

# Prevalence of Diabetic Foot Ulcers and Risk Classifications in Type 2 Diabetes Mellitus Patients at Rajavithi Hospital

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**Background:** Diabetic foot ulcers are a major cause of non-traumatic lower limb amputation in patients with type 2 diabetes. In 2014, the Diabetes Association of Thailand issued new guidelines for classifying type 2 diabetes patients' levels of risk of developing foot ulcers, but no research on the prevalence of type 2 diabetes using these new classification criteria had been performed prior to the current study.

**Objective:** To study the prevalence of diabetic foot ulcers overall and in different risk groups in type 2 diabetes mellitus patients in Rajavithi Hospital, and to evaluate risk factors of these groups and correlations with ankle brachial index (ABI) and cardio-ankle vascular index (CAVI).

**Material and Method:** 593 type 2 diabetes patients at Rajavithi Hospital were studied and classified into risk groups based on the classification criteria issued by the Thailand Diabetes Association in 2014. ABI measurements were taken from 132 patients, and measurements of CAVI were taken from 101 patients.

**Results:** The prevalence of foot ulcers was 3.4% and 2.2% of patients had a history of amputation. The percentages of patients at low, intermediate and high risk of developing foot ulcers were 55.8%, 33.6% and 10.6%, respectively. Age, duration of diabetes, estimated glomerular filtration rate (eGFR), history of hypertension, dyslipidemia, nephropathy, cardiovascular disease (CVA), deformity of foot, numbness, abnormal protective sensation, pulse deficit, ulcer, and amputation were factors significantly associated with a high risk of foot ulcers ( $p < 0.05$ ), but fasting plasma glucose (FPG) and HbA1c were not significant factors. There was an association between cerebrovascular accident and abnormal ABI.

**Conclusion:** Nearly half of these type 2 diabetes patients were in the groups with an intermediate or high risk of developing foot ulcers. Screening of patients at risk of foot ulceration is necessary in order to classify patients into risk groups and provide appropriate education, as well as proper monitoring and management.

**Keywords:** Foot ulcer, Type 2 diabetes, ABI, CAVI

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Type 2 diabetes mellitus is a major health problem the world over. The International Diabetes Federation estimates that there will be 552 million patients with diabetes mellitus and a further 398 million patients at risk of developing it by the year 2030<sup>(1)</sup>. The UK Prospective Diabetes Study (UKPDS) found that type 2 diabetes mellitus was a progressive disease.

The lifetime risk of foot ulcers in diabetic

patients may be as high as 25%<sup>(2)</sup>, and type 2 diabetes mellitus is the most common cause of non-traumatic lower limb amputation. Pathophysiology of diabetic foot ulcers are infectious, neuropathic and ischemic ulcers. The risk factors<sup>(3-8)</sup> of foot ulcers are the history of foot ulcers or amputation, neuropathy, vasculopathy, impaired vision, foot deformities, callus, nail deformities, unsuitable footwear, long duration of diabetes, poor control of glucose, smoking and diabetic nephropathy. Identification of lower limb amputation risk factors and education about foot care can reduce the number of amputations<sup>(9)</sup>. The Thai guidelines for foot care for diabetic patients issued in 2014 classified the risk of lower limb amputation in patients with foot ulcers into three groups: low risk, intermediate risk, and high risk.

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A team approach towards wound care prevents limb amputation, and foot examination should be carried out every year in low-risk patients, every 1-6 months in patients at intermediate risk, and at each visit in patients in the high-risk group. Foot examination and education about foot care may improve outcomes and prevent incidences of amputation. There have been some studies of the prevalence of diabetic foot ulcers in Thailand, but this is the first research performed to examine the prevalence of foot ulcers in risk groups based on classification guideline issued by the Diabetes Association of Thailand in 2014. The objective of this study was to determine the prevalence of foot ulcers and to classify patients into groups at different levels of risk of foot amputation according to these guidelines<sup>(10)</sup>.

### Material and Method

This was a cross-sectional study of patients with type 2 diabetes mellitus at Rajavithi Hospital, a tertiary care hospital, in which the authors collected baseline characteristics and foot ulcer, risk data. Based on the Diabetes Association of Thailand's guideline issued in 2014 for diabetic foot ulcer management (Fig. 1), the patients were classified into three risk groups for developing foot ulcers: low, intermediate and high.

### Sample size

$$n = \frac{Z_{\omega/2}^2 p(1-p)}{d^2}$$

The value of  $\alpha = 0.05$

$$Z_{\omega/2} = 1.96$$

$p =$  The Thailand Diabetes Registry study found that the prevalence of foot ulcers in these patients was 5.9%.

$$d = 2\%$$

$$n = \frac{1.96^2 \times 0.059 \times (1 - 0.059)}{0.02^2} = 533.2$$

The total number of patients required was 534. Allowing for 10% missing data, the minimum sample size to be used in this study was calculated as 586 patients.

