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A Study on the Prevalence and Associated Factors of Diabetic Foot at-Risk in Patients with Type 2 Diabetes in Primary Care in Hong Kong

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Abstract

Background: Diabetes mellitus is a major global health issue, which can cause a wide range of complications. One of the most devastating complications is infected foot ulcer requiring lower limb amputation. Diabetic neuropathy - leading to loss of protective sensation and/or deformity, and peripheral vascular disease are major predisposing conditions, which increase the risk of development of foot ulcer. With an emphasis on preventive care, primary care strategies should be implemented to reduce risk of diabetic foot ulcer. A major preventive strategy would be to identify patients at risk, in order to enhance early intervention to reduce risk of development of diabetic foot ulcer. This study was performed to evaluate the prevalence of patients with type 2 diabetes who were identified at risk of developing foot ulcer "diabetic foot at-risk", and the associated factors in primary care setting.

Methods: A cross-sectional study was performed on all Chinese adult patients who attended diabetic complication assessment during period 1st July 2019 to 30th June 2022 in eight government primary care clinics in Hong Kong. The primary outcome was the prevalence of diabetic foot at-risk, based on the International Working Group on the Diabetic Foot (IWGDF) 2023 Risk Stratification System. The secondary outcome was the associated factors of diabetic foot at-risk.

Results: 37,359 patients were included. The prevalence of diabetic foot at-risk was 7.6%, with 4.3%, 3.2% and 0.1% patients in IWGDF 2023 diabetic foot risk category 1, 2 and 3 respectively. 0.2% had active foot ulcer disease. Male, older age, current smoker, ex-smoker, obesity, HbA1c >7%, presence of diabetic retinopathy, presence of albuminuria or proteinuria were found to have significant positive association with diabetic foot at-risk. Regular physical activity of moderate intensity, taking lipid lowering drug were found to have significant negative association.

Conclusions: Diabetic foot at-risk was not uncommon among patients in primary care. Optimization of the control of modifiable risk factors, and focus on management of pre-ulcerative conditions for at-risk patients should be adopted to prevent the development of foot ulcer.

Keywords: Diabetic foot; Foot at-risk; Prevalence; Risk factor; Hong Kong; Primary care

Abbreviations: ACR: Albumin Creatinine Ratio; ADA: American Diabetes Association; BMI: Body Mass Index; CDARS: Clinical Data Analysis and Reporting System; CI: Confidence interval; CMS: Clinical Management System; DN: Diabetic Neuropathy; eGFR: Estimated Glomerular Filtration Rate; HbA1c: Glycated haemoglobin A1c; HDL-C: High Density Lipoprotein Cholesterol; IQR: Inter-Quartile Range; IWGDF: International Working Group on the Diabetic Foot; LDL-C: Low Density Lipoprotein Cholesterol; LOPS: Loss of Protective Sensation; MRAM: Metabolic Risk Assessment Module; N: Number; OR: Odds ratio; PAD: Peripheral Artery Disease; PCR: Protein Creatinine Ratio; Ref: Reference Variable; SD: Standard Deviation; TG: Triglycerides

Background

Diabetes mellitus is a major global health issue which can cause a wide range of complications. One of the most devastating complications is infected foot ulcer requiring lower limb amputation. Worldwide, a lower limb is amputated approximately every 20 seconds due to diabetic foot ulcers. The mortality at 5 years for a diabetic patient with foot ulcer is 2.5 times that of a diabetic without foot ulcer [1,2]. The global prevalence of diabetic foot ulcer was found to be 6.3%, and in China, the prevalence was found to be 4.1% [3].

Diabetic neuropathy (DN) leading to loss of protective sensation and/or deformity, and peripheral artery disease (PAD) are major predisposing conditions which increase the risk of development of foot ulcer [4-7].

The overall prevalence of DN in 14 different countries was found to be around 25% [8]. DN can affect sensory, motor and autonomic nervous system [9]. Distal sensory neuropathy is the most common form of DN, typically result in loss of distal sensation of lower limbs, and when profound this would result in loss of protective sensation

exposing the patients to increased risks of various forms of trauma and injuries. Motor neuropathy results in disturbance of nervous supply to the intrinsic muscles of foot, and consequently cause deformity such as splaying of foot, high arch foot, claw toe deformity [5]. Such deformity leads to mechanical change which increases plantar pressure, inducing callus formation [5]. Foot deformities and callus lead to excessive plantar pressure over an area and hence increase the risk of foot ulcer formation [10]. Autonomic neuropathy causes loss of sweating, leading to dry skin and is often complicated by fissure formation, increasing susceptibility to infection [5]. With any one of the above factors, any trivial trauma can trigger off the formation of foot ulcer. Trauma is found to be commonly due to rubbing from tight footwear, barefoot walking, cutting nails, injuries including falls, cellulitis complicating tinea pedis [7,10]

