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Characteristics of type 2 diabetes patients with overt cardiovascular diseases in Malaysia: the real-world evidence from the National Diabetes Registry

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Abstract

Objective The characteristics of diabetes patients with cardiovascular disease (CVD) in Malaysia are not well understood, especially in terms of metabolic control and treatment profiles. We aimed to determine the characteristics of type 2 diabetes patients with CVD in public primary care clinics in Malaysia. A cross-sectional analysis of the baseline information of an established retrospective cohort dataset was done.

Results Among 18,312 patients, 4.1% had CVD. In the multiple logistic regression model, CVD was associated with males, older age, longer diabetes duration, hypertension, dyslipidaemia, nephropathy, insulin, antiplatelet agents, and glycosylated haemoglobin A1c control. In contrast, LDL cholesterol control was less common among patients with CVD. The percentage of patients with CVD who achieved the recommended glycosylated haemoglobin A1c ≤ 8%, blood pressure ≤ 135/75 mmHg, and LDL cholesterol < 1.8 mmol/L were 59.5%, 25.3%, and 13.7%, respectively. Meanwhile, 44.7%, 25.6%, and 42.7% of patients without CVD achieved glycosylated haemoglobin A1c ≤ 7.0%, blood pressure ≤ 135/75 mmHg, and LDL cholesterol ≤ 2.6 mmol/L, respectively. Many patients did not achieve the recommended treatment targets. There are ample opportunities to optimise the quality of diabetes management in primary care settings in Malaysia.

Keywords Blood pressure, Cardiovascular disease, Diabetes, Glycosylated haemoglobin A1c, LDL cholesterol, Primary care, Type 2 diabetes

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Introduction

Cardiovascular disease (CVD) is a leading cause of mortality worldwide and in Malaysia [1, 2], and accounts for half of all deaths in type 2 diabetes (T2D) patients [3]. About 18.3% or almost 3.9 million adult population in Malaysia are living with diabetes, making it a major public health concern in this upper-middle-income country in Asia [4].

It is known that good metabolic control of clinical indices such as glycosylated haemoglobin A1c (HbA1c), blood pressure (BP), and low-density lipoprotein (LDL) cholesterol prevents or delays CVD complications in T2D patients [5, 6]. Hence, clinical practice guidelines (CPG) for diabetes management have explicitly set individualised treatment targets [5, 7]. For example, BP and LDL cholesterol goals are tighter for CVD patients [5, 7]. Certain medications are also recommended. Aspirin is recommended for the secondary prevention of CVD while angiotensin-converting enzyme (ACE) inhibitor is the preferred antihypertensive agent in patients with concurrent hypertension [5, 7].

Using an established retrospective cohort dataset, we previously determined the LDL cholesterol trends over five years in Malaysia and found that CVD patients had lower mean LDL cholesterol [8]. However, the characteristics of patients by CVD status were not described [8]. This posed a knowledge gap as the characteristics of T2D patients with and without CVD in Malaysia are not well understood.

While traditional CVD risk factors are well-established in the literature, understanding real-world granular data in terms of metabolic control and treatment profiles can offer new insights with potential clinical and policy implications. Thus, we aimed to determine the characteristics of T2D patients with CVD in Malaysia.

Methods

A cross-sectional analysis of the baseline information of an established five-year retrospective open cohort dataset was conducted, and the details of the cohort were published [8–12]. Briefly, the cohort of T2D patients was assembled via data integration methodology from five cross-sectional datasets between 2013 and 2017 from the Malaysian National Diabetes Registry [8–11]. The study settings were public primary care clinics in Negeri Sembilan, Malaysia. The results could be externally generalised and were applicable to T2D patients receiving treatments in those clinics in Malaysia because of comparable demographic and comorbid features [8–12]. The total number of patients was 18,312, the same as our previously reported study in which their general characteristics had been described [8].

