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Original Article

Physiology Section

Assessment of QRISK3 Score in Normoglycaemic, Prediabetic and Diabetic Subjects: An Observational Study

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ABSTRACT

Introduction: Cardiovascular Disease (CVD) and diabetes mellitus have a high correlation. Compared to individuals without diabetes, adults with diabetes have a greater prevalence rate of CVDs. This risk steadily increases along with Fasting Blood Glucose (FBG) levels, even before they are high enough to be classified as diabetes. One of the factors contributing to death among people with diabetes mellitus is CVD. QRISK3 algorithm calculates a person's risk of developing a heart attack or stroke over the next 10 years.

Aim: To assess the QRISK3 cardiovascular risk score in normoglycaemic, prediabetic and diabetic subjects.

Materials and Methods: The present analytical observational study was carried out in the Department of Physiology and Medicine, RUHS College of Medical Sciences and associated Hospital, Jaipur, India, from November 2021 to April 2022. A total of 200 subjects were recruited with >20% QRISK3 CVD risk scores out of 7154 screened patients. Subjects were categorised into three groups (normoglycaemic, prediabetics and diabetics) according to American Diabetes Association criteria. The following parameters were recorded for data collection: anthropometric {Body Mass Index (BMI) Waist Hip Ratio (WHR)}, blood pressure and biochemical {Fasting Blood Glucose (FBG), Glycated Haemoglobin (HbA1c) and lipid profile parameters). All data collected was entered into Microsoft excel sheet 2019 and was analysed with help of Statistical Package for the Social Sciences (SPSS) software version 21.0 and tests of significance considering level of significance as p-value <0.05. Data was analysed by applying Analysis of Variance (ANOVA).

Results: Out of the total 200 high-risk subjects, according to the American Diabetes Association (ADA) for Diabetes Classification, there were 44 (26.19%) normoglycaemic, 21 (12.5%) prediabetic and 103 (61.31%) diabetic subjects and 32 were excluded. The mean age was 49.06±9.65 years, 51.15±11.05 years and 51.02±9.74 years for normoglycaemic, prediabetic and diabetic subjects, respectively. There was significant difference of mean values of FBG, HbA1c, total cholesterol, High Density Lipoprotein (HDL), Cholesterol (Chl)/ HDL ratio, Low Density Lipoprotein (LDL), Triglycerides (TG) and QRISK3 score in three groups. But there was no significant difference in following parameters i.e., age, weight, height, Body Mass Index (BMI), waist-hip circumference, WHR, Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP). There was hypertriglyceridaemia and low HDL level in prediabetic and diabetic subjects.

Conclusion: The present study showed that the cluster of risk factors for CVD also grows as FBG levels and HbA1c levels increase. This study could also assert that these risk factors also increases with progression of diabetes, which eventually results in increase in risk of CVDs.

Keywords: Cardiovascular disease, Fasting blood glucose, Triglycerides

INTRODUCTION

The non communicable diseases which are thought to be responsible for over 60% of all fatalities, frequently include CVD, different malignancies, chronic respiratory disorders, diabetes, and so on. As per World Health Organisation (WHO), there are 17.7 million deaths worldwide from CVDs, which are the main cause and include cerebrovascular diseases like stroke and ischaemic heart disease [1]. The World Health Organisation says that one-fifth of these fatalities occur in India [2]. It is thought that the traditional risk factors, such as hypertension, diabetes mellitus, dyslipidaemia, smoking, and obesity, contribute to the higher prevalence of Coronary Artery Disease (CAD) among Indians [3]. The first and most important step in treating individuals who need primary CVD prevention is estimating the risk of future cardiovascular events. QRISK3 is a web-based algorithm to estimate the 10-year CVD risk. The performance of QRISK3 has been validated on a different set of population, and the results were excellent. High-risk CVD is defined as QRISK3 10-year CVD risk score more than 20% [4]. The interconnected metabolic and inflammatory pathways are implicated in epigenetic, genetic, and cell signalling abnormalities that contribute to the development of CVD in hyperglycaemia. Multiple environmental variables, including a high calorie intake, smoking, glycation end products, glucose toxicity, and some drugs can cause these metabolic abnormalities, which are particularly prevalent in the endothelium, liver, skeletal muscle, and cells [5]. Furthermore, the study conducted by Tabak AG, et al., showed that the weight gain, insulin resistance, and beta-cell dysfunction occurred along with the progression from prediabetes towards Type 2 Diabetes Mellitus (T2DM) [6].

