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# Prevalence of Cardiovascular Disease Risk Factors And Assessment of 10-Year Risk of Developing Cardiovascular Diseases in Premenopausal and Postmenopausal Women with Type 2 Diabetes: A Comparative Analysis

## ABSTRACT

**Objective:** This study aimed to assess the prevalence of cardiovascular disease (CVD) risk factors and compare the performance of the World Health Organization/International Society of Hypertension (WHO/ISH) risk prediction score and Framingham risk score (FRS) in predicting CVD risk among pre- and postmenopausal females.

**Materials and methods:** This cross-sectional study was conducted on a total of 293 female subjects with type 2 diabetes at Colombo South Teaching Hospital, Sri Lanka. The 10-year risk of developing CVD was calculated using WHO/ISH charts and FRSs and compared. The tools were validated through the use of elevated LDL-C levels, high diastolic blood pressure, high HbA1c and elevated fasting plasma glucose levels.

**Results:** Among the study population, 25.9%, 54.9%, 50.8%, 98.0% and 0% had dyslipidemia, hypertension,

obesity/overweight, central obesity, and smoking, respectively. The CVD risk was significantly greater among postmenopausal women than premenopausal women ( $p < 0.05$ ). The FRS identified 23.2%, 48.8%, 20.8% and 7.2% of women as low risk ( $< 10\%$ ), moderate risk (10–19.9%), high risk (20–29.9%) and very high risk ( $\geq 30\%$ ), respectively, whereas the WHO/ISH identified 78.8%, 14.3%, 2.0% and 4.8%, respectively. There was a significant discrepancy in the agreement between the two tools ( $k$  value = 0.068,  $p < 0.05$ ). WHO/ISH charts revealed that the majority of women with elevated LDL-C levels (80.2%) were low-risk individuals, while FRSs identified the majority of women with raised LDL-C levels (92.2%) as moderate/high risk. **Conclusions:** There was a significant discrepancy in the performance of the WHO/ISH and FRS. WHO/ISH underestimates CVD risk, while the FRS identifies high-risk women who require therapeutic interventions. (Clin Diabetol 2024; 13, 2: 93–100)

**Keywords:** cardiovascular diseases, type 2 diabetes, menopausal women, Framingham risk score (FRS), World Health Organization/International Society of Hypertension Risk Prediction Charts (WHO/ISH risk prediction charts)

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## Introduction

Cardiovascular diseases (CVDs) are the leading cause of mortality and account for one-third of deaths worldwide [1]. In Sri Lanka, the incidence of CVD has rapidly increased during the past few decades, and CVD has become the leading cause of death during the last 40 years [2]. Therefore, CVDs place heavy social and economic burdens on Sri Lanka. Type 2 diabetes (T2D) is considered a prime risk factor for developing CVDs which has been proven by many studies [3, 4]. T2D is the most prevalent type of diabetes in the world [5]. It is associated with relative insulin deficiency and peripheral insulin resistance [6]. The global prevalence of diabetes has increased rapidly over the past few decades [5], and T2D is one of the major noncommunicable diseases leading to death in the Sri Lankan population [2]. Cardiovascular diseases are considered leading causes of mortality and morbidity among patients with T2D in Sri Lanka [7]. Endothelial damage and dysfunction due to hyperglycemia are the major pathological causes of CVD development in T2D patients. Cardiovascular diseases represent one-third of all deaths among women, and women with T2D have a greater risk of mortality than men [8]. It is well known that estrogen plays a protective role against cardiovascular complications in nonmenopausal women compared to men [9]. However, oxidative stress induced by hyperglycemia alters the effects of estrogen on endothelial estrogen receptors and thereby reduces the beneficial effect of estrogen hormones in women with T2D [10]. Therefore, assessing the risk of CVD development in patients with T2D is mandatory to initiate primary preventive strategies.

