Original Article

QRISK 3® and ASCVD Risk Calculator in Patients with Diabetes and Their Correlation with Coronary Artery Calcium Scores

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Abstract

Introduction: Diabetes mellitus is an independent risk factor for asymptomatic cardiovascular disease (CVD). The QRISK 3® score and atherosclerotic cardiovascular disease (ASCVD) risk scores determine the risk of developing CVD over 10 years. The CT coronary artery calcium score (CACS) is a non-invasive imaging modality that identifies sub-clinical atherosclerosis. We studied the correlation between the QRISK 3® and ASCVD scores and the CACS and determined the cut-off for QRISK 3® and ASCVD scores that corresponded to a moderate or accentuated CACS (≥100). **Methods:** In this prospective study, outpatients with diabetes and no prior coronary artery disease (CAD) or their equivalents, or having symptoms suggestive of angina or heart failure, had their QRISK 3® and ASCVD scores calculated. They subsequently underwent 256 slice cardiac CT, and CACS was calculated by the Agatston method. **Results:** A statistically significant correlation (r = 0.28) was found between QRISK 3® and ASCVD with CACS ($P = 0.004$ and $P = 0.007$, respectively). A QRISK® score >23 and ASCVD score >10 predicted a CACS score >100 with sensitivities of 85% and 90%, respectively. **Conclusion:** The QRISK 3® and ASCVD scores can be used to triage patients who require further evaluation with CACS to determine the risk of future CVD.

Keywords: ASCVD, coronary artery calcium score, diabetes, QRISK 3®

Introduction

Asymptomatic coronary artery disease (CAD) is seen in 26% of diabetes patients, and the risk of adverse cardiac events is increased three-and-a-half-fold in them.[1] The identification of these individuals is fundamental for the implementation of targeted screening and preventive strategies. The QRISK 3® algorithm determines the risk of developing a coronary event or stroke over the next 10 years.[2] Several studies have attempted to compare various risk scores for future CVD risk estimation. A prospective study conducted by Xiaodie Mu *et al*.[3] discovered that QRISK 3® had a high sensitivity of 91.3% on a 10% cut-off dichotomy, but a higher specificity of 90.7% on a 20% cut-off dichotomy for assessing CVD risk in individuals with type 2 diabetes mellitus. They compared the ability of the QRISK 3® and the Framingham risk score (FRS) to identify the risk of development of CVD related to T2DM. In the low-risk and high-risk categories for development of ASCVD, the QRISK 3® score exhibits higher consistency.[3] CT coronary artery calcium score (CACS) is a non-invasive modality that identifies sub-clinical atherosclerosis.[4]

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The atherosclerotic cardiovascular disease (ASCVD) risk score estimates the absolute risk of development of ASCVD in a patient over the next 10 years. The Agatston method for CAC scoring is the sum of the attenuation and area of all calcified lesions in the coronary arteries. A study conducted by Michael J. Blaha *et al*.[5] revealed that the best risk assessment across all scores was observed for the ASCVD risk score by pooled cohort equation (PCE) plus CAC, with overall C-statistics of 0.82 for CHD death (95% confidence interval [95% CI]: 0.80–0.84) and 0.80 (95% CI: 0.79–0.82) for CVD death. Amani A Alsulami *et al*.[6] compared the prognostic value of CACS, ASCVD risk estimator, cardiovascular risk score (QRISK2), and triglyceride glucose index (TyG). They discovered that the integration of

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various scores in the estimation of cardiovascular-associated fatal and non-fatal events among primary care patients is highly effective. In our study, we try to establish a correlation between the QRISK 3®, ASCVD scores and the CACS and determine the cut-off for QRISK 3® and ASCVD scores that correspond to a moderate or accentuated CACS (≥100).

Materials and Methods

This was a hospital-based prospective cohort study including patients with type 2 diabetes mellitus presenting to the outpatient department of Endocrinology. Individuals with prior stroke, peripheral arterial disease, abdominal aortic aneurysm, CAD, or current symptoms of CAD were excluded from the study. The QRISK 3® and ASCVD scores were calculated for all the participants, following which they underwent a 256-slice cardiac CT (calcium score screening protocol) without intravenous contrast. CACS was calculated using the Agatston method. Further treatment was continued as per standard treatment protocols. Patients with CACS >100 or those with large discrete calcification in LAD were referred to cardiology for further evaluation.

