) Adult Treatment Panel-3 (ATP-3) guidelines which defined it as presence of high total cholesterol (≥200 mg/dl), high LDL cholesterol (≥130 mg/dl), low HDL cholesterol (<40 mg/dl), high non-HDL cholesterol (≥160 mg/dl), high cholesterol remnants [very low density lipoprotein cholesterol = total − (HDL + LDL) cholesterol ≥ 25 mg/dl] or high triglycerides (≥150 mg/dl) but it was not an all essential factor in measuring the CVD risk.[16]

Obesity was defined as per the WHO criteria underweight (<18.5 kg/m^2), normal weight (18.5–24.9 kg/m^2), overweight (25–29.9 kg/m^2), and obese (≥30 kg/m^2).[17]

Smoking was defined as per national health interview survey (NHIS) definitions.[18] Individuals who had smoked 100 cigarettes in their lifetime and smoked cigarettes every day or some days were classified as smokers. Light smoker was defined as less than 10 cigarettes, moderate smoker as 10 to 19 and heavy smoker as 20 or more cigarettes per day. Ex-smoker was defined as participants who had quit smoking >1 year before the assessment were considered.

For calculation of Modified Q risk 2 (mQRISK2), smoking included use of tobacco in smokeless form. Smokers were defined as individuals who had smoked 100 cigarettes in their lifetime and smoked cigarettes every day or some days or taking tobacco in smokeless form everyday or some days for more than 1 year. Light smoker was defined as individual consuming tobacco in smokeless form only or smoking only less than 10 cigarettes, moderate smoker was defined as individual consuming 10 to 19 cigarettes or less than 10 cigarettes with tobacco consumption in smokeless form, heavy smoker was defined as individual consuming more than 20 cigarettes or 10 to 19 cigarettes along with tobacco consumption in smokeless form.

Based on their data, prevalence of risk factors and 10-year cardiovascular risk assessment was done. Among participants who had underwent lipid profile, cardiac risk assessment was done by Framingham risk score (FRS) calculator using lipid[10] and QRISK2-2017calculator[19] and modification of QRISK2- 2017 calculator with modification of smoking status as described in methodology using same online calculator.

In participants who had not undergone measurement of lipid profile, cardiac risk assessment was done by FRS calculator using BMI[10] and Q risk2 - 2017 calculator[19] and modification of Q risk2 - 2017 calculator with modification of smoking status as described in methodology using same online calculator. Minor adjustments were done in risk factors as per requirement of calculator.

Participants were divided into different risk categories (as per 10 year risk obtained from calculator) into low risk (10 year risk score <10%), moderate risk (10 year risk score 10–20%) and high risk score (10 year risk score >20%). For statin eligibility, Canadian cardiovascular society guidelines was used for primary prevention of cardiovascular diseases, which considered participants with 10 year risk score of ≥20%[20] and NICE guidelines which considered 10 year Q Risk2 score of ≥10%.[21]

2.2. Statistical analysis

For statistical analysis data were analyzed by SPSS (version 24.0; SPSS Inc., Chicago, IL, USA) and GraphPad Prism version 5. Summarization of data was done as mean and standard deviation for numerical variables and count and percentages for categorical variables. Agreement between different scoring systems was assessed using Krippendorff's alpha. Typically, the possible values for a reliability index range from 0 to 1, where 0 suggests the absence of reliability and 1 suggests perfect reliability. It is commonly suggested that Krippendorff's α ranges from 0.6 to 0.8 for tentative conclusions although a cut-off threshold value of 0.8 is a marker of good reliability. These threshold values are often employed with the knowledge of their largely arbitrary determination, and used in spite of suggestions that they are likely unsuitable for generalization.[22,23]