The prevalence of PAD in people with diabetes over 40 years of age had been estimated to be 20%, the prevalence increased to 29% in patients with diabetes over 50 years of age [11]. It is important to note that many diabetic patients with PAD are asymptomatic or present with atypical symptoms [12]. This is because PAD is often accompanied by neuropathy in patients with diabetes, causing impairment of pain perception. Consequently, patients with concomitant PAD and diabetes may present at an advanced stage, such as ischaemic ulcer or gangrene [11,12]. Cohort studies found that the risk of amputation was fourfold higher with concomitant diabetes and PAD [13]. Data from a cohort study of diabetic foot ulcer disease in Hong Kong also found that major amputation was more likely in the presence of ischaemia [14].

With an emphasis on preventive care, primary care strategies should be implemented to reduce the risk of diabetic foot ulcer. A major preventive care strategy would be to identify patients at risk, in order to enhance early intervention to reduce risk of development of diabetic foot ulcer. The International Working Group on the Diabetic Foot (IWGDF) in 2023 provides a risk stratification system, which categorise risk of foot ulcer development into 4 levels (categories 0, 1, 2 and 3) [15]. The categorisation is based principally on 3 major factors: loss of protective sensation (LOPS), PAD and foot deformity. IWGDF risk stratification system is a validated screening assessment tool for predicting groups that are more likely to develop diabetes related foot complications [16,17]. It also provides guidance on subsequent corresponding foot screening and examination frequency [15]. Patients with category 0 are considered at very low risk for ulceration, and require only annual assessment, whilst category 1 or above are considered "at-risk" and require more frequent screening and assessment: 6 to 12 monthly for category 1, 3 to 6 monthly for category 2, and 1 to 3 monthly for category 3 [15].

Another major aspect of preventive care strategy involves identifying the risk factors associated with diabetic foot ulcer. A systemic review and meta-analysis on global diabetic foot ulceration studies had found that diabetic foot ulceration was more prevalent in patients who were male, older or with longer diabetes duration, hypertension, diabetic retinopathy and history of smoking [3]. Community based study in India found that advanced age, low socio-economic status, sedentary physical activity and longer duration of diabetes were independently correlated with diabetic foot ulcer risk when classified with IWGDF risk stratification [18]. According to meta-analysis and multicenter studies, DN was significantly associated with factors including longer diabetes duration [19-21] high HbA1c level [19, 21], older age [19-21], presence of diabetic retinopathy [20], obesity [19] and smoking [19].

With the growing population of diabetes, there is a need to enhance strategy in prevention of diabetic foot ulcer in primary care. Worldwide, there is a lack of large-scale studies on the prevalence and the associated factors of diabetic foot at-risk, since research efforts in the past had concentrated on diabetic foot ulcer disease rather than pre ulcerative foot condition. Our study therefore aimed to evaluate the prevalence of diabetic foot at-risk, the distribution of our patients in accordance to different grades of risk of foot ulcer development and the associated factors of diabetic foot at-risk.

Methods

Study Design

A cross-sectional study was performed on all Chinese adult patients who attended for diabetic complication assessment during the period from 1st July 2019 to 30th June 2022 in eight government primary care clinics in Hong Kong. Data were collected from diabetic complication assessment records and computerized consultation for statistical analysis.

The inclusion and exclusion criteria are listed below:

- Inclusion criteria

1. Patients with type 2 diabetes who attended the diabetic complication assessment programme within the study period from 1st July, 2019 to 30th June, 2022

- Exclusion criteria

1. Non-Chinese patients
2. Patients aged below 18 years old
3. Patients with diabetes not confirmed
4. Patients with type I diabetes
5. Patients with gestational diabetes

The list of patients who fulfilled the inclusion criteria was generated from the Hospital Authority Clinical Data Analysis and Reporting System (CDARS). Data were collected from computerized consultation and diabetic complication assessment records for statistical analysis. All the subjects who fulfilled the inclusion and exclusion criteria within the study period were recruited and were categorized according to the IWGDF 2023 Risk Stratification System, which outlines the risk of ulcer development [15].