The QRISK 3® was calculated based on the following parameters:

1. Age
2. Ethnicity
3. Weight
4. Height
5. BMI
6. Blood pressure (systolic and diastolic)
7. Smoking status
8. Diabetes
9. Hypertension on treatment
10. Family history in first-degree relative < 60 years of age
11. Cholesterol/HDL ratio
12. Other co-morbidities: atrial fibrillation, migraine, rheumatoid arthritis, SLE, CKD, severe mental illness, atypical anti-psychotics use, erectile dysfunction, steroids intake

The ASCVD risk score was calculated based on the following parameters:

1. Age
2. Sex
3. Diabetes
4. Smoking status
5. Systolic blood pressure
6. HDL cholesterol
7. Total cholesterol

The CACS was calculated as per the Agatston method:

Absent or 0 score is suggestive of a very low risk of future coronary events. A score of 1–100 means the patient has a low risk of future coronary events and a low probability of myocardial ischaemia. CACS of 101–400 is suggestive of an increased risk of future coronary events (aggravating factor), and >400 suggests an increased probability of myocardial ischaemia.

Sample size calculation and statistics

Based on a recent (2020) study by Samit Ghosal *et al.*,[7] the risk of asymptomatic CVD in Indians with diabetes is 28%. With a precision of 10% and 95% confidence interval, the minimum required sample size was 79. We enrolled 100 subjects in this study. Statistical analysis was done using Statistical Package for Social Sciences (SPSS) version 21.0. and © 2020 EasyMedStat.

Ethical aspects

The institutional ethics committee approved the study (NHH/AEC-CL-2021-715 Approval date: 11th August 2021). Written and informed consent was obtained from the participants in the study for use of patient data for research and educational purposes. The study protocol and procedures followed the guidelines laid down by the Indian Council of Medical Research and the Declaration of Helsinki (1964).

Results

A total of 100 patients with diabetes were enrolled in the study. The baseline characteristics of the cohort are mentioned in Table 1. The mean (SD) age of the study population was 55 (10) years (range: 26–76) with 59% males. Out of the 100 subjects, 38% had a CACS of 0, 37% were in the discrete category, the moderate category included 11% of the subjects, and 14% were classified as accentuated category. An increasing trend of mean QRISK3 and ASCVD scores was observed as the CACS score increased in severity. A sizeable portion (36%) of those who had smoked in the past (ex-smokers) had an accentuated

Table 1: Baseline characteristics of the cohort of patients with type 2 DM

Characteristics	No. of individuals
Age (Mean)	55±9.95 years
Sex	
Male	59
Female	41
BMI	27.62 (4.56)
Non-smoker	67%
Light smoker (less than 10 cig per day)	14%
Moderate smoker (10–19 cig per day)	8%
Ex-smoker	11%
Mean (SD) duration of DM (years)	9.25 (6.16)
Mean (SD) HbA1c (%)	8.1 (1.82)
Receiving insulin	40%
Mean (range) dose of insulin (units)	13.45 (10–90)
Mean (SD) BP (mmHg)	
SBP	138 (18.19)
DBP	83 (12.38)
Receiving anti-hypertensive medication	68%
CKD stages1	
1	53%
2	36%
3a	10%
3b	1%

CACS. Amongst the light smokers, 35.7% had accentuated CACS, with a majority (42.8%) having a discrete CACS. Even amongst the moderate smokers, a majority (75%) had discrete CACS. Among the non-smokers, the maximum proportion of subjects (50.7%) had a CACS of 0. The comparison between the duration of diabetes and CACS showed that the mean value of duration in the accentuated category (13.36 years) was the highest, followed by the moderate category (12.45 years), then the discrete category (8.34 years), and the least in the absent category (7.69 years). The subjects in the accentuated group required the highest dose of insulin, with a mean dose of 29.86. Amongst the 14 CKD subjects with accentuated CACS, 21.4% had CKD 3, 35.7% had stage 2, and 42.9% had stage 1 according to eGFR criteria.

The mean (SD) QRISK 3® and ASCVD scores were 25.5 (14.4) and 18.2 (14.2), respectively.