Several risk assessment tools, including the Framingham risk score (FRS), the United Kingdom Prospective Diabetes Study (UKPDS) risk engine and the World Health Organization/International Society of Hypertension (WHO/ISH) risk prediction chart, have been developed over the past two decades. Although several studies have been conducted worldwide to assess the efficacy of these risk assessment tools, a limited number of studies have been conducted in Sri Lanka. However, the performance of various CVD risk assessment tools among Sri Lankans may not be the same as that of other well-studied populations. Moreover, in Sri Lanka, the performance of CVD risk assessment tools in postmenopausal women with T2D has not yet been studied. The Ministry of Health, Sri Lanka, recommends WHO/ISH as a cost-effective method for assessing the risk of developing CVD within 10 years in the primary care setting. However, a study conducted in the southern province of Sri Lanka proved that both the UKPDS risk engine and the WHO/ISH method have

poor sensitivity as screening tools for assessing CVD risk among T2D patients in Sri Lanka [11]. The FRS has been used as a valid risk assessment tool in different Asian countries in recent years [12, 13]. The sensitivity of the FRS as a risk assessment tool for screening CVD risk among patients with diabetes has not yet been studied in Sri Lanka. In addition, neither the FRS nor the WHO/ISH method are diabetes-specific risk assessment tools; hence, it is important to determine the local applicability of these risk assessment tools for assessing CVD risk in women with T2D in Sri Lanka.

## Methods

### Study population

This cross-sectional study was conducted at the Diabetes and Endocrinology Clinic at Colombo South Teaching Hospital (CSTH). A total of 343 female patients aged between 40 and 79 years with T2D who attended the clinic between October 2021 and February 2022 were recruited for the study. Patients with type 1 diabetes; other chronic severe illnesses, such as cancer and thyroid dysfunction; a history of CVD complications (stable and unstable angina; myocardial infarction; heart failure; coronary artery bypass graft; coronary angioplasty/stenting; and stroke); pregnant or lactating women; and estrogen replacement therapy and hysterectomy women were excluded from the study. An information sheet was provided regarding the study to all participants in their preferred languages (English, Sinhala or Tamil), and written informed consent was subsequently obtained from the patients prior to the study. The present study was approved by the ethical review committee of CSTH.

### Data collection

Data related to sociodemographic and clinical characteristics, such as age, reproductive data, family history of DM and CVD, smoking status and diabetes duration, were collected using interviewer-administered questionnaires and medical records. Biochemical data such as fasting plasma glucose (FPG), total cholesterol, high-density lipoprotein cholesterol (HDL-C), low-density lipoprotein cholesterol (LDL-C), and HbA1c were obtained from routine clinical investigations conducted at the biochemistry laboratory at CSTH. Anthropometric data, including height, weight, waist circumference and hip circumference, were measured by trained investigators according to WHO guidelines. Blood pressure measurements, including systolic blood pressure (SBP) and diastolic blood pressure (DBP), were collected by medical officers at the clinic. We classified the 293 patients into premenopausal ( $n = 71$ ), postmenopausal ( $< 5$  years;  $n = 56$ ) and postmenopausal

( $\geq 5$  years;  $n = 166$ ) groups based on their menopausal status and time since menopause.

### CVD risk factors

Subjects were classified as dyslipidemic if the following criteria were met: total cholesterol level  $\geq 240$  mg/dL, LDL-C level  $\geq 130$  mg/dL, triglycerides level  $> 150$  mg/dL and HDL-C level  $< 40$  mg/dL. In addition, individuals on lipid-lowering medications were also considered to have dyslipidemia [14]. Hypertension was defined as an SBP  $\geq 140$  mmHg, a DBP  $\geq 90$  mmHg, and a known hypertensive status or use of antihypertensive drugs [15]. Overweight was defined as a body mass index (BMI)  $\geq 25$  kg/m<sup>2</sup>, and obesity was defined as a BMI  $\geq 30$  kg/m<sup>2</sup> [16]. Central obesity in women was defined as a waist circumference (WC)  $> 80$  cm and/or a waist-hip ratio (WHR)  $\geq 0.85$  cm as a substantially increased risk of CVD [17]. CVD risk was calculated using the FRS and WHO/ISH risk prediction tools.