If blood glucose levels are extremely high in addition to the classic symptoms of high blood sugar, a second test to identify diabetes is not necessary, according to American Diabetes Association (ADA) categorisation criteria [7]. Prediabetes, if HbA1c is between 5.7-6.4% and diabetes, if HbA1c is greater than or equal to 6.5% [7]. Fasting plasma glucose test diagnose prediabetes, if value between 100 mg/dL to 125 mg/dL and diabetes if FBG higher than 126 mg/dL [7].

As per our knowledge very few or no study has been conducted in India to estimate the CVD risk score using QRISK3 web calculator. CVD and diabetes mellitus have a high correlation [8]. Compared to individuals without diabetes, adults with diabetes have a greater

prevalence rate of CVD. This risk steadily increases along with FBG levels, even before they are high enough to be classified as diabetes [6]. One of the factors contributing to death among people with diabetes mellitus is CVD [8]. In contrast to past research conducted by Charan Reddy KV et al., which only determined the prevalence of FBG and its relationship with cardiovascular risk disease, whereas the current study was aimed to assess, the QRISK3 cardiovascular risk score in normoglycaemic, prediabetic and diabetic subjects [8].

MATERIALS AND METHODS

The present analytical observational study was conducted in the Department of Physiology and Medicine, RUHS College of Medical Sciences and affiliated Hospital, Jaipur, India, November 2021 to April 2022. Study was carried out after receiving the Institutional Ethics Committee (Letter No. RUHS-CMS/Ethics Comm./2021/70 dated 29/09/2021).

Sample size calculation: Sample size was calculated as 200, at 95% Confidence Interval (CI) and 5% Type I error and 80% Power [9], using mean and standard deviation formula. Random sampling was done to choose the study population.

Inclusion criteria: Subjects of age range 40-70 years, QRISK3 score ≥20% [4] were included in the study.

Exclusion criteria: Subjects with previously diagnosed coronary artery disease criteria were excluded from the study.

Study Procedure

Out of the 7154 screened patients who came to the Outpatient Department (OPD), 200 participants with >20% QRISK3 10-year CVD risk scores were recruited [4]. Thirty-two were excluded because they did not meet the American Diabetes Association criteria for prediabetes and diabetes. Because in these 32 participants neither FBG or HbA1c test result were in prediabetic or diabetic range and not together, neither were they falling in the normoglycaemic range. Written informed consent form were obtained. All the participants underwent medical history and complete physical examination. The following parameters were recorded for data collection: anthropometric (Weight, Height, BMI, Waist-Hip circumference, WHR) [10], Blood pressure [11], biochemical (FBG, HbA1c, Lipid profile parameters) [12,13].

Weight was measured while standing, wearing the barest amount of clothes, with a precision of 0.1 kg. Using a common stadiometer, the subject's height was calculated to the closest of 0.1 m, obtained after the individual take off their shoes. BMI was computed by multiplying weight in kg by height in metre squared, with overweight being defined as BMI ≥23 kg/m^2 and obesity as a BMI ≥25 kg/m^2, according to WHO criteria for the Asia-Pacific region [14]. Waist circumference was measured on bare skin using an in elastic measuring tape to the nearest 0.1 cm. Hip circumference measured using a measuring tape, to the closest of 0.1 cm. WHR ≥0.9 cm in males and ≥0.8 cm in females was considered truncal obesity. According to Joint National Committee (JNC) criteria blood pressure ≥140/90 mmHg or the presence of a known hypertensive led to the diagnosis of hypertension [15].

All participants' venous blood was drawn, and FBG, HbA1c, and cholesterol profiles were all investigated. Serum total cholesterol by Cholesterol Oxidase Peroxidase (CHOD-POD) enzymatic colorimetric assay, serum HDL-cholesterol by accelerator selective detergent method, Serum LDL-Cholesterol and Very Low Density Lipoprotein (VLDL)-cholesterol calculated using the formula of FriedWald and Levy Serum Triglyceride by glycerol phosphate oxidase GPO-PAP enzymatic colorimetric assay. Commercially available kit in automated analyser was used for investigating FBG.

Three categories were made according to the ADA criteria for diabetes based on FBG levels and HbA1c levels i.e., Normoglycaemic was defined as FBG less than 100 mg/dL and HbA1c less than 5.7% (Group-1), Prediabetic if FBG between 100 mg/dL and 125 mg/dL and HbA1c between 5.7%-6.4% (Group-2) and diabetic when fasting glucose was ≥126 mg/dL and HbA1c ≥ 6.5% (Group-3) [7].

STATISTICAL ANALYSIS

All data collected were entered into Microsoft excel sheet 2019 and analysed with help of SPSS software version 21.0 and ANOVA as test of significance considering level of significance as p-value <0.05. All values were expressed as the mean±Standard Deviation (SD).