Correlation between QRISK 3® and CACS

Those with CACS 0 accounted for 38% of the study population. The mean (SD) QRISK 3 score was 17.12 (11.65) in those with CACS of 0, it was 28.99 (14.92) in the group with CACS of 1–100, 32.73 (10.47) amongst those with CACS 101–400, and those with >400 showed a mean QRISK 3® of 33.51 (11.59). We observed a linear trend of mean QRISK 3® score with increasing CACS, and a positive correlation was noted (r = 0.28) with *P* value = 0.004 [Figure 1].

Correlation between ASCVD score and CACS

The mean (SD) ASCVD score was 10.10 (7.53) in the group of patients with CACS 0, it was 22.01 (16.98) in the group with CACS 1–100, 20.23 (11.65) amongst those with CACS 101–400, and those with CACS >400 showed mean ASCVD as 26.80 (12.69). Hence, as with the QRISK 3® score, an increasing trend of mean ASCVD score was observed as the CACS increased in severity. We observed a linear trend of mean ASCVD score with increasing CACS, and a positive correlation was noted (r = 0.28) with *P* value = 0.007 [Figure 1].

Cut-off for the QRISK 3® score corresponding to CACS ≥ 100

Based on the ROC curve and the Youden index [Table 2], a QRISK 3® score >23 corresponded to a CACS of ≥100. The area under the curve (AUC) of the ROC was 0.738 (95% CI: 0.637–0.839). This suggested that the probability of QRISK 3® score to predict a CACS ≥100 is 74% [Figure 2] with a sensitivity of 84% and specificity of 60% [Table 2].

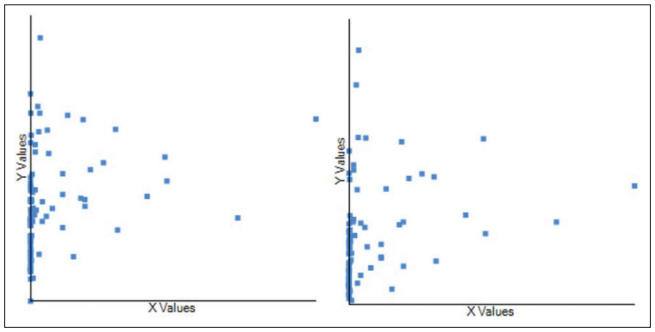

Figure 1: Pearson's correlation coefficient for QRISK 3® and CACS, and for ASCVD and CACS

Cut-off for the ASCVD score corresponding to CACS ≥ 100

Based on the ROC curve and the Youden index [Table 3], ASCVD scores >10 corresponded to a CACS of ≥100. The AUC of the ROC was 0.714 (95% CI: 0.599–0.829), implying that the probability of the ASCVD score to predict a CACS of ≥100 is 71% [Figure 2] with a sensitivity of 91.3% and specificity of 47.6% [Table 3].

Discussion

This was a cross-sectional study of 100 persons with diabetes without prior CAD. Our study revealed a statistically significant but small positive correlation of the QRISK3® and ASCVD risk scores with the CACS. Furthermore, we discovered that the QRISK 3® and ASCVD scores are sensitive screening methods to identify individuals with moderate and accentuated CACS and thus require further testing and intensification of management.

Siddiqi Z *et al.*[8] discovered a high prevalence of risk of developing CAD in the study population with diabetes and asymptomatic CAD, as assessed by the CACS. The American College of Cardiology Foundation/American Heart Association (ACCF/AHA) consensus included 27,622 patients asymptomatic for CVD from various studies.[9] They calculated the relative risks of major cardiovascular events correlating to the CACS. This suggested that increasing CACS corresponds to increasing relative risk of developing a major cardiovascular event. In individuals with CACS >100, the mortality rate was significantly increased irrespective of age and other risk factors.[10] A study conducted by Shrivastava *et al.*[11] found that in individuals with intermediate-to-high risk, CACS was useful for identifying significant CAD. CAC >100 warrants discussion of aspirin therapy and intensive BP goals.[12-14] Studies suggest that an initial CAC scan of >100 is an indication to initiate statins and other relevant preventive medications early on—without the need for repeat CAC scanning later. A baseline rather than a follow-up CAC score would inform such allocation, and this would happen in mostly statin-naïve populations.[14-16] According to the American guidelines for primary prevention, in individuals with an intermediate CVD risk, CACS ≥100 reclassifies them in a higher risk category; therefore, statin therapy should be initiated.[17] Hence, a CACS of >100 warrants for administering the QRISK 3® and ASCVD score to identify individuals pertaining to this group for further CT CACS imaging.