Two risk assessment tools, namely, the female FRS and WHO/ISH risk prediction charts, were used to predict the 10-year risk of CVD in premenopausal and postmenopausal women with T2D. The WHO/ISH risk prediction charts for Southeast Asian epidemiological subregion B (SEAR B) were used to estimate CVD risk. The individuals were categorized into five risk categories by WHO/ISH risk prediction charts: low risk ( $< 10\%$ ), 10–20%, 20–30%, 30–40% and  $\geq 40\%$ . Five parameters, namely, age, total cholesterol (TC) level, SBP, smoking status and diabetes status (yes or no), were used to determine an individual's risk category by the color of each parameter corresponding to the cell on the chart. The level of risk was coded by color [18]. The calculation of CVD risk by the female FRS was based on six parameters, namely, age, TC level, HDL-C level, SBP, smoking status and diabetes status (yes or no). According to the female FRS, a risk point was given for each risk factor category, and the FRS was calculated after summing the risk points for each risk factor. CVD risk percentage (%) was estimated according to the total points [19].

### Comparison of two risk assessment tools

To compare the performance of the two risk assessment tools, the patients were categorized into four groups based on WHO/ISH risk prediction chart categorization and the FRS corresponding risk percentage: low risk ( $< 10\%$ ), moderate risk (10–19.9%), high risk (20–29.9%), and very high risk ( $\geq 30\%$ ). The proportions of patients at different risk levels according to the FRS and WHO/ISH risk prediction charts were compared. Agreement in risk categorization with two prediction tools was compared using Cohen's kappa coefficient ( $\kappa$ ).

### Validity of two risk assessment tools

Elevated LDL-C levels, high DBP, high FPG and elevated HbA1c are important modifiable CVD risk factors in patients with T2D. However, LDL-C, DBP, FPG and HbA1c were not considered CVD risk factors according to either risk assessment tool. Therefore, to compare the validity of the two risk assessment tools, the proportions of patients with elevated LDL-C ( $\geq 100$  mg/dL), high DBP ( $> 90$  mmHg), FPG ( $\geq 126$  mg/dL) and HbA1c ( $> 7.0\%$ ) requiring therapeutic intervention in the four risk categories were estimated for both risk assessment tools [20]. Cut-off values were taken as recommended by the American Diabetes Association (ADA) [21]. The sensitivity and specificity of each risk assessment tool for identifying elevated LDL-C, DBP, FPG and HbA1c levels requiring therapeutic intervention were subsequently calculated.

### Statistical analysis

The study population was classified into three categories based on menopausal status and time since menopause: premenopausal and postmenopausal. SPSS ver. 26 (SPSS, Inc., Chicago, IL, USA) was used to analyze the data statistically. All the data are expressed as the mean  $\pm$  standard deviation (SD) or percentage. One-way ANOVA (for continuous variables) and the chi-square test (for categorical variables) were used to compare the data between different groups. Non-parametric tests were used when the data were not normally distributed.

### Results and discussion

This study assessed CVD risk in female patients with T2D using WHO/ISH risk prediction charts and the FRS. WHO/ISH risk prediction charts have been recommended as easy and cost-effective risk assessment tools for predicting future CVD risk. Studies conducted in several countries, including a few South Asian countries, to assess the sensitivity and validity of the FRS have shown that the FRS is more sensitive in predicting future CVD risk [12, 13]. However, the performance of the FRS as a CVD risk assessment tool for predicting future CVD risk among women with T2D has not yet been studied in Sri Lanka.

### Demographic and clinical characteristics among women with T2D

All the sociodemographic and clinical characteristics are summarized in Table 1. The variables considered are age, family history of diabetes, family history of CVD, diabetes mellitus duration, weight, BMI, WHR, FPG, total cholesterol, LDL-C, triglyceride, HDL, TC/HDL ratio, LDL/HDL ratio and smoking.