The dependent variable was CVD, defined as having overt coronary heart disease and/or stroke, and was based on clinical diagnoses [13]. The independent variables were demographic factors (age, sex, ethnic groups), smoking history, comorbidities, complications, medications, and treatment targets, as previously defined [8, 9]. The LDL cholesterol goal was < 1.8 mmol/L for patients with CVD and ≤ 2.6 mmol/L for patients without CVD [5]. The tighter LDL cholesterol goal for patients with CVD was appropriate to prevent further complications [5]. Meanwhile, the BP target was ≤ 135/75 mmHg for both patients with and without CVD [5]. In contrast, HbA1c ≤ 7.0% was the target for T2D patients without CVD [5]. A less stringent HbA1c ≤ 8.0% was targeted for those with CVD because of multiple medications, risk of hypoglycaemia, concomitant comorbidities, and predicted short life expectancy [5].

For data analysis, IBM SPSS version 23 was employed. We performed Pearson's chi-square tests to compare proportions. Depending on whether the data distribution was normal, continuous variables were reported as mean ± standard deviation or median (interquartile range). To compare means, the Student's T-test was employed, and to compare medians, the Mann-Whitney U test was utilised. Multiple binary logistic regression was conducted, and $P < 0.05$ was set as the statistical significance cutoff for factors associated with CVD in T2D patients. The adjusted odds ratios (aOR) and 95% confidence intervals (CI) were presented. The Medical Research and Ethics Committee of the Ministry of Health Malaysia approved this study (NMRR-18-2731-44032, letter reference number: KKM.NIHSEC.P18-2032(5)) and waived the need for written informed consent because the data was analysed retrospectively with no patient identification information.

Results

Among 18,312 patients, 746 (4.1%) were found to have CVD. CVD was more commonly observed among males, older adults, Chinese ethnicity, patients with a longer diabetes duration, smokers, and those with hypertension, dyslipidaemia, nephropathy, retinopathy, and diabetic foot complications (Table 1). A higher proportion of patients treated with insulin, antiplatelet agents, lipid-lowering agents, and ≥ 3 antihypertensive agents had CVD. The use of statins, ACE-inhibitor/angiotensin II receptor blockers, and aspirin was more common in patients with CVD. Nevertheless, it should be noted that 21.0% of CVD patients were not on statins, 31.1% were not given antiplatelet agents, and 31.7% of patients with CVD and hypertension were not on ACE-inhibitor/ARB.

In addition, T2D patients with CVD had higher mean HbA1c but lower diastolic BP and LDL cholesterol values. The proportion of patients with CVD who achieved HbA1c ≤ 8%, BP ≤ 135/75 mmHg, and LDL cholesterol < 1.8 mmol/L was 59.5%, 25.3%, and 13.7%,

Table 1 Characteristics of type 2 diabetes patients subcategorised by the presence or absence of cardiovascular disease ($n = 18,312$)