3. Results

A total of 4045 study participants were recruited for the study, of which 2358 (58.3%) were male. The population characteristics of participants were as shown in Table 2. Mean age for the study participants was 46 ± 13 years. Mean BMI of study participants was 25.26 kg/m^2. Among study participants, 3520 (87%) had never done smoking in their lifetime while only 46 (1.1%) were heavy smokers. Smokeless tobacco consumption was seen in 1153 (28.5%) participants. Among study participants, 422 (10.4%) diabetics, 1096 (27.1%) were known hypertensive, 353 (8.7%) had family history of CVD. Among the study participants, 2035 (50.3%) were obese. Lipid profile data of 1078 (26.7%) study participants was available. Mean serum Cholesterol level was 192.3 mg/dl, serum HDL was 11.19 mg/dl, Serum LDL was 113.37 mg/dl and serum VLDL was 34.19 mg/dl.

FRS scoring system has categorized maximum number of study participants in High risk category 826 (20.4%) while QRISK2 scoring system categorized 509 (12.6%) and mQRISK scoring system has categorized 627 (15.5%) study participants into high risk for CVD (Fig. 1).

When applying NICE 2014 guidelines for initiating statins as a primary prevention measure for cardiovascular diseases, 1191 (29.4%) participants were eligible for initiating statin therapy in accordance with QRISK2 and 1323 (32.7%) were eligible in accordance with mQRISK2 scoring. Nearly 826 (20.4%) participants were eligible for initiation of statin therapy in accordance with the Canadian guideline using FRS-CVD risk scoring which was less when compared to NICE 2014 guidelines.

Krippendorff's alpha was calculated to see agreement of risk scoring systems in categorizing participant's 10-year CVD risk. K alpha was 0.58 with QRISK2 scoring and 0.61 with mQRISK2 scoring, which shows mQRISK2 was in good agreement with BMI FRS-CVD scoring system (Table 3). Krippendorff's alpha was calculated to see agreement of risk scoring systems in categorizing participants 10-year CVD risk. K alpha was 0.60 with Q risk 2 scoring and 0.62 with mQRISK2 scoring, which shows mQRISK2 was in good agreement with Lipid FRS-CVD scoring system (Table 3).

4. Discussion

Cardiovascular diseases have become the most common cause of mortality contributing to a quarter of all in India.[24] As compared to western population, cardiovascular disease presents a decade earlier in Indians.[2–5] Multiple cross-sectional studies have tried to give the most out of epidemiological studies conducted across India; however, no nationwide data are available. In our study, another attempt was made to find the prevalence of various risk factors.

In 2013, Diabetes Mellitus was estimated in 65.1 million Indians by International Diabetes Federation.[25] In last 20 years, prevalence of diabetes has doubled in urban population and quadrupled in rural population and reached to 17% and 9% in urban and rural cities in India respectively.[26] In our study also diabetes mellitus was found in 10.4% of participants similar to previous studies.

Hypertension is another major risk factor, found in 30% of population in adult Indians.[27] In our study Hypertension was seen in 27.1% of participants. In a study by Sekhri et al, family history of

Table 2
Demographics of participants enrolled in study (N = 4045).