**Table 1. Demographic and Clinical Characteristics of Women with T2D in the Three Groups According to Reproductive Status**

Variable	Total	Group			P-value*
	n = 293	Premenopausal (n = 71)	Postmenopausal < 5 y (n = 56)	Postmenopausal ≥ 5 y (n = 166)	
Age [years]	55.05 ± 7.56	45.82 ± 4.5 <sup>bc</sup>	53.61 ± 4.04 <sup>ac</sup>	53.61 ± 4.04 <sup>ab</sup>	< 0.001
Family history of diabetes (%)	185 (63.1%)	50 (70.4%)	30 (53.6%)	105 (63.3%)	0.135
Family history of CVD	97 (33.1%)	27 (38.0%)	15 (26.8%)	55 (33.1%)	0.364
Diabetes duration [months]	119.11 ± 91.15	82.96 ± 85.94 <sup>c</sup>	105.65 ± 82.81 <sup>c</sup>	138.17 ± 91.16 <sup>ab</sup>	< 0.001
Weight [kg]	60.96 ± 12.00	62.50 ± 12.50	60.37 ± 8.64	60.50 ± 12.75	0.487
BMI	26.22 ± 5.57	26.54 ± 4.24	25.95 ± 3.56	26.18 ± 5.01	0.697
WHR	0.94 ± 0.05	0.93 ± 0.04	0.94 ± 0.04	0.94 ± 0.05	0.710
FPG [mg/dL]	144.00 ± 57.10	159.66 ± 61.92 <sup>c</sup>	145.30 ± 57.77	136.87 ± 53.61 <sup>a</sup>	0.014
Total cholesterol [mg/dL]	176.70 ± 43.38	185.86 ± 47.02	177.83 ± 45.56	172.42 ± 40.57	0.070
LDL-C [mg/dL]	99.19 ± 36.89	108.60 ± 41.10 <sup>c</sup>	99.04 ± 39.93	95.19 ± 33.24 <sup>a</sup>	0.024
TG [mg/dL]	137.82 ± 59.48	149.31 ± 64.68	143.44 ± 59.97	131.36 ± 56.36	0.103
HDL [mg/dL]	49.85 ± 14.99	46.66 ± 8.92	50.30 ± 10.96	51.06 ± 17.83	0.110
TC/HDL ratio	3.69 ± 1.00	4.05 ± 1.02 <sup>bc</sup>	3.62 ± 0.97 <sup>a</sup>	3.55 ± 0.96 <sup>a</sup>	< 0.001
LDL/HDL ratio	2.08 ± 0.83	2.38 ± 0.93 <sup>bc</sup>	2.02 ± 0.87 <sup>a</sup>	1.97 ± 0.76 <sup>a</sup>	< 0.001
Hypoglycemic agents (oral drugs)	283 (93.6%)	69 (97.2%)	55 (98.2%)	159 (95.8%)	0.677
Hypoglycemic agent (insulin injection)	85 (29%)	18 (25.4%)	13 (23.2%)	54 (32.5%)	0.236
Antihypertensive	185 (63.1%)	29 (40.8%)	33 (58.9%)	123 (74.1%)	< 0.001
Lipid modulators	232 (79.2%)	44 (62.0%)	43 (76.8%)	145 (87.3%)	< 0.001
Smoking	0 (0%)	0 (0%)	0 (0%)	0 (0%)	

<sup>a</sup>Compared with the premenopausal group,  $p < 0.05$ ; <sup>b</sup>Compared with the postmenopausal < 5 y group,  $p < 0.05$ ; <sup>c</sup>Compared with the postmenopausal ≥ 5 y group,  $p < 0.05$ ; \*Compared among groups; BMI — body mass index; CVD — cardiovascular disease; FPG — fasting plasma glucose; HDL — high-density lipoprotein; LDL — low-density lipoprotein; TC — total cholesterol; TG — triglycerides; WHR — waist-hip ratio