Characteristics	Cardiovascular disease		*P* values
	Yes, n (column %)	No, n (column %)	
	746 (100.0)	**17,566 (100.0)**	
Sex			
Male	406 (54.4)	7,674 (43.7)	< 0.001
Female	340 (45.6)	9,892 (56.3)	
Age, years			
Mean ± standard deviation	64.1 ± 9.6	59.1 ± 10.6	< 0.001
18 to 49	44 (5.9)	3,011 (17.1)	< 0.001
50 to 59	199 (26.7)	6,012 (34.2)	
≥ 60	503 (67.4)	8,543 (48.7)	
Ethnicity			
Malay	450 (60.2)	11,400 (64.9)	0.039
Chinese	136 (18.2)	2,609 (14.9)	
Indian	155 (20.9)	3,441 (19.6)	
Others	5 (0.7)	116 (0.6)	
Duration of diabetes, years			
Median (interquartile range)	8.0 (8.0)	5.0 (7.0)	< 0.001
< 5	146 (19.6)	8,148 (46.4)	< 0.001
5 to 10	332 (44.5)	6,288 (35.8)	
> 10	268 (35.9)	3,130 (17.8)	
Smoker	69 (9.2)	1,096 (6.2)	0.001
Body mass index, kg/m^2 ($n = 17,497$)			
Mean ± standard deviation	27.8 ± 4.8	28.0 ± 5.1	0.096
Underweight, < 18.5	5 (0.7)	195 (1.2)	0.055
Normal, 18.5–24.9	189 (27.5)	4,552 (27.1)	
Overweight, 25.0–29.9	307 (44.6)	6,797 (40.4)	
Obese, ≥ 30.0	187 (27.2)	5,265 (31.3)	
Hypertension	716 (96.0)	14,582 (83.0)	< 0.001
Dyslipidaemia	668 (89.5)	13,772 (78.4)	< 0.001
Nephropathy	104 (13.9)	943 (5.4)	< 0.001
Retinopathy	47 (6.3)	481 (2.7)	< 0.001
Diabetes foot complication	15 (2.0)	161 (0.9)	0.003
Diabetes treatment modality			
Lifestyle modification only	14 (1.9)	441 (2.5)	< 0.001
OHA only	442 (59.2)	12,286 (70.0)	
Insulin only	97 (13.0)	1,039 (5.9)	
Both OHA and insulin	193 (25.9)	3,800 (21.6)	
One or two lipid-lowering agents	602 (80.7)	12,672 (72.1)	< 0.001
Statin	589 (79.0)	12,467 (71.0)	< 0.001
Number of antihypertensive agents			
Zero	59 (7.9)	3,473 (19.7)	< 0.001
One	193 (25.9)	5,217 (29.7)	
Two	277 (37.1)	5,192 (29.6)	
Three or more	217 (29.1)	3,684 (21.0)	
ACE-inhibitor/ARB	489 (65.5)	9,580 (54.5)	< 0.001
One or two antiplatelet agents	514 (68.9)	5,090 (29.0)	< 0.001
Aspirin	472 (63.3)	4,856 (27.6)	< 0.001
HbA1c, % ($n = 18,297$)			
Mean ± standard deviation	8.06 ± 2.17	7.87 ± 2.02	0.014
Achieved HbA1c control	443 (59.5)	7,840 (44.7)	< 0.001
Blood pressure, mmHg ($n = 18,286$)			
Systolic BP, mean ± standard deviation	135.6 ± 17.1	134.7 ± 16.7	0.186
Diastolic BP, mean ± standard deviation	77.1 ± 9.4	78.3 ± 9.4	0.001
Achieved BP control	188 (25.3)	4,485 (25.6)	0.872

Table 1 (continued)

Characteristics	Cardiovascular disease		*P* values
	Yes, n (column %)	No, n (column %)	
	746 (100.0)	17,566 (100.0)	
LDL cholesterol, mmol/L			
Mean ± standard deviation, mmol/L	2.75 ± 0.96	2.92 ± 0.94	< 0.001
Achieved LDL cholesterol control	102 (13.7)	7,500 (42.7)	< 0.001

Note: The HbA1c targets for patients with and without CVD were ≤ 8% and ≤ 7.0%, respectively. The LDL cholesterol goal was < 1.8 for patients with CVD and ≤ 2.6 mmol/L for patients without CVD. The blood pressure target was ≤ 135/75 mmHg for both patients with and without CVD

Table 2 Factors associated with cardiovascular disease, *n* = 18,285

Characteristics	Adjusted odds ratio	95% confidence intervals	*P* values
Sex – male	1.60	1.36–1.87	< 0.001
Age			
18–49 years	1.00		
50–59 years	1.44	1.02–2.03	0.036
≥ 60 years	1.81	1.30–2.51	< 0.001
Duration of diabetes			
< 5 years	1.00		
5–10 years	2.40	1.94–2.96	< 0.001
> 10 years	3.79	2.99–4.79	< 0.001
Hypertension	2.76	1.89–4.03	< 0.001
Dyslipidaemia	1.74	1.35–2.23	0.001
Nephropathy	1.79	1.40–2.27	< 0.001
Diabetes treatment modality			
Lifestyle modification only	1.00	0.73–2.24	0.384
OHA only	1.28	1.28–4.31	0.006
Insulin only	2.35	0.97–3.13	0.063
Both OHA and insulin	1.74		
Antiplatelet agent	4.13	3.49–4.88	< 0.001
Achieved HbA1c control	3.19	2.66–3.83	< 0.001
Achieved LDL cholesterol control	0.15	0.12–0.19	< 0.001

The forward stepwise selection method was used. Multicollinearity and interaction terms were assessed. The Omnibus test of the model coefficient was significant, $P < 0.001$ and the model was valid, $P = 0.204$ for the Hosmer and Lemeshow test. The overall correct percentage based on the classification table was 96.0%, and the coefficient of determination was 24.0%.

respectively. The proportions of patients without CVD who achieved HbA1c ≤ 7.0%, BP ≤ 135/75 mmHg, and LDL cholesterol ≤ 2.6 mmol/L were 44.7%, 25.6%, and 42.7%, respectively. The lowest achievement was the intensified LDL cholesterol target for patients with CVD.