Variables		Male	Female	Total
Smoking	Non smoker	1851(45.8%)	1669(41.3%)	3520(87%)
	Ex smoker	86(2.1%)	04(0.1%)	90(2.2%)
	Light smoker	257(6.4%)	14(0.3%)	271(6.7%)
	Mod. smoker	117(2.9%)	01(0.02%)	118(2.9%)
	Heavy smoker	45(1.1%)	01(0.02%)	46(1.1%)
Modified smoking	Non smoker	1202(29.7%)	1453(35.9%)	2655(65.6%)
	Ex-Smoker	67(1.7%)	03(0.07%)	70(1.7%)
	Light Smoker	826(20.4%)	226(5.6%)	1052(26%)
	Mod. smoker	186(4.6%)	06(0.1%)	192(4.7%)
	Heavy Smoker	75(1.9%)	01(0.02%)	76(1.9%)
Diabetes	Yes	250(6.2%)	172(4.3%)	422(10.4%)
	No	2106(52%)	1517(37.5%)	3623(89.6%)
Family History of CVD	Yes	280(6.9%)	73(1.8%)	353(8.7%)
	No	2076(51.3%)	1616(39.9%)	3692(91.3%)
History of CKD	Yes	18(0.44%)	08(0.2%)	26(0.6%)
	No	2338(57.8%)	168(41.6%)	4019(99.4%)
History of AF	Yes	12(0.3%)	22(0.5%)	34(0.8%)
	No	2344(57.9%)	1667(41.2%)	4011(99.2%)
HTN on treatment	Yes	597(14.8%)	499(12.3%)	1096(27.1%)
	No	1759(43.5%)	1190(29.4%)	2949(72.9%)
History of RA	Yes	02(0.04%)	07(0.2%)	09(0.2%)
	No	2354(58.2%)	1682(41.6%)	4036(99.8%)
Dyslipidaemia (N = 1078)*	Yes	427(39.6%)	525(48.7%)	952(88.3%)
	No	123(11.4%)	03(0.3%)	126(11.7%)
S. Cholesterol (N = 1078) *	Normal	378(35%)	410(38%)	788(73.1%)
	Abnormal	172(15.9%)	118(10.9%)	290(26.9%)
TG Levels (N = 1078)*	Normal	231(21.4%)	242(22.4%)	473(43.8%)
	Abnormal	319(29.6%)	286 (26.5%)	605(56.1%)
S.HDL Levels (N = 1078) *	Normal	516(47.8%)	13(1.2%)	529(49.1%)
	Abnormal	34(3.2%)	515(47.8%)	549(50.9%)
S.LDL Levels (N = 1078) *	Normal	160(14.8%)	164(15.2%)	324(30.1%)
	Abnormal	390(36.2%)	364(33.8%)	754(69.9%)
HTN	Yes	942(23.3%)	704(17.4%)	1646(41.7%)
	No	1414(34.9%)	985(24.4%)	2399(59.3%)
BMI Grading	Underweight	159(3.9%)	112(2.8%)	271(6.7%)
	Normal	618(15.3%)	385(9.5%)	1003(24.8%)
	Over weight	454(11.2%)	282(6.9%)	736(18.2%)
	Obese	1125(27.8%)	910(22.5%)	2035(50.3%)
10-year Cardiac Risk with QRISK2	Low Risk	1515(37.5%)	1339(33.1%)	2854(70.6%)
	Moderate Risk	451(11.2%)	231(5.7%)	682(16.9%)
	High Risk	390(9.6%)	119(2.9%)	509(12.6%)
10-year Cardiac Risk with mQRISK2	Low Risk	1408(34.8%)	1314(32.5%)	2722(67.3%)
	Moderate Risk	458(11.3%)	238(5.9%)	696(17.2%)
	High Risk	490(12.1%)	137(3.4%)	627(15.5%)
10 Year cardiac risk as per BMI FRS	Low risk	1246(30.8%)	1213(29.9%)	2459(60.8%)
	Moderate Risk	492 (12.2%)	268(6.6%)	760(18.8%)
	High Risk	618(15.3%)	208(5.1%)	826(20.4%)
Statin eligibility with QRISK2 score	Yes	844(20.9%)	347(8.6%)	1191(29.4%)
	No	1512(37.4%)	1342(33.2%)	2854(70.6%)
Statin Eligibility with mQRISK2	Yes	951(23.5%)	372(9.2%)	1323(32.7%)
	No	1405(34.7%)	1317(32.6%)	2722(67.3%)
Statin eligibility as per BMI FRS	Yes	621(15.4%)	205(5.1%)	826(20.4%)
	No	1735(42.9%)	1484(36.7%)	3219(79.6%)

CVD-Cardiovascular disease; CKD-Chronic Kidney disease; AF- Atrial fibrillation; HTN-Hypertension; RA-Rheumatoid arthritis; TG-Triglyceride; HDL-High density lipoprotein; LDL-Low density lipoprotein; BMI-Body mass index; mQRISK 2-Modified Q RISK 2; FRS- Framingham risk score; * indicates no of patients.

