A Cross-Sectional Study to Evaluate Cardiovascular Risk Score in Type 2 Diabetes Mellitus

Abstract

**Background:** Cardiovascular disease is the leading cause of mortality worldwide, including in low- and middle-income countries. Cardiovascular risk assessment is essential to prevent the mortality caused by diabetes. **Aim:** The current study was conducted to assess the prevalence of cardiovascular risk factors in type 2 diabetes and to compare the United Kingdom Prospective Diabetes Study (UKPDS) and World Health Organization (WHO)/International Society of Hypertension (ISH) chart in assessing cardiovascular risk score. **Materials and Methods:** Cardiac risk assessments were done in fifty patients attending the medicine outpatient department in an institutional hospital after ethical clearance and taking informed consent from patients. Two assessment tools were applied on the same patient. **Results:** Overall, 10% of people were obese (body mass index >30). Smoking was prevalent in 20% (10/50) of patients. Hypertension was observed in 60% (30/50) of patients. Raised total cholesterol (TC) was the most common lipid abnormality affecting 94% of patients. The WHO/ISH prediction charts identified 14% and 10% of patients with cardiovascular risk category <10 and 10–20, whereas the UKPDS engine predicted 24% and 38% in the same category. In high-risk categories 30–40 and >40, the WHO/ISH score predicted a higher proportion of patients (18% and 32%) than the UKPDS engine (8% and 4%, respectively). Kappa value was calculated to calculate the degree of agreement between two tools, and it was found to be 0.781 (P < 0.01). **Conclusion:** Raised TC and hypertension were the most prevalent risk factors. There was no significant discrepancy between two assessment tools in predicting cardiovascular risk score among type 2 diabetes mellitus patients in our study.

**Keywords:** Cardiovascular risk score, International Society of Hypertension, type 2 diabetes mellitus, United Kingdom Prospective Diabetes Study

Introduction

Cardiovascular disease (CVD) is the leading cause of mortality worldwide, including in low- and middle-income countries. India contributed one-fifth (18.6%) of the global CVD burden as measured by disability-adjusted life years in 2016. It is well known that diabetes is associated with increased cardiovascular morbidity and mortality. Primary preventive measures are effective in reducing cardiovascular events in type 2 diabetes mellitus (T2DM), especially lipid-lowering therapy with statin, lowering blood pressure with antihypertensives, and antiplatelet therapy with aspirin. These measures are indicated depending on cardiac risk of the patient.

There are several cardiac assessment tools to assess the cardiac risk such as Framingham Risk Score, United Kingdom Prospective Diabetes Study (UKPDS) risk engine and World Health Organization/International Society of Hypertension (WHO/ISH) charts, QRisk, Reynolds, and InterHeat. Unlike other tools, the UKPDS risk engine is diabetes-specific and it incorporates glycemia, systolic blood pressure (SBP), and lipid levels as risk factors, in addition to age, sex, ethnic group, smoking status, and time since diagnosis of diabetes. The WHO/ISH chart was developed on the epidemiologic findings of the South Asian region and includes five parameters that can be measurable at low-resource and primary care setting and include sex, age, SBP, smoking status, and serum total cholesterol (TC). Using the WHO/ISH charts, an individual’s risk of developing a vascular event during the next 10 years is predicted as a probability. However, the major modifiable CVD risk factors in diabetes such as low-density
lipoprotein (LDL) cholesterol and diastolic blood pressure for which therapeutic interventions have shown proven benefits have not been included in the WHO/ISH charts in order to reduce the cost of its application in the resource-poor setting.[7]

This study was designed to estimate the prevalence of CVD risk factors in T2DM patients and to compare the CVD risk estimated between the UKPDS risk engine and the WHO/ISH chart.

Materials and Methods

A cross-sectional observational study was conducted in T2DM patients (n = 50) attending the medicine outpatient department in our hospital after obtaining ethical approval. Written informed consent was obtained from all the study participants. Inclusion criteria were as follows: age >40 years, sex – both male and female, patients with fasting blood sugar >110 mg/dl and glycosylated hemoglobin (Hb1Ac) >8%, and diabetes duration >1 year. Children, pregnant women, seriously and acutely ill patients, patients unwilling to give written informed consent, and patients with prior history of CVD such as myocardial infarction, stroke, and coronary artery disease were excluded.

In all study patients (n = 50), pro forma was filled to obtain demographic and medical information such as age, sex, rural/urban, history of smoking, height, weight, blood pressure, and diabetes duration. The UKPDS risk engine and WHO/ISH risk prediction charts (South-East Asian Region [SEAR] D) were used to assess the prevalence of CVD risk among patients with T2DM over 10 years. Each patient’s 10-year CVD risk was classified by both risk assessment tools into one of the five risk levels: <10%, 10%–20%, 20%–30%, 30%–40%, and >40%.

All the data obtained were analyzed using SPSS software version 19 (by IBM, New York, USA). Baseline characteristics and prevalence of cardiovascular risk factors were calculated using descriptive statistics (means and frequencies). Assessment of cardiovascular risk tools was done using the Chi-square test [Figures 1 and 2].

Results

There were fifty patients with T2DM. Out of which, 42% were males (n = 21) and the mean age of males was 60.33 (standard deviation = 8.7) and 58% were females (n = 29) and the mean age of females was 57.62 (standard deviation = 9.7). The mean body mass index (BMI) was 25.26 ± 3.65, hemoglobin was 10.90 ± 1.32 g, and Hb1Ac was 8.34% ± 0.66% [Table 1].