The method of feet assessment used in the diabetic complication assessment program was adopted from recommendation by Comprehensive Foot Examination and Risk Assessment article published by task force of the foot care interest group of American Diabetes Association (ADA) in 2008 [22]. LOPS was defined as either one or two abnormal feet peripheral neuropathy tests, i.e.10g monofilament test and vibration test with biothesiometer. For 10g monofilament test, force was applied until the monofilament buckles, and it was tested on four sites: 1st, 3rd, 5th metatarsal heads and the plantar surface of hallux. Vibration perception threshold (VPT) was measured using biothesiometer, tested over the pulp of hallux. The mean of three VPT readings were taken, and result of >25V being regarded as abnormal. PAD was defined by either history of lower limb revascularization, symptoms of claudication or rest pain, or examination finding of ischaemic change of lower limb or abnormal foot pulse. End-stage renal disease was defined as estimated glomerular filtration rate (eGFR) <15 ml per minute per 1.73m^2.

Outcomes

The primary outcome was the prevalence of diabetic foot at-risk identified during diabetic foot screening among patients with type 2

diabetes in primary care in Hong Kong, with level of risk categorised by the IWGDF 2023 Risk Stratification System. The secondary outcome was the associated factors for patients with diabetic foot at-risk.

Statistical method

SPSS version 26 was used for statistical analysis. For descriptive statistics, continuous variables with symmetrical distribution were presented as means and standard deviation (SD). Skewed continuous variables were presented as median and inter-quartile range (IQR). Categorical variables of descriptive statistics were presented as percentages.

Comparison of continuous variables with symmetrical distribution was done by independent sample t-test. Comparison of continuous variables with skewed distribution was done by Mann-Whitney U test. Categorical variables were compared with Pearson Chi-square test. A p-value <0.05 was considered statistically significant. Prevalence was presented as percentage with 95% confidence interval. Logistic regression model was used for multivariate analysis to assess variables associated with diabetic foot at-risk. Missing values were replaced by multiple imputation method.

Results

There were 37,776 patients who underwent diabetic complication assessment programme in the study clinics within the study period. 417 patients were excluded as shown in figure 1 and therefore 37,359 patients were recruited in this study.

Demographic and clinical characteristics of study population

The demographic and clinical characteristics of recruited patients were shown in table 1. The mean age was 66.6 years. There were more female patients (52.8%). 10.9% of patients were smokers. The median duration of diabetes since diagnosis was 7 years. The median HbA1c was 6.7%, with 64.4% patients had HbA1c below 7%. 21.9% patients were overweight while 51.6% patients were obese. 30.5% and 48.9% patients had LDL-C controlled to <1.8 mmol/L (<32.4mg/dL) and 1.8-2.5 mmol/L (32.4-46.7mg/dL) respectively. 19.2% patients developed diabetic retinopathy. A quarter of patients (25.0%) had albuminuria or proteinuria.

Prevalence of diabetic foot at-risk

The overall prevalence of patients with diabetic foot at-risk was 7.6%. According to IWGDF 2023 risk stratification system, 92.2% patients were normal, whilst 4.3%, 3.2% and 0.1% patients were in risk category 1, 2 and 3 respectively (Table 2). In addition, there were 64 patients (0.2%) who had active foot ulcer disease at the time of feet assessment. As this study was designed to assess diabetic foot at-risk in primary care setting, aiming to enhancing the prevention of diabetic foot ulcer development, these patients with active foot ulcer disease were not included in secondary outcome data analysis.

The prevalence of PN, as evidenced by LOPS was 2,601 (7.0%). As an additional information, 6,182 (16.5%) patients were noted to have active tinea pedis at the time of feet assessment. Although tinea