premature coronary artery disease was found in 4.4% and 6% of males and females respectively in a collected data on 12,608 government employees living in different parts of India.[28] Our study showed family history of premature coronary heart disease in 8.7% of the participants. This higher prevalence of presence of family history may be attributed to the fact that sample of population was taken from participants visiting hospital along with the patients thus increasing the probability of having a positive family history. Overweight participants constituted around 50% of population, which is higher than the national reports of National Family Health Survey-4 (NFHS).[29] Tobacco consumption is highly prevalent in India with more than one-third Indians consuming tobacco in smoke or smokeless form.[9] In our study also, tobacco consumption was recorded in around 25% of participants with around one third consuming in smokeless form. Dyslipidemia, although calculated in only 30% of the population, was present in majority of the participants (88%) with low HDL level in 50.9% similar to Jaipur Heart Watch Studies.[30]

In a country like India, where burden of cardiovascular diseases is reaching a pandemic, estimation of future risk of cardiovascular disease may potentially benefit patients through primary preventive therapy. Beside traditional Framingham model, multiple other models like SCORE,[31] ASSIGN SCORE,[32] PROCAM,[33] Reynolds,[34] and INTERHEART modifiable risk score[35] are available. The major limitations of these risk scores are limitations in the number of factors and variables, such as socioeconomic status, circumstances, and ethnicity, which have been found to influence risk. Lifestyle factors, such as dietary intake, physical activity, and cigarette smoking

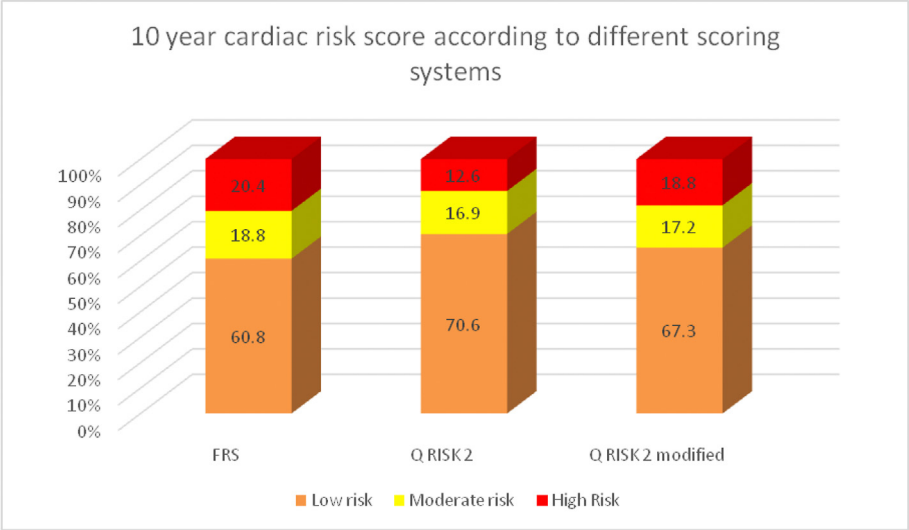


Fig. 1. 10 year risk score among study participants based on different criteria (n = 4045).

Table 3
Krippendorff's alpha between Framingham 10-years cardiac score with Q risk 2 and Modified Q risk 2 risk score.

Cardiac Risk score (vs. BMI- Framingham 10-years cardiac risk score)	K alpha
Q risk 2–10 year cardiac risk score	0.58(0.56–0.60)
Modified Q risk 2–10 year cardiac risk score	0.61(0.59–0.63)
Cardiac Risk score (vs. Lipid- Framingham 10-years cardiac risk score with Q risk score)	K alpha
Q risk 2 10-year cardiac risk score	0.60(0.56–0.64)
Modified Q risk 2–10 year cardiac risk score	0.62(0.58–0.66)

BMI- Body Mass Index.

rates, may differ significantly between communities and to a greater extent between countries; thus, their influence on risk may not accurately reflect the importance of these factors in different populations.