The four studies by Sarwar *et al.*, Blaha *et al.* (retrospective cohort), MESA (prospective cohort), and Heinz Nixdorf Recall (prospective cohort)[18] discovered that the mortality rate amongst patients with CAC = 0 was very low.[18-21] There is emerging data that determining the CACS is superior to any other tests, such as serum biomarkers. The QRISK 3® score included 1,59,488 individuals of Indian origin in the derivation

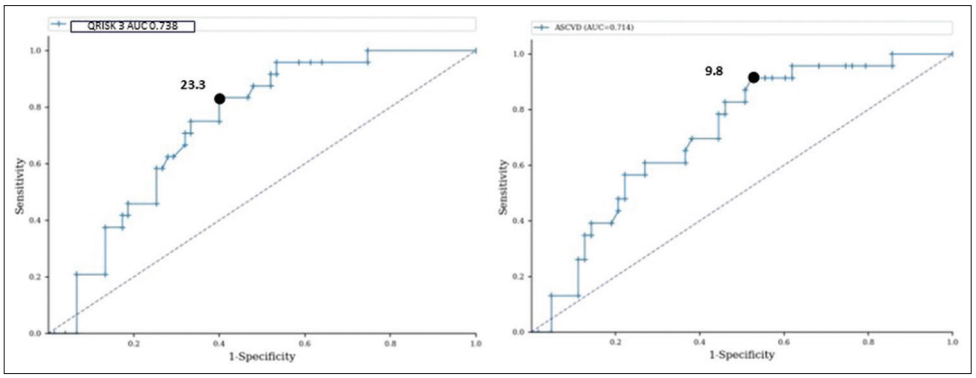

Figure 2: ROC curve for QRISK 3® and for ASCVD score

Table 2: Sensitivity, specificity, and Youden index of QRISK 3® score

QRISK 3®	True-positive	True-negative	False-positive	False-negative	Sensitivity	Specificity	Youden	PPV	NPV
>23.2	21	45	30	4	84%	60.0%	0.433	41.2%	91.8%

Table 3: Sensitivity, specificity, and Youden index of ASCVD score

ASCVD	True-positive	True-negative	False-positive	False-negative	Sensitivity	Specificity	Youden	PPV	NPV
>9.8	22	30	33	2	91.3%	47.60%	0.389	38.9%	93.8%

cohort.[3] Hence, it is appropriate for the Indian population, considering Indians are at higher risk of CVD. When the QRISK 3® score was overlaid with the CACS of the subjects in our study, an increasing trend of mean QRISK 3® score was observed as the CACS score increased in severity, and a statistically significant association was found between the increasing QRISK 3® score and CAC score. A study conducted by Hippisley Cox *et al.*[2] considered age and co-morbid conditions such as CKD as risk factors for developing QRISK 3® score for the estimation of 10-year risk of cardiovascular disease. Samit Ghosal *et al.*[7] studied the 10-year CVD risk in individuals with diabetes and asymptomatic CVD by means of the QRISK 3® score. They defined a QRISK 3® score of ≥20 as a high risk for CV events in 10 years. They found the mean QRISK 3® score to be 28.4 in their study population. This finding was similar to our study, which showed a mean QRISK 3® score of 25.5 (SD 14.4) with an increasing trend of QRISK3 score. The QRISK 3® score of ≥23 corresponds to a CACS of ≥100.

The AHA and the ACC developed the ASCVD risk score, which estimates the absolute 10-year risk and the lifetime risk for developing ASCVD.[22] The morbidity and mortality associated with a first ASCVD event are much higher in persons with diabetes in the age group of 40–75 years compared with those without diabetes.[23] A study conducted by Nora Alalem *et al.*[24] concluded that the estimation of the CVD risk by QRISK 2 score in all individuals provides for a cost-effective approach for their management. This resonated with our study, which discovered that the QRISK 3® (sensitivity = 84%) and ASCVD scores (sensitivity = 91.3%) are sensitive screening tools to identify those requiring CACS.