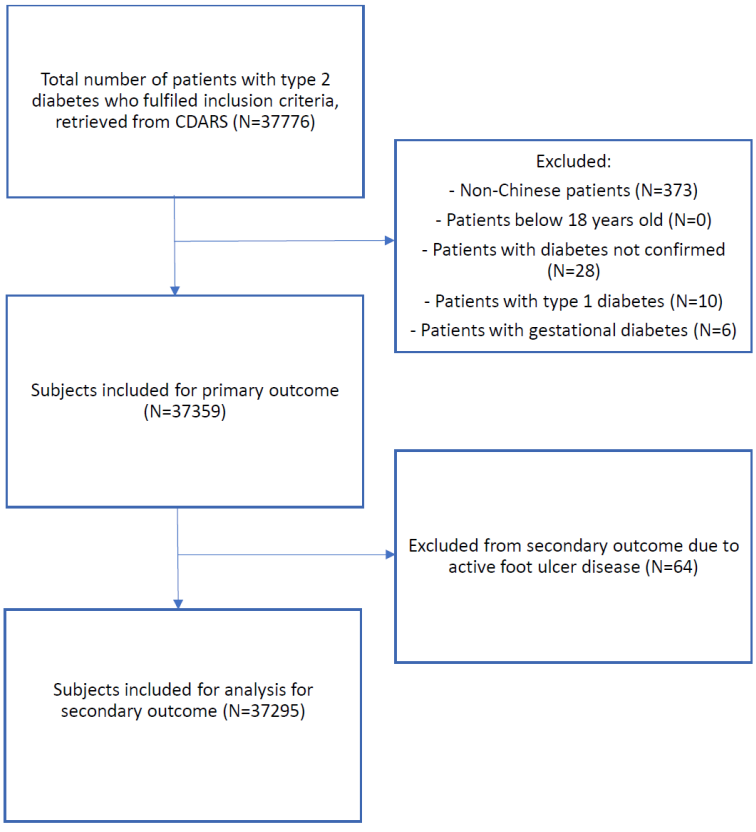

Figure 1: Flowchart of study subject recruitment.

Table 1: Demographic data and clinical characteristics of patients (N=37359).

	Mean ± SD	Median (IQR)	Number (%)
Age (years old)	66.6 ± 10.7		
Gender			
Female			19713 (52.8%)
Male			17646 (47.2%)
Smoking status			
Smoker			4056 (10.9%)
Ex-smoker			6820 (18.2%)
Non-smoker			26483 (70.9%)
BMI (kg/m^2)		25.2 (22.9-27.8)	
<18.5 (Underweight)			660 (1.8%)
18.5-22.9 (Normal)			9186 (24.6%)
23-24.9 (Overweight)			8164 (21.9%)
≥ 25 (Obese)			19295 (51.6%)
Unknown			54 (0.1%)
Regular physical activity of moderate intensity			
No			32039 (85.8%)
Yes			5320 (14.2%)
History of hypertension			
No			5633 (15.1%)
Yes			31726 (84.9%)
Duration of diabetes (years)		7.0 (3.0-13.0)	
<5 years			13274 (35.5%)
5-10 years			10841 (29.0%)
>10-20 years			10599 (28.4%)
>20 years			2644 (7.1%)
Unknown			1 (0.003%)
Current treatment of diabetes			
On diet control only			7877 (21.1%)
On oral antidiabetic drug without insulin			28363 (75.9%)
On insulin			1119 (3.0%)
HbA1c (%)		6.7 (6.4-7.2)	
<6.0			2936 (7.9%)
6.0-6.9			21125 (56.5%)
7.0-7.9			9442 (25.3%)
8.0-8.9			2293 (6.1%)
≥ 9.0			1469 (3.9%)
Unknown			94 (0.3%)
Current use of lipid lowering drug			
No			9427 (25.2%)
Yes			27932 (74.8%)
LDL-Cholesterol (mmol/L)		2.1 (1.7-2.5) (37.8mg/dL) [30.6-45.0mg/dL]	
<1.8 (<32.4mg/dL)			11408 (30.5%)
1.8-2.5 (32.4-46.7mg/dL)			18262 (48.9%)
2.6-3.4 (46.8-61.3mg/dL)			5572 (14.9%)
>3.4 (>61.3mg/dL)			1747 (4.7%)
Unknown			370 (1.0%)
Triglycerides (mmol/L)		1.3 (0.9-1.8) (23.4mg/dL [16.2-34.0mg/dL])	
<1.7 (<30.6mg/dL)			26480 (70.9%)
≥ 1.7 (≥30.6mg/dL)			10865 (29.1%)
Unknown			14 (0.04%)
eGFR (ml/min/1.73m^2)		89.2 (73.5-98.7)	
≥ 90			18036 (48.3%)
60-89			15196(40.7%)
30-59			3927 (10.5%)
15-29			175 (0.5%)
<15			14 (0.04%)
Unknown			11 (0.03%)
Albuminuria (Urine ACR, mg/mmol) / **Proteinuria** (Urine PCR, mg/mg)			
Normoalbuminuria » Urine ACR <2.5 (male), <3.5 (female)			27822 (74.5%)
Microalbuminuria » Urine ACR 2.5-25 (male), 3.5-35 (female)			7454 (20.0%)