No risk prediction model is validated for Indian populations but Framingham Risk Score calculator is the most widely used and Q Risk 2 has been externally validated for South Asians.[6,10–12]

Smokeless tobacco use is highly prevalent in India and has been associated with increased risk of cardiovascular diseases.[7] However none of the risk prediction model includes smokeless tobacco, which might lead to underestimation of cardiac risk in the Indian population.

In this study, we calculated 10 year cardiac risk in study participants by 3 cardiac risk score calculators i.e. Framingham risk score, QRISK2 and mQRISK2 modified. Risks were calculated in participants either by using lipid profile or by using body mass index. Framingham risk score screened maximum number of participants with high 10 year cardiac risk followed by mQRISK2 and QRISK2 score. Risk estimated by FRS was higher since it estimates risk for a larger combination of outcomes including coronary death, myocardial infarction, coronary insufficiency, angina, ischemic stroke, hemorrhagic stroke, transient ischemic attack, peripheral artery disease and heart failure while QRISK2 estimates risk for only angina, myocardial infarction, stroke and transient ischemic attack. However, FRS has been found to overestimate cardiovascular risk by approximately 5% in British population.[11] Risk calculated by our study was higher than that calculated by previous similar studies conducted in India.

Inclusion of smokeless tobacco is a first of its kind modification in cardiac risk assessment models. Performance of QRISK2 risk calculator has good discriminative and calibration properties when compared to NICE version of FRS.[11] In our study, the QRISK2 score after modification for tobacco stratified participants with better agreement with the FRS, thus necessitating the need of inclusion of smokeless tobacco as a risk factor in QRISK2 model.

Statin therapy is one of the most important strategies in primary prevention of cardiovascular diseases and has been recommended by various treatment guidelines in high risk patients. In our study, 29.4% participants were eligible for statin therapy as per the NICE 2014 guidelines in accordance with QRISK2 score while 32.7% participants required statins in accordance with the mQRISK2 score. As per the Canadian guidelines, using FRS- CVD risk scoring, nearly 20.4% participants were eligible for initiation of statin therapy. This risk stratification can help in the identification of high-risk subgroups and can thereby help prevent cardiovascular disease by applying primary prevention.

5. Limitation

Larger population groups may be required for true quantification of cardiovascular burden in India. Few modifications were made as per the requirement of risk score calculator which could have influenced the risk score. Lipid data was not available for all study subjects. Quantification of smokeless tobacco intake could not be done. During data collection QRISK2 was the latest available QRISK model hence the new QRISK scoring system i.e. QRISK3 could not be used. It was a cross sectional study and a follow up study would have better compared the real world picture of the risk models.

6. Conclusions

Risk stratification of population plays an important role in primary prevention of cardiovascular diseases and local

epidemiological feature like use of smokeless tobacco in India should be a part of cardiovascular risk scores. Modified Q RISK 2 by addition of smokeless tobacco helps in better prediction of 10 year cardiac risk as compared to Q RISK 2 score.

Funding

None.

What is already known about this subject?

CV risk stratification plays an important role in prevention of cardiovascular diseases and multiple risk score calculators are available like FRS and Q risk 2. Smoking is an important risk factor included in almost all the risk scores calculators but the impact of smokeless tobacco in risk stratification is unknown.

What does this study add?

This study points towards impact of epidemiological variability of various risk factors in risk score calculation and suggests addition of smokeless tobacco in risk stratification of Indian population.

How might this impact the clinical practice?

Owing to a significant prevalence of smokeless tobacco in the Indian population, its absence in Q Risk 2 score is likely to underestimate the CV risk in this population. Addition of smokeless tobacco in Q Risk 2 score helps in better prediction of cardiovascular risk in Indian population hence more patients can benefit from primary prevention strategy.

Declaration of competing interest

None.

Acknowledgement

None.

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