In the multiple logistic regression model, CVD was more likely to be observed in males, older age groups, patients with longer diabetes duration, those with hypertension, dyslipidaemia, nephropathy, and patients who achieved HbA1c control (Table 2). In terms of treatment modality, insulins and antiplatelet agents were more likely to be associated with patients with CVD than without CVD. In contrast, achieving LDL cholesterol control was associated with a lower adjusted odds ratio for CVD.

Discussion

In this study, we determined the characteristics of T2D patients with overt CVD in Malaysia using real-world evidence from the National Diabetes Registry. We found that the factors associated with CVD were similar to those documented in the literature. Males, increasing age, hypertension, and dyslipidaemia are independent risk factors for CVD [14]. Meanwhile, chronic kidney disease is used in the cardiovascular risk stratification [14]. In the Framingham Heart Study, a longer duration of diabetes was linked with a higher risk of coronary heart disease and mortality [15]. Insulin is recommended in patients with more severe diabetes to control HbA1c [5]. Thus, insulin could be a proxy marker for disease severity, and this may partially explain why CVD was more commonly observed among insulin users in this study. Meanwhile, the association between antiplatelet agents and CVD is expected because aspirin is needed for the secondary prevention of CVD [5].

Our CVD patients were likelier to achieve the HbA1c goal but less likely for the LDL cholesterol target. These observations can be partly explained by different treatment goals recommended by the CPG [5]. T2D patients with CVD have less stringent HbA1c goals because of concomitant comorbidities with multiple medications, risk of hypoglycaemia, and predicted short life expectancy [5]. In contrast, they had tighter LDL cholesterol goals to avoid further adverse outcomes [5].

Identifying the factors associated with CVD can help the clinical management of T2D patients. It implies the need to the need to risk-stratify patients and manage higher-risk patients more aggressively to prevent cardiovascular complications, especially since diabetes increases CVD risks by two-fold [16]. The CPG recommends using a CVD risk calculator such as the Framingham Risk Score, and if the score falls in the high or intermediate risk group, efforts should be made to intensify the management of CVD risk factors [5]. Besides the risk factors used in the Framingham Risk Score, this study identifies additional CVD-related factors, such as longer diabetes duration, nephropathy, and insulin. These factors should alert clinicians about the increased CVD risks among these subgroups of patients to manage accordingly. Indeed, based on the United Kingdom

Prospective Diabetes Study (UKPDS), the duration of diabetes and microalbuminuria have been included in the risk engine and estimator [17, 18].

The attainment of HbA1c, LDL cholesterol, and BP goals among our patients is suboptimal, similar to the conclusion arrived for the worldwide achievement of guideline goals for T2D patients [19]. The Lancet Commission on Diabetes places a strong focus on lowering HbA1c, systolic BP, and LDL cholesterol as they individually decrease the risk of CVD, death, or both, independently of other CVD risk factors [20]. The gaps between CPG targets and real-world performance represent a potentially preventable burden of diseases, and therefore, it is crucial to improve the control among T2D patients [8, 21]. The lowest achievement among our patients was the intensified LDL cholesterol target for patients with CVD. As we have previously postulated, one potential reason is therapeutic inertia with inadequate intensification of statins [8]. The subpar performance is especially worrying because LDL cholesterol is the most essential one among the three evidence-based guideline goals to lower cardiovascular risks [21].

In addition, we observed evidence of inadequate adherence to CPG. A percentage of these patients were not given aspirins and statins for the secondary prevention of CVD events. In addition, some of those with CVD and hypertension were not on ACE inhibitors or ARBs despite these medications being explicitly recommended to reduce the risk of CVD events [5]. The gaps in CPG and actual clinical practice in public primary care clinics in Malaysia would affect the quality of care received by patients [22]. Thus, further studies are warranted to identify the root cause of suboptimal adherence to CPG at the physician, patient, and systemic levels to solve the issue [22].