Macroalbuminuria » Urine ACR >25 (male), >35 (female)			1880 (5.0%)
For patients without Urine ACR:			
Normoproteinuria » Urine PCR <0.2			4 (0.01%)
Proteinuria » Urine PCR ≥ 0.2			14 (0.03%)
Unknown			185 (0.5%)
Presence of diabetic retinopathy			
No			29999 (80.3%)
Yes			7169 (19.2%)
Unknown			191 (0.5%)

*Abbreviations: BMI=Body Mass Index; HbA1c=Glycated haemoglobin A1c; LDL-C=Low Density Lipoprotein Cholesterol; TG=Triglycerides; eGFR=Estimated Glomerular Filtration Rate

Table 2: Prevalence of diabetic foot at-risk (N=37359).

IWGDF 2023 Foot Risk Category	Ulcer risk	Characteristics	Number (%)
0	Very low	No LOPS and No PAD	34459 (92.2%)
1	Low	LOPS or PAD	1619 (4.3%)
2	Moderate	LOPS+PAD, or LOPS+Foot deformity, or PAD+Foot deformity	1194 (3.2%)
3	High	LOPS or PAD, and one or more of the following: o History of a foot ulcer o A lower extremity amputation (minor or major) o End-stage renal disease	23 (0.1%)
Active Foot Ulcer Disease	-		64 (0.2%)

*LOPS=Loss of protective sensation (Either 1 or 2 abnormal feet peripheral neuropathy tests: 10g monofilament and biothesiometer)
†PAD=Peripheral artery disease (Either history of lower limb revascularization, symptoms of claudication or rest pain, or examination finding of ischaemic change of lower limb or abnormal foot pulse)
‡End-stage renal disease: Estimated glomerular filtration rate <15 ml/min/1.73m^2

pedis was not included in IWGDF foot risk category, it was a treatable condition and was a potential source of trauma that might trigger foot ulcer development.

Associated factors of diabetic foot at-risk

After excluding those patients with active foot ulcer disease, 37,295 patients were included in analysis of factors associated with diabetic foot at-risk. Missing values were replaced by multiple imputation method for data analysis.

The associated factors of diabetic foot at-risk (IWGDF foot risk category 1, 2, 3) were analysed using univariate analysis (Table 3). It revealed that age, gender, smoking status, BMI, history of hypertension, duration of diabetes, HbA1c, LDL-C, TG and eGFR levels, presence of albuminuria or proteinuria, and presence of diabetic retinopathy were related to diabetic foot at-risk with statistical significance.

This was followed by logistic regression (Table 4) to identify the significant variables of the factors associated with diabetic foot at-risk, i.e. comparing IWGDF foot risk category 0 with category 1, 2, 3 (foot at-risk)Patients who had regular physical activity of moderate intensity [OR 0.83, p=0.003], those taking lipid lowering drug [OR 0.87, p=0.006] and triglycerides ≥ 1.7mmol/L [OR 0.91, p=0.046] were found to have significant negative association, suggesting these groups are less likely associated with diabetic foot at-risk.

Discussion

In our study, around 1 in every 13 patients were classified in IWGDF foot risk category 1 or above, 4.3% patients were at low risk (IWGDF foot risk category 1), 3.2% patients were at moderate risk (IWGDF foot risk category 2) and 0.1% patients were at high risk (IWGDF foot risk category 3).

A study carried out in India [18] which used IWGDF foot risk category showed a prevalence of 51.8% patients with diabetic foot at-risk. In comparison, the prevalence of diabetic foot at-risk in our study was substantially lower. The lower prevalence might be attributed to a better diabetic control with lower mean HbA1c level (6.9% versus 7.8%), different ethnicities, and different levels of care (patients under primary, secondary and tertiary level care, versus patients under primary care in our study).

Patients with high HbA1c, obesity and current smoking and past history of smoking was found to be significantly associated with increased diabetic foot at-risk. This was in keeping with findings from previous studies of diabetic neuropathy (19, 21), the key component of diabetic foot at-risk. Among our patients, 35.5% patients had HbA1c controlled at or above 7%. With the advances and availability of new anti-diabetic drug treatment in recent years, we anticipated more patients to achieve personal target HbA1c and hence reduce the risk of developing diabetic foot ulcer. More than 50% of patients in our

Table 3: Univariate analysis of factors of diabetic foot at-risk (N=37295).