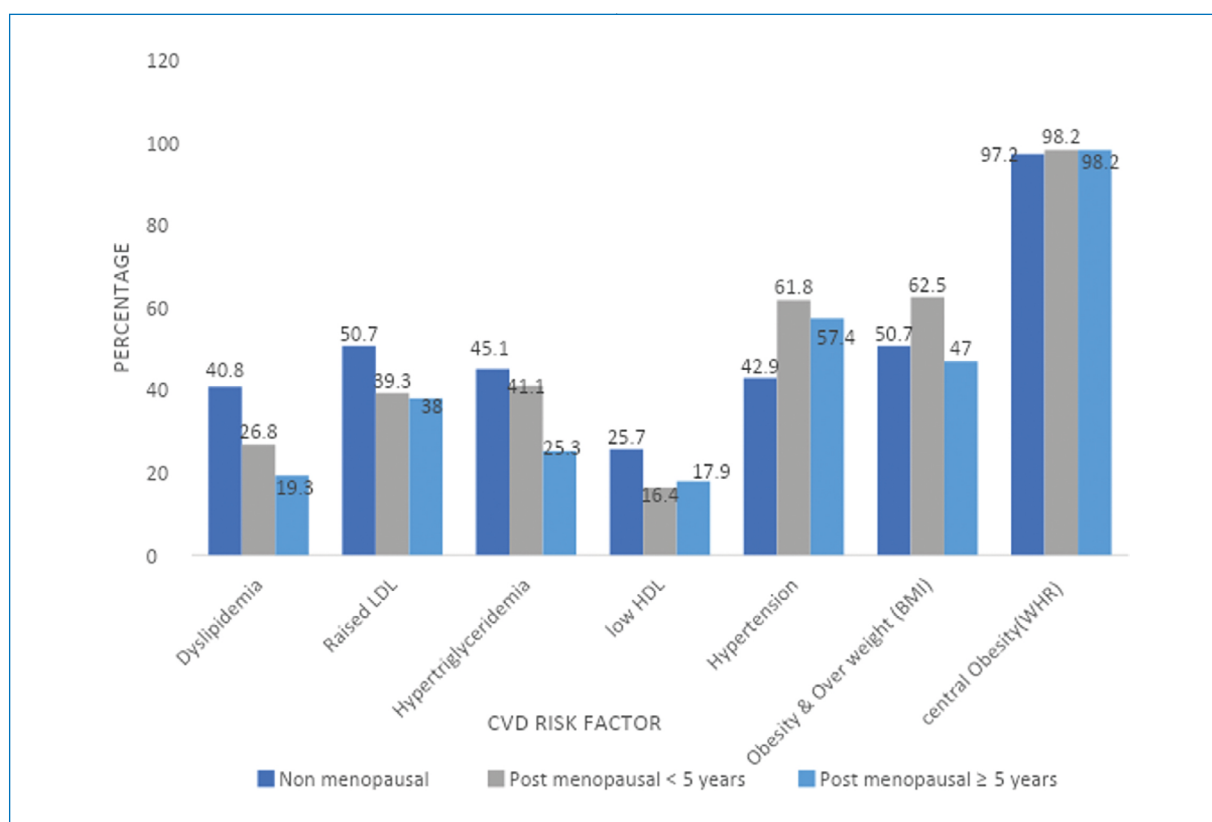
### CVD risk factors among women with T2D

According to the present study findings, the prevalence of dyslipidemia, increased LDL cholesterol levels, hypertriglyceridemia, low HDL cholesterol, hypertension, obesity and overweight, central obesity and smoking among T2D patients were 25.9%, 41.3%, 33.1%, 19.5%, 54.9%, 50.8%, 98% and 0%, respectively. The prevalence of elevated LDL cholesterol levels, hypertriglyceridemia, hypertension, obesity/overweight and central obesity was high among the studied population, but the majority of the patients were receiving hypotensive drugs (63.1%) and lipid modulators (79.2%). This discrepancy may be attributed to multiple factors, including poor adherence to therapeutic agents, inappropriate dietary habits, sedentary lifestyles and poor clinical attention due to the COVID-19 pandemic. It is well known that the hormone estrogen plays a protective role in preventing CVD events in healthy nonmenopausal women by controlling LDL cholesterol

levels [22]. However, according to the current study, the incidence of dyslipidemia, elevated LDL cholesterol, hypertriglyceridemia and low HDL cholesterol was considerably greater among premenopausal women than among postmenopausal women (Fig. 1). This may be due to elimination of the beneficial effect of estrogen due to metabolic changes of T2D [10] which is further aggravated by the poor adherence to therapeutic agents and inappropriate lifestyle and due to COVID-19 lockdown period.