While our CVD prevalence is comparable to that reported in Thailand, the result is substantially lower than the global prevalence of 32.2% [3, 23]. However, the comparison should not be directly made and must be interpreted cautiously. Our operational definition of CVD included only overt coronary heart disease and stroke. It does not include other types of CVD, such as heart failure, as reported in the systematic review [3]. Moreover, our study population is younger and has a shorter diabetes duration than those reported in the review [3]. Importantly, our study setting is focused on primary care clinics, whereas the review included hospitalised patients and patients followed up in hospital specialist clinics [3]. Healthcare services in Malaysian public facilities are organised into primary, secondary, and tertiary care [24]. T2D patients in primary care clinics with symptoms of CVD are referred promptly to secondary and tertiary hospitals for further management [5, 24]. In asymptomatic patients, the Malaysian CPG does not recommend routine screening for coronary heart disease [5]. Hence, our CVD prevalence would understandably be lower due to different study definitions, populations, and settings.

A key strength of this paper is the characterisation of T2D patients with CVD using real-world data that reflect actual clinical practice. Besides deepening the pool of existing evidence for factors associated with CVD, our analysis offers insights into the quality of diabetes care. The achievement of treatment goals is suboptimal, with evidence of inadequate adherence to CPG. These unmet needs offer opportunities for interventions to optimise CVD risk factor control in T2D patients in Malaysia.

Limitations

The main limitation is that the study definition of CVD included only overt coronary heart disease and stroke. A more elaborate definition that includes heart failure, cardiomyopathy, arrhythmia, peripheral vascular disease, and sudden cardiac death would provide a more comprehensive view of CVD issues among T2D patients in Malaysia [1]. However, this limitation is unavoidable as the data are not captured in the registry, and the addition of new variables could be considered in future system updates. Another limitation is the cross-sectional analysis of the study, in which the results only imply association and not causation because the temporal effect is unclear [25]. Hence, the positive associations between insulin use and HbA1c control with CVD should be carefully interpreted. Patients with CVD were more likely to be on insulin and achieve the less stringent HbA1c target; it was not that insulin users and patients who achieved the HbA1c goals were more likely to have CVD.

Conclusions

In conclusion, males, older adults, longer diabetes duration, hypertension, dyslipidaemia, nephropathy, insulin, antiplatelet agents, and achievement of HbA1c goal were more commonly observed among T2D patients with CVD in Malaysia. In contrast, LDL cholesterol control was less common among them. Many patients did not achieve the recommended HbA1c, BP, and LDL cholesterol targets. Contrary to the CPG recommendations, some patients did not start aspirins and statins.

Abbreviations

aOR	Adjusted odds ratio
ACE inhibitor	Angiotensin-converting enzyme inhibitor
ARB	Angiotensin II receptor block
BP	Blood pressure
CPG	Clinical practice guidelines
CVD	Cardiovascular disease
GLP-1 RA	Glucagon-like peptide-1 receptor agonist
HbA1c	Glycosylated haemoglobin A1c
IQR	Interquartile range
LDL	Low-density lipoprotein
OHA	Oral hypoglycaemic agent

SD	Standard deviation
SGLT-2 inhibitor	Sodium-glucose transport protein 2 inhibitor
T2D	Type 2 diabetes
UKPDS	United Kingdom Prospective Diabetes Study

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Author contributions
K.S.W conceived the study, curated the data, did statistical analysis, interpreted the results, and drafted the manuscript. N.N.H, F.M, M.F.M.Y, M.I, F.M.M and N.A.A conceived the study, interpreted the results, finalised the manuscript. All authors reviewed and approved the final manuscript.

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Data availability
No datasets were generated or analysed during the current study.

Declarations

Ethics approval and consent to participate
The Medical Research and Ethics Committee of the Ministry of Health Malaysia approved this study (NMRR-18-2731-44032) and waived the need for written informed consent because the data was analysed retrospectively with no patient identification information. All methods followed the Declaration of Helsinki and the Malaysian Good Clinical Practice Guidelines.

Consent for publication
Not applicable.

Competing interests
The authors declare no competing interests.

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