	IWGDF 2023 Foot Risk Category					
	0 (n=34459 unless specified)		1, 2, 3 (n=2836 unless specified)			
	Number (%)	Mean ± SD[1] / Median (IQR)[2]	Number (%)	Mean ± SD[1] / Median (IQR)[2]	OR (95% CI)	p-value
Age		65.9 ±10.4[1]		75.13 ± 9.70[1]	1.10(1.09-1.10)	<0.001*
Gender						<0.001*
Female	18588 (53.9)		1094 (38.6)		1	
Male	15871 (46.1)		1742 (61.4)		1.87(1.72-2.02)	
Smoking status						<0.001*
Smoker	3716 (10.8)		332 (11.7)		1.29(1.14-1.46)	
Ex-smoker	6010 (17.4)		795 (28.0)		1.91(1.75-2.09)	
Non-smoker	24733 (71.8)		1709 (60.3)		1	
BMI (kg/m^2) (N=37241 0: n=34431, 1,2,3: n=2810)		25.2 (22.9-27.8)[2]		24.9 (22.7-27.4)[2]		<0.001*
<18.5 (Underweight)	581 (1.7)		77 (2.7)		1.55(1.21-1.99)	<0.001*
18.5-22.9 (Normal)	8449 (24.5)		721 (25.7)		1	
23-24.9 (Overweight)	7498 (21.8)		652 (23.2)		1.02(0.91-1.14)	
≥ 25 (Obese)	17903 (52.0)		1360 (48.4)		0.89(0.81-0.98)	
Regular physical activity of moderate intensity						0.004*
No	29499 (85.6)		2484 (87.6)		1	
Yes	4960 (14.4)		352 (12.4)		0.84(0.75-0.95)	
History of hypertension						<0.001*
No	5367 (15.6)		258 (9.1)		1	
Yes	29092 (84.4)		2578 (90.9)		1.84(1.62-2.10)	
Duration of diabetes (years) (N=37294)		7.0 (3.0-13.0)[2]		10.0 (4.0-16.0)[2]		<0.001*
< 5	12494 (36.26)		758 (26.73)		1	<0.001*
5-10	10100 (29.31)		719 (25.35)		1.17(1.06-1.30)	
>10-20	9563 (27.75)		1022 (36.04)		1.76(1.60-1.94)	
>20	2301 (6.68)		337 (11.88)		2.41(2.11-2.77)	
HbA1c (%) (N=37201)						<0.001*
<6.0	2680 (7.8)		247 (8.7)		1.25(1.08-1.43)	
6.0-6.9	19640 (57.1)		1453 (51.3)		1	
7.0-7.9	8664 (25.2)		764 (27.0)		1.19(1.09-1.31)	
8.0-8.9	2092 (6.1)		197 (7.0)		1.27(1.09-1.49)	
≥ 9.0	1293 (3.8)		171 (6.0)		1.79(1.51-2.12)	
Current use of lipid lowering drug						0.184
No	8724 (25.3)		686 (24.2)		1	
Yes	25735 (74.7)		2150 (75.8)		1.06(0.97-1.16)	
LDL-C (mmol/L) (N=36926)						<0.001*
<1.8 (<32.4mg/dL)	10285 (30.15)		1100 (39.12)		1.40(1.29-1.52)	
1.8-2.5 (32.4-46.7mg/dL)	16963 (49.65)		1293 (45.98)		1	
2.6-3.4 (46.8-61.3mg/dL)	5228 (15.33)		339 (12.06)		0.85(0.75-0.96)	
>3.4 (>61.3mg/dL)	1665 (4.88)		80 (2.84)		0.63(0.50-0.79)	
TG (mmol/L) (N=37281)						<0.001*
<1.7 (<30.6mg/dL)	24308 (70.6)		2126 (75.0)		1	
≥ 1.7 (≥ 30.6mg/dL)	10140 (29.4)		707 (25.0)		0.80(0.73-0.87)	
eGFR (ml/min/1.73m^2) (N=37284)						<0.001*
≥ 90	17273 (50.14)		734 (25.90)		1	
60-89	13759 (39.94)		1416 (49.96)		2.42(2.21-2.66)	
30-59	3276 (9.51)		640 (22.58)		4.6(4.11-5.14)	
15-29	129 (0.37)		43 (1.52)		7.84(5.51-11.16)	
<15	13 (0.04)		1 (0.04)		1.81(0.24-13.86)	
Presence of Albuminuria or Proteinuria						<0.001*
No	26303 (76.3)		1674 (59.0)		1	
Yes	8156 (23.7)		1162 (41.0)		2.24(2.07-2.42)	
Presence of Diabetic Retinopathy (N=37105)						<0.001*
No	27846 (81.2)		2119 (75.3)		1	
Yes	6444 (18.8)		696 4.7)		1.42(1.30-1.55)	

†Albuminuria (Urine albumin creatinine ratio ≥ 2.5 mg/mmol for male, ≥ 3.5 mg/mmol for female)
‡Proteinuria (Urine protein creatinine ratio ≥ 0.2 mg/mg)

Table 4: Multivariate logistic regression analysis for association of factors of diabetic foot at-risk.