RESULTS

A total of 200 subjects were recruited, who were at high risk for CVD development out of the 7154 OPD patients screened at RDBP Jaipuria Hospital, Jaipur, India. These 200 high-risk subjects were divided into three groups based on their FBG level and HbA1c level according to the American Diabetes Association for Diabetes Classification as normoglycaemic 44 (26.19%), prediabetic 21 (12.5%), and diabetic 103 (61.31%) subjects. Out of the total 200 high-risk subjects, 32 were excluded because they did not meet the American Diabetes Association criteria for prediabetes and diabetes.

[Table/Fig-1] depicts mean±SD distribution of various parameters in normoglycaemic, prediabetic and diabetic subjects of high-risk CVD. There was significant difference of mean values of FBG, HbA1c, total cholesterol, HDL, Chl/HDL ratio, LDL, TG and QRISK3 score in three groups. But there was no significant difference in following parameters: age, weight, height, BMI, waist-hip circumference, WHR, SBP and DBP. There was hypertriglyceridaemia and low HDL level in prediabetic and diabetic subjects.

Variables	Normal (n=44) Mean±SD	Prediabetic (n=21) Mean±SD	Diabetic (n=103) Mean±SD	F-value	p-value
Age (years)	49.06±9.65	51.15±11.05	51.02±9.74	0.654	0.521
Weight (kg)	73.69±11.33	73.69±11.33	74.04±10.54	0.043	0.958
Height (m)	1.63±0.09	1.62±0.07	1.61±0.09	0.819	0.443
BMI (kg/m^2)	27.68±4.16	27.93±4.16	28.72±3.92	1.166	0.314
Waist circumference (cm)	102.56±8.76	102.89±11.85	104.63±9.4	0.847	0.431
Hip circumference (cm)	102.58±9.68	104.37±13.22	104.81±10.29	0.695	0.501
WHR	1.002±0.05	0.99±0.06	1±0.06	0.410	0.664
SBP (mmHg)	145.15±17.5	151.26±24.43	147.64±17.26	0.805	0.449
DBP (mmHg)	91.1±8.72	94.74±12.05	92.76±11.09	0.871	0.420
FBG (mg/dL)	89.03±10.6	111.17±7.9	140.35±16.99	196.102	**<0.0001**
HbA1c (%)	4.71±0.65	6.11±0.24	8.46±1.91	97.214	**<0.0001**
Total chl (mg/dL)	208.76±38.91	213.73±30.84	227.96±43.35	4.875	**0.009**
HDL (mg/dL)	43.04±10.22	38.1±9.7	38.04±6.74	6.061	**0.003**
Chl/HDL ratio	4.85±1.14	5.61±1.53	5.99±1.42	10.727	**<0.0001**
LDL (mg/dL)	125.18±31.11	130.39±23.89	139.94±36.71	3.119	**0.047**
VLDL (mg/dL)	38.51.33±18.66	44.61±16.23	50.6±17.73	7.271	**0.001**
TG (mg/dL)	168.7±56	181.8±55.92	196.22±53.07	4.094	**0.018**
QRISK3 score	24.79±5.77	27.61±6.91	29.82±8.14	7.119	**0.001**

[Table/Fig-1]: Distribution of variables.
BMI: Body mass index; WHR: Waist hip ratio; SBP: Systolic blood pressure; DBP: Diastolic blood pressure; HbA1c: Glycated haemoglobin; HDL: High density lipoprotein; LDL: Low density lipoprotein; VLDL: Very low-density lipoprotein; Chl/HDL: Cholesterol- HDL ratio; TG: Triglycerides. Analysis of Variance (ANOVA) test used. The p-value in bold font indicates statistically significant values

DISCUSSION

The QRISK3, a web calculator, was used to calculate the risk of developing CVD over the next 10 years by answering simple questions. It is suitable for people who, do not already have a

diagnosis of coronary heart disease (including angina/heart attack) or stroke/transient ischaemic attack [16]. It displays the average risk of persons who have the same risk variables as those specified for that person. Calculator available on official website https://qrisk.org/three/ and subjects were categorised as per score; and a score of 20% or more was considered high risk [16].