### Comparison of the two assessment tools

This study showed that the WHO/ISH risk prediction chart categorized the majority of subjects in the low-risk category (78.8%), while the FRS categorized only 23.2% in the low-risk category. However, in the high-risk subgroup (≥ 30%), both tools were consistent and identified a similar proportion of patients (4.8% [14/293] vs. 7.2% [21/293]) (Tab. 2).



**Figure 1.** Prevalence of CVD Risk Factors among Women with T2D in One of Three Reproductive States  
BMI — body mass index; CVD — cardiovascular disease; HDL — high-density lipoprotein; LDL — low-density lipoprotein; T2D — type 2 diabetes; WHR — waist-hip ratio

**Table 2.** Comparison of the Categorization of Women with T2D according to the FRS and WHO/ISH Risk Tools

Category	WHO/ISH		FRS	
	Frequency	Percent	Frequency	Percent
Low risk (< 10%)	231	78.8%	68	32.2%
Moderate risk (10–19.9%)	42	14.3%	143	48.8%
High risk (20–29.9%)	6	2.0%	61	20.8%
Very high risk (≥ 30%)	14	4.8%	21	7.2%
Total	293	100%	293	100%

FRS — Framingham risk score; ISH — International Society of Hypertension; T2D — type 2 diabetes; WHO — World Health Organization

The FRS categorizes the highest proportion (48.8%) of subjects in the moderate-risk category. Similarly, a study conducted in Sri Lanka revealed that according to WHO/ISH data, the highest proportion of patients were categorized in the low-risk category [20]. Similarly, several studies have reported that a greater proportion of patients are categorized in the low-risk subgroup according to the WHO/ISH criteria than according to other risk prediction tools. [23–25]. Thus, the categorization of a high proportion of women as having low

cardiac risk may be mainly due to the poor ability of WHO/ISH charts to identify high-risk individuals. Even though WHO/ISH charts are considered a cost-effective tool for assessing future CVD risk in developing countries, these charts might underestimate the CVD risk of women with T2D irrespective of their reproductive stage. As reported in the present study, the FRS categorizes most patients in the moderate risk category. Selvarajah et al., 2014 [25], recommended the FRS to assess CVD risk in women in Malaysia and reported that

**Table 3. Validation of the WHO/ISH and FRS Charts by LDL, DBP, FPG and HbA1c Levels**

	LDL (> 100 mg/dL)		DBP (> 90 mmHg)		FPG (> 126 mg/dL)		HbA1c (> 7.5%)	
	WHO/ISH (%)	FRS (%)	WHO/ISH (%)	FRS (%)	WHO/ISH (%)	FRS (%)	WHO/ISH (%)	FRS (%)
Low risk (< 10%)	80.2	14.0	81.2	7.1	79.2	26.2	65.9	17.1
Moderate risk (10–19.9%)	14.9	56.2	10.6	49.4	12.9	49.0	22.0	61.0
High risk ( $\geq$ 20%)	5	36	8.2	43.5	7.9	24.8	9	22.0
Sensitivity	20	86	19	93	21	74	34	83
Specificity	78	30	86	30	78	16	79	36

DBP — diastolic blood pressure; FPG — fasting plasma glucose; FRS — Framingham risk score; HbA1c — glycated hemoglobin; ISH — International Society of Hypertension; LDL — low-density lipoprotein; WHO — World Health Organization

the FRS can be used to categorize high-risk patients more accurately than can the WHO/ISH risk prediction charts. Most of the studies conducted on the FRS have shown that it accurately categorizes CVD risk among the population. However, few studies have concluded that the FRS overestimates CVD risk [26]. According to the current study, there was a significant disagreement between WHO/ISH risk prediction charts and the FRS in predicting future CVD risk, as the kappa value was 0.068 ( $p < 0.05$ ). This finding was supported by several other studies conducted among the Asian population [24, 25, 27].