Associated factors	OR	95% CI	p-value
Male	1.99	1.80-2.20	<0.001*
Age	1.10	1.09-1.10	<0.001*
Smoking status			
Smoker	1.25	1.09-1.44	0.002*
Ex-smoker	1.15	1.03-1.28	0.013*
BMI (Ref: normal BMI)			
Underweight	1.30	0.99-1.70	0.055
Overweight	1.04	0.93-1.17	0.484
Obese	1.14	1.03-1.26	0.015*
Regular physical activity of moderate intensity	0.83	0.74-0.94	0.003*
Duration of diabetes, years (Ref: <5 years)			
5-10	0.92	0.83-1.03	0.171
>10-20	1.00	0.90-1.12	0.997
>20	0.97	0.83-1.14	0.731
HbA1c, % (Ref: 6.0 – 6.9)			
<6	1.08	0.93-1.26	0.299
7.0-7.9	1.14	1.04-1.26	0.007*
8.0-8.9	1.30	1.10-1.54	0.002*
≥ 9.0	2.00	1.66-2.40	<0.001*
Current use of lipid lowering drug	0.87	0.79-0.96	0.006*
LDL-C, mmol/L (Ref: 1.8 – 2.5 mml/L [32.4-46.7mg/dL])			
<1.8 (<32.4mg/dL)	1.11	1.01-1.21	0.024*
2.6-3.4 (46.8-61.3mg/dL)	1.02	0.89-1.16	0.803
>3.4 (>61.3mg/dL)	0.96	0.75-1.23	0.734
TG ≥ 1.7 mmol/L (≥30.6mg/dL)	0.91	0.82-1.00	0.046*
History of hypertension	0.95	0.82-1.10	0.485
Presence of diabetic retinopathy	1.47	1.34-1.62	<0.001*
Presence of Albuminuria or Proteinuria	1.37	1.26-1.50	<0.001*
eGFR, ml/min/1.73m^2 (Ref: >= 90)			
60-89	1.00	0.90-1.11	0.975
30-59	1.08	0.94-1.24	0.285
15-29	1.37	0.93-2.02	0.11
<15	0.49	0.06-3.86	0.496

*p<0.05
‡Hosmer and Lemeshow goodness-of-fit test: Chi-square statistics=13.540, df=8, p=0.095
Nagelkerke R-square=0.171

study were obese, which was classified as BMI ≥ 25 kg/m^2 in Chinese adults in Hong Kong. Regular physical activity of moderate intensity was found to be a protective factor in this study. However, among our subjects, only around 14% patients adopted this healthy lifestyle. This highlighted the importance of promotion of regular moderate intensity exercise and body weight control for our diabetic patients. Current smoking and past history of smoking were also found to be significantly associated with diabetic foot at-risk. Therefore, it is crucial to maintain smoking prevention campaign efforts.

High LDL-C level was previously found to have small association with diabetic neuropathy in meta-analysis [21]. On the contrary, low LDL-C level group (<1.8 mmol/L [<32.4mg/dL]) was found to be more likely in IWGDF foot risk category 1 to 3 in our study. This might be explained by the fact that stricter LDL-C target was adopted for secondary prevention in patients with established cardiovascular disease. Hence, patients in low LDL-C level group might in fact had underlying cardiovascular comorbidities. This was also supported by the finding that lipid lowering drug was found to be a protective factor in this study. High triglyceride level group (≥ 1.7 mmol/L[≥ 30.6mg/dL]) was found to be less likely in IWGDF foot risk category 1 to 3 in our study. In meta-analysis of diabetic neuropathy, hypertriglyceridaemia was not found to be a significant associated factor [21]. The reason of this finding in our study is unclear, but it might be possible that more patients in at-risk groups had stricter LDL control due to underlying cardiovascular comorbidities, therefore were on higher strength of lipid lowering drugs, which had more lowering effect on triglyceride. Future prospective study would be helpful in providing more information in this area.