According to the 2013 ACC/AHA Prevention Guidelines, patients with CAC >300 or above the 75th percentile for age/gender/race are candidates for high-intensity statin therapy.[25] The CACS is not just a predictor of risk of CVD but also a useful tool to determine the initiation of therapy.

The population under study had a mean age of 55 years. Out of the 100, 41% were females and 59% were males. When the subjects in our study underwent CT coronary calcium screening, we found 38% were in the absent category, 37% in the discrete category, 11% in the moderate category, and 14% in the accentuated category for CACS. This wide variation reflects the varied risk factors of the subjects included in the study, including age, gender, etc., An interesting finding in our study was that the CACS and the risk scores increased in severity as the mean age of the subjects increased, and this association was statistically significant. Atherosclerosis increases as age increases; therefore, the coronary artery calcium, being a marker of atherosclerotic burden, also increases with age.[26] This has also been elucidated by various other studies.[4,27]

Another finding was that out of the 14 subjects with accentuated CACS, 21.4% were females while 78.6% were males, and even though this was statistically insignificant, it reiterates the protective effect of oestrogen.[28]

Yet another significant risk factor found in our study was the duration of diabetes mellitus. The comparison between the duration of diabetes and CACS showed that subjects in the accentuated category had the longest duration of diabetes mellitus, followed by the moderate category, then the discrete category, and the least in the absent category. This clearly demonstrated that the longer the duration of diabetes, the

higher the CAC score. Another study from India had similar findings with the duration of diabetes and smoking leading to a significantly increased CAD risk by having greater severity of coronary calcification.[10] These findings have been replicated in various international studies as well, including the PROCEED study.[14,29]

In our study, the other statistically significant correlation was between CACS and chronic kidney disease stage. We found that amongst those patients in the absent, discrete, or moderate groups, no subjects had CKD stage 3b or above according to the eGFR category, while there was one patient in the accentuated group who had stage 3b of CKD. This was also the case with proteinuria, and when it was compared to CACS, it was found that the number of patients excreting >300 mg/day of albumin increased as we went from the absent towards the accentuated group. An increasing trend of the risk scores was observed as the proteinuria and CKD stage increased. Even though these two results were statistically significant, it could have been because of the small number of subjects being studied or the skewed distribution of the subjects across various categories. Nonetheless, the importance of pathological calcification of soft tissue in chronic kidney disease has been established. In a seminal paper, Braun *et al.*[30] documented an extremely high CACS in long-term haemodialysis patients. Thereafter, many studies showed that there was advanced coronary and other cardiovascular calcification in patients with chronic kidney disease (CKD) in the pre-dialysis period, on haemodialysis, peritoneal dialysis, and following kidney transplantation.[20] However, the CACS was developed and validated in the general population without CKD, and data regarding its validity and the significance of CACS levels in the CKD population are scarce; moreover, some studies have found imprecisions of the CACS in CKD.

Hence, we conclude that for all patients with diabetes, the QRISK 3® and/or ASCVD risk score be calculated and the individuals with a score above the cut-off value of 23 or 10, respectively, be referred for a CT CACS scan. Calculating QRISK 3® and ASCVD scores in outpatients with diabetes facilitates the identification of asymptomatic individuals with potential future risk of cardiovascular diseases.

Conclusion

There is a linear, significant, albeit small correlation between the QRISK 3® and ASCVD scores and CACS. To the best of our knowledge, this is the first study to be conducted, where a cut-off value of predictive scores that reflect severity in CACS is determined. The strengths of our study are that it includes a heterogenous study population in a tertiary care centre in South India; thus, the results can be generalised over a vast population. Our study has limitations, including the lack of lipid-lowering medicines and anti-platelet use in the patient cohort. The CACS score was not followed up with a definitive study to diagnose flow-limiting CAD. A long-term follow-up of this cohort is also required to validate our findings. The study needs to be reproduced at a larger scale in multiple centres in the future. Hence, it is concluded that CT CACS scan is recommended for individuals with diabetes for triaging those requiring further management of moderate or severe CACS.

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Authors' contribution

Dr. SK and Dr. MM conceptualized the project and reviewed the manuscript, Dr. SM and SK were involved in data collection and analysis and Dr. SM presented this as part of her DNB thesis.

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Nil.

Conflicts of interest

There are no conflicts of interest.

Data availability

The data that support the findings of this study are available from the corresponding author [SSC] and first author [SK], upon reasonable request.

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