### Validation of the two assessment tools

The present study validated the use of risk prediction tools by demonstrating that individuals with elevated LDL, high DBP, high FPG and high HbA1c need therapeutic intervention (Tab. 3). The WHO/ISH risk prediction charts failed to identify the majority of the patients with elevated LDL, high FPG, high DBP and poor control of blood glucose (high HbA1c) as high-risk individuals, while the FRS categorized the majority of individuals as moderate/high risk. WHO/ISH charts had poor sensitivity and high specificity for all four validation methods. Thus, if the therapeutic interventions are decided alone by WHO/ISH charts, most of the women who require therapeutic interventions will be advised against the treatment. These findings are comparable to the results of a study conducted in Sri Lanka. [20]. In contrast, the present study revealed that the FRS is able to categorize the majority of patients with CVD risk factors into moderate (10–19.9%) and high risk ( $\geq$  20%) categories by indicating the need for therapeutic intervention, unlike the WHO/ISH, which completely underestimates high-risk subjects into the low-risk category. The sensitivity of the FRS for all four validation methods was high, but the specificity was

low. Even though the FRS showed better performance than did the WHO/ISH score, six risk factors were common to both risk prediction tools. Thus, the high sensitivity of the FRS could be attributed to the use of a more comprehensive CVD risk definition and the inclusion of HDL cholesterol levels for risk calculations. This could be further explained by the high prevalence of women with low HDL cholesterol among the studied population. In this study, it was revealed that CVD risk is significantly greater among postmenopausal women than among premenopausal women. Moreover, Yang et al. [28] reported that postmenopausal women had a significantly greater risk of both fatal and nonfatal CVD compared with premenopausal women. This study has several limitations. The present study was conducted in a cohort of women with T2D registered at the Diabetes and Endocrinology Clinic at CSTH. Thus, the findings cannot be generalized to other groups in Sri Lanka, as the study was based on data from a single center. Neither tool we utilized to assess CVD risk among women with T2D was specifically designed to assess CVD risk among diabetes patients.

### Conclusions and future directions

Even though the majority of patients in the study population were receiving therapeutic interventions, the prevalence of major CVD risk factors was high among the studied women with T2D. Close monitoring and proper adherence to treatment modalities along with appropriate lifestyle changes will reduce the prevalence of CVD risk factors. The CVD risk is higher in women who experienced menopause than in premenopausal women. Further studies on sex hormone levels are recommended to determine the mechanism underlying the high CVD risk among postmenopausal women. There is a significant discrepancy between WHO/ISH risk prediction charts and the FRS in predict-

ing CVD risk among women with T2D. The WHO/ISH risk prediction charts underestimate high-risk women, while the FRS is able to identify high-risk women who require therapeutic interventions. The FRS can be used to predict CVD risk and initiate therapeutic interventions in the clinical setting. However, the tool must be validated by large-scale multicenter studies with greater numbers of participants. In addition, a sensitive, cost-effective tool specific for T2D, which can easily be used in a low-resource setting to accurately identify high-risk individuals, should be identified or designed for the female population with diabetes, considering reproductive risk factors.

## Article information

### Ethical consideration

This study was approved by the ethical review committee of Colombo South Teaching Hospital, Kalubowila, Sri Lanka, and followed the guidelines of the Declaration of Helsinki.

### Data availability

The raw quantitative datasets used to support the findings of this study are deidentified participant data and are available from the corresponding author upon reasonable request. Please contact Ms. PK Weerawickrama.

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### Author contributions

This manuscript is a revised and updated version of the final year thesis of PK Weerawickrama, WMCP Weerasinghe, and IKAS Fernando. AMDS Karunarathna, Chaminda Garusinghe, PK Weerawickrama, WMCP Weerasinghe and IKAS Fernando participated in the design and conception of the study. PK Weerawickrama, WMCP Weerasinghe & IKAS Fernando conducted the study and acquired the data. PK Weerawickrama, WMCP Weerasinghe and IKAS Fernando entered the data into the statistical software and cross-checked for any errors. AMDS Karunarathna & PK Weerawickrama analyzed the data, performed the statistical analysis and, together with Chaminda Garusinghe, contributed to the data interpretation. AMDS Karunarathna and PK Weerawickrama wrote the paper. All the authors participated in reviewing and revising the manuscript and approved the final version. PK Weerawickrama is

responsible for the integrity of the work as a whole and serves as guarantor of this work.

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### Conflict of interest

The authors declare no conflict of interest.

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