Presence of diabetic retinopathy was demonstrated to have significant association with diabetic foot at-risk in our study, in keeping with findings from studies on risk factors of diabetic foot ulcer and diabetic neuropathy [3,20,21]. Presence of albuminuria

or proteinuria was also found to have significant association with diabetic foot at-risk in our study. Together, these support the need to achieve better diabetic control in prevention of concurrent micro- and macrovascular complications.

Our study provided new data on the epidemiological characteristics on diabetic foot at-risk in primary care. With better understanding on the current situation of diabetic foot at-risk, we hope this could contribute to a reduction of foot ulcer disease and hence the devastating outcome of limb amputation in diabetic patients by strengthening the preventive measures. For instance, since around 70% of our diabetic patients were overweight or obese, providing additional support for weight reduction such as motivation, education and structured weight reduction programs could be highly beneficial. Since approximately 20% of our diabetic patients were either smokers or ex-smokers, enhancing smoking cessation campaigns and providing robust support for quitting smoking could be beneficial in preventing diabetic foot at-risk in our locality. Diabetic patients being identified with foot at-risk would require more frequent foot screening. As a guidance, IWGDF 2023 suggested the following frequency of foot screening in accordance to the category of diabetic foot at-risk: annually for category 0, 6 to 12 monthly for category 1, 3 to 6 monthly for category 2, and 1 to 3 monthly for category 3. Also, patients with foot at-risk require a more focused approach with special attention on assessment and management on pre-ulcerative conditions including callus, infection, fissure and foot deformity. This would require a proactive approach by a multi-disciplinary team including primary care physicians, diabetes nurses and podiatrists.

Limitations

Several limitations were acknowledged in our study. Firstly, this study could not assess other co-existing causes of neuropathy other than diabetes, such as vitamin B12 deficiency, syphilis infection, autoimmune disease, etc. Secondly, the establishment of causal relationship between the associated risk factors and diabetic foot-at risk was limited by the cross-sectional design of this study. Thirdly, the retrospective design of our study poses a limitation, as it restricts the collection of data on other potentially relevant associated factors, as well as limiting the ability to establish the causal relationships between the associated factors and the observed outcomes. Lastly, our study subjects were recruited from eight government out-patient clinics situated in two districts in Hong Kong. This might limit the generalisability of results to the whole population in Hong Kong.

Conclusion

Our study demonstrated a prevalence of 7.6% foot at-risk among diabetic patients in primary care. Male gender, older age, history of smoking, obesity, poor glycaemic control, presence of diabetic retinopathy, presence of albuminuria or proteinuria were shown to have significant association with diabetic foot at-risk. Regular physical activity of moderate intensity, and use of lipid lowering drug were shown to have protective effect on diabetic foot at-risk. Modifiable risk factors should be identified at early stages with effort to improve control in preventive care stage. Patients with foot at-risk require more frequent foot screening and a focused approach to manage pre-ulcerative condition. In line with this, the IWGDF 2023 guideline recommend tailoring the frequency of foot screening based on the risk category of diabetic foot, although adjustments may be necessary based on local resource availability. Such an approach necessitates proactive engagement by primary care physicians, and coordinated care involving a multi-disciplinary team including diabetes nurses and podiatrists.

Ethics Approval

This study was approved by the Research Ethics Committee (Kowloon Central/Kowloon East), Hospital Authority Hong Kong on 30/09/2022 (Ref: KC/KE-22-0151/ER-1). This study was conducted in compliance with the Declaration of Helsinki. This was a retrospective study, and the need for patients' consent to participate was waived by Research Ethics Committee (Kowloon Central/Kowloon East), Hospital Authority Hong Kong.

Consent for Publication

Not applicable

Availability of Data and Materials

The data and materials of this study are available from the corresponding author on reasonable request.

Competing Interests

All authors declare that they have no competing interests.

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No funding was received for conduction of this study.

Clinical Trial Number

Not Applicable.

Authors' Contributions

Dr. Suen Victoria G. K. was the principal investigator who wrote the manuscript. Dr. Chan Pang Fai, Dr. Lai Kit Ping Loretta contributed to the development of the protocol of this study, the data analysis and interpretation. They also edited the manuscript and made significant contribution in improvement of the content. Dr. Lai Kit Ping Loretta, Dr. Fung Hoi Tik, Dr. Luk Man Hei Matthew contributed on data collection. Dr. Luk Man Hei Matthew contributed on design of this study, analysis and interpretation of the data.

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