Prevalence of cardiovascular disease risk factors

Raised TC was the most common lipid abnormality affecting 94% (47/50) of patients. Overall, 10% (5/50) of people were obese (BMI >30), of which the prevalence of obesity in females was 80% in comparison to 20% in males. Smoking was prevalent in 20% (10/50) of patients. Hypertension was observed in 60% (30/50) of patients, whereas the prevalence of low HDL cholesterol and hypertriglyceridemia was 8% (4/50), respectively.

Cardiovascular disease risk categories by two assessment tools

The WHO/ISH prediction charts identified 14% and 10% of patients with cardiovascular risk category <10 and 10–20 which was lower when compared to 24% and 38% as predicted by the UKPDS engine, respectively, in both categories. A similar proportion of the sample (26% by the WHO/ISH and UKPDS) was categorized in 20–30 category. In high-risk categories 30–40 and >40, the WHO/ISH score predicted a higher proportion of patients (18% and 32%) than the UKPDS engine (8% and 4%, respectively).

A comparison of the WHO/ISH and UKPDS risk charts in their ability to categorize patients with T2DM into different risk categories. Both tools recognized 8% (4/50) and 6% (3/50) of the sample as having low cardiac risk <10 and 10–20 categories, respectively. The UKPDS engine recognized 6% in 10–20 and 20–30 categories, whereas the WHO/ISH tool recognized them in <10 category. Similarly, the WHO/ISH risk chart recognized 26% (13/50) of the sample in 20–30 category and the UKPDS recognized the same 4% (2/50) of the sample in <10 category, 16% (8/50) in 10–20 category, 4% (2/50) in 20–30 category, and 2% (1/50) in 30–40 category [Table 2].
Kappa value was calculated to calculate the degree of agreement between two tools, and it was found to be 0.781 ($P < 0.01$). These findings reveal no significant difference between two tools [Table 3].

**Discussion**

This study evaluated the prevalence of cardiovascular risk factors and compared the two cardiovascular risk calculators – UKPDS (risk engine) and WHO/ISH. The UKPDS engine is used for diabetes worldwide and the WHO/ISH risk prediction chart for the South East region (SEAR D) specific for India is used. This is the first study in the northern region of India to compare the assessment tools.

A study in Sri Lanka compared these two assessment tools and found that there was a significant discrepancy between two tools. The WHO/ISH risk chart classified a higher proportion (78.4%) of patients into low cardiac risk category (<10%) than the UKPDS risk engine (52.3%). However, at high-risk threshold of ≥30%, both methods were comparable and identified a similar proportion of patients (1.9% vs. 2.1%). This study revealed that the prevalence of raised cholesterol was the most common cardiovascular risk factor, followed by hypertension, obesity, and smoking. The WHO/ISH prediction chart identified a low proportion of patients in lower category risk patients, whereas the UKPDS predicted a higher proportion in the same category. In high-risk categories, the WHO/ISH predicted a higher proportion of patients than the UKPDS. These findings show that the WHO/ISH prediction chart identified a higher proportion as the risk increased and the UKPDS engine predicted a lower proportion as the risk increased. This trend might be due to the UKPDS engine’s poor ability to recognize high-risk patients and hence labeling them as a low cardiac risk.

There was no significant statistical difference found between two assessment tools in predicting cardiovascular risk. One previous study had shown that the UKPDS risk chart recognized a higher percentage of patients of Indian origin as high risk than the other ethnic groups. The UKPDS engine had an advantage of predicting fatal cardiovascular risk, stroke risk, and fatal stroke risk and takes into account glycemia, age, ethnicity, duration of diabetes, and smoking status, and the WHO/ISH prediction chart used has been designed for SEAR and takes into account of TC.

There were a number of limitations with this study. The sample size was small. The study did not take into account LDL cholesterol or the use of statin therapy which could have helped further in assessing the validity of tool. Furthermore, this study was conducted in one institution of northern India. The multicentric study would have shown up results on ethnic basis too.

This study revealed that any of the tools can be used for assessing the cardiovascular risk score in diabetes patients in Indian population as there was no significant difference found between two tools. Both tools are cost-effective as they are available free online. The assessment of cardiovascular risk score by any of the tools can be used by clinicians to educate the patient about their cardiovascular risk and it will help the physician too, to adjust the dose of drugs accordingly.

**Conclusion**

Raised TC and hypertension were the most prevalent risk factors. Obesity and smoking were the least prevalent risk factors. There was no significant discrepancy between two assessment tools in predicting cardiovascular risk. 

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**Table 3: Measurement of kappa value to calculate the degree of agreement**

| Value                         | Asymptom SE\textsuperscript{a} | Approximate $T^b$ | Approximate significant |
|-------------------------------|---------------------------------|-------------------|-------------------------|
| Measurement of kappa value    | 0.016                           | 0.062             | 0.278                   | 0.781                  |
| Number of valid cases         | 50                              |                   |                         |                       |

\textsuperscript{a}Represents the asymptotic standard error; \textsuperscript{b}Using the asymptotic standard error assuming the null hypothesis. SE: Standard deviation
score among T2DM patients in our study. The WHO/ISH prediction chart identified a low proportion of patients in lower category risk patients, whereas the UKPDS predicted a low proportion of patients in high risk.

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Conflicts of interest
There are no conflicts of interest.

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