Using the online QRISK3 calculator, the present study evaluated the patients presenting to the OPD at the Government RDBP Jaipuria Hospital in Jaipur for high-risk CVD individuals in this observational study. Subjects were grouped into three groups according to their FBG level and HbA1c level given by American Diabetes Association for Diabetes Classification as normoglycaemic (n=44, 26.19%), prediabetic (n=21, 12.5%) and diabetic (n=103, 61.31%). From 25.7 million cases in 1990 to 54.5 million cases in 2016, India saw an upsurge in the prevalence of CVD [17]. Even with recent advances in technology and medicine and a little decline in the overall mortality rate from CVD, the condition continues to be the leading cause of death and a significant economic burden [17]. Unnikrishnan AG et al., concluded that Indian T2DM patients are at high CVD risk [18]. The following variable in the current study did not significantly change between the three groups: age, height, weight, BMI, Waist-hip circumference, WHR, SBP and DBP. However, there were significant difference of mean values of FBG, HbA1c, HDL, Chl/HDL ratio, LDL, VLDL, TG and QRISK3 score in three groups [Table/Fig-1]. According to the recommended BMI provided by the WHO for Asian populations, BMI indicates that all group subjects were obese. Additionally, a WHO consultation found that a considerable fraction of Asian adults had BMIs below the current WHO cut-off limit for overweight (≥25 kg/m^2) and are at high risk of type 2 diabetes and CVD [19]. The WHR in the current study exceeded the standards recommended for Asians (0.95 in men and 0.80 in women) [20,21].

According to Czernichow S et al., BMI was the worst predictor of cardiovascular events and deaths in individuals with type 2 diabetes, whereas WHR was the best [22]. Additionally, study conducted by Meaney A et al., revealed that there are regional differences in the association between anthropometric parameters (BMI and WC) and CVD risk [23]. All research participants had hypertension, however no significant differences were found in the present study. A further risk factor for hypertension in Chinese people is Impaired Fasting Glucose (IFG) [24]. Diabetes linked to both macrovascular (big arteries like conduit vessels) and microvascular (small arteries and capillaries) disorders. A multitude of mechanisms, including: 1) increased formation of Advanced Glycation End products (AGEs) and activation of the Receptor For Advanced Glycation End products (RAGE) AGE-RAGE axis; 2) oxidative stress; and 3) inflammation, are involved in the development of vascular complications of diabetes because of chronic hyperglycaemia and insulin resistance [25]. Three groups; normoglycaemic to diabetic, had substantially higher FBG and HbA1c levels. It is generally known that those with and without diabetes who have high HbA1c levels have a higher risk of developing CVD [26,27].

Mahmood SS et al., suggested the rates of CVD events were greater in people with prediabetes identified by either criterion, but multivariate models indicate that this rise in CVD is largely due to the many CVD risk factors in people at risk for diabetes. Mechanisms underlying the metabolic syndrome (also known as hypertension and dyslipidaemia), an insulin-resistant state that comes before diabetes, have been described in a number of populations [28]. It is well known that having high triglyceride, low HDL and high LDL levels increases the risk of developing CVD [29]. Elevated levels of TG, LDL, VLDL, and total cholesterol were seen in our research. This exceeds the cholesterol limits for South Asians set by the National Cholesterol Education Program Adult Treatment Panel III (NCEP ATP III) trial from the the United States, which serves as the reference benchmark [30]. The diabetes group in the current study had low HDL levels, which substantially differed from the prediabetic to diabetic groups. Because of its ability to reverse cholesterol transport, HDL cholesterol was considered to be "good cholesterol," and Apolipoprotein A-I (ApoA-I) was a crucial part of HDL for healthy production. Previous research suggested that CVD events and ApoAI levels were inversely related [31,32].

The diabetic group had a considerably higher Chl/HDL ratio, indicating a greater risk of CVD. Total cholesterol/High-Density Lipoprotein (HDL) cholesterol ratio, also known as atherogenic or Castelli index, and the LDL/HDL cholesterol ratio are two crucial factors and predictors of vascular risk, according to research conducted by Kinosian B et al., in 1994 [33]. No matter whether there is insulin deficit or an insulin resistance, changes in serum lipids (dyslipidaemia) are frequently observed in diabetic populations. Study conducted by Taskinen MR in 2003, concluded that the risk for CVD is more frequently associated with hypertriglyceridaemia and low HDL [34]. Also, persons with diabetes had higher QRISK3 scores than those with prediabetes, demonstrating that as diabetes progresses, both the risk score and the predisposing factors increases.

Limitation(s)

The limitation of the present study was that, it only included one tertiary care hospital and had a limited sample size. The authors are planning to conduct the same study with large sample size and intervention of any physical activity which includes combination of exercise or yoga and diet.

CONCLUSION(S)

The present study concludes that QRISK3 score increases as there is increase in FBG levels and glycosylated haemoglobin levels increases. The above study's finding supports the notion that the cluster of risk factors for CVD also grows as FBG and HbA1c levels increase. Compared to prediabetics these variables were harsher on diabetic individuals. Therefore, if the lifestyle is altered to lessen or eliminate these risk factors, the progression towards developing CVD can be prevented or chances can be lowered.

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