### Inclusion criteria

#### Patients who:

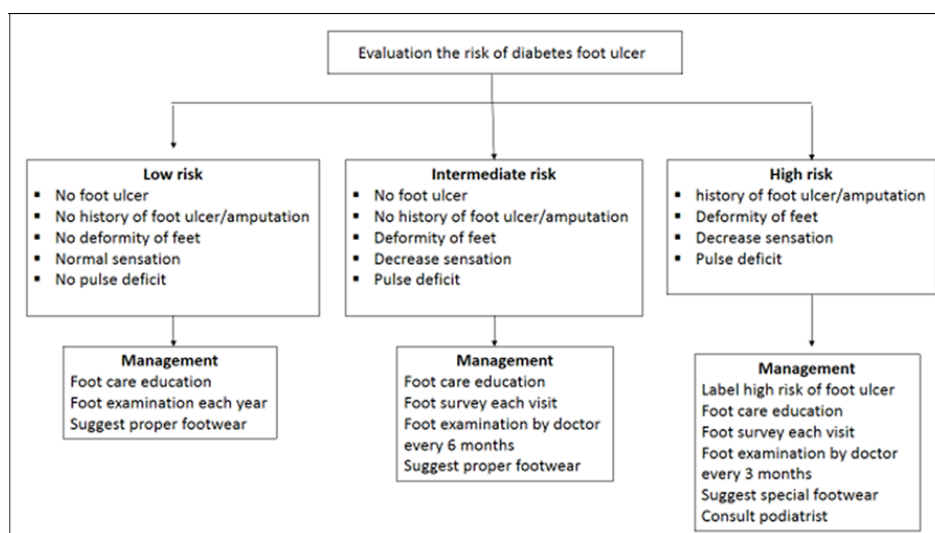
- 1) Were type 2 diabetes mellitus patients at Rajavithi Hospital.
- 2) Were over 18 years old.
- 3) Had signed informed consent forms.

### Exclusion criteria

Other types of diabetes mellitus (type 1 DM, gestational diabetes, and secondary diabetes mellitus) were excluded from this study.

### Screening for risk of foot ulcers

The authors collected data on baseline characteristics and foot ulcer risk factors including history of previous foot ulcer; deformity of foot determined by physical examination; numbness; fungal



**Fig. 1** Guidelines issued by the Diabetes Association of Thailand in 2014 for the evaluation and management of diabetic foot ulcers.

infection of foot; vascular insufficiency detected by palpation pulse of anterior tibial arteries and posterior peroneal arteries in both feet; and protective sensation test performed in accordance with the Diabetes Association of Thailand's guidelines issued in 2014 using the Semmes-Weinstein 5.07 Monofilament Test. The results of glycemic control and other micro or macrovascular complications were recorded.

The following laboratory tests were performed: FPG, HbA1c, serum Cr and estimated glomerular filtration rate (eGFR). Some patients over 60 years old were tested for ankle brachial index (ABI) and cardio-ankle vascular index (CAVI) in order to determine their risk of arterosclerosis.

### **Operative definitions**

#### **Classification of foot ulcer risk**

Following the issuance of Thai guidelines for risk of foot ulcers in diabetes, we classified diabetes patients into three groups: low risk, intermediate risk and high risk. The low-risk group consisted of diabetes mellitus patients with no history of foot ulcers or amputation and who had normal foot examination (no deformity, normal sensation and pulse examination). The intermediate-risk group comprised diabetes mellitus patients who had no history of foot ulcer or amputation, but found to have abnormal protective sensation or pulse deficit from foot examination. The high-risk group was composed of diabetes mellitus patients with a history of foot ulcer or amputation, deformity of foot, or abnormal sensation or pulse examination.

#### **Ankle brachial index (ABI)**

Ankle brachial index (ABI) is one of the tests used for predicting atherosclerosis. In this study, abnormal ABI was defined as an ABI measurement of less than 0.9.

#### **Cardio-ankle vascular index (CAVI)**

Cardio-ankle vascular index (CAVI) is a method of determining stiffness of arteries and atherosclerosis of thoracic, abdominal, common iliac, femoral and tibial arteries independent of blood pressure<sup>(11-13)</sup>. Abnormal CAVI is defined as CAVI equal to or more than 9 and leads to diagnosis of suspected atherosclerosis<sup>(14)</sup>. A few studies have reported that CAVI has a high sensitivity in detecting diabetic complications<sup>(15,16)</sup>.

#### **Primary research question**

The primary research question was to determine the proportions of diabetes mellitus type 2

patients with foot ulcers as well as those at risk of developing them.

#### **Secondary research question**

The secondary research question was to determine the risk factors of foot ulcers in type 2 diabetes mellitus patients, and their association with foot ulcers, and to determine the relationship between macrovascular risk factors and abnormal ABI and CAVI.

#### **Statistical analysis**

Statistical analysis was performed with the SPSS version 17.0. Descriptive statistics such as numbers, percentages, means and SD were used to describe baseline characteristics. Chi-square test was performed to compare the risk factors of foot ulcers based on categorical variables.

#### **Results**

The baseline characteristics of the 593 type 2 diabetic patients are shown in Table 1. The percentages of patients in the groups at low risk, intermediate risk and high risk of developing foot ulcers were 55.8%, 33.6%, and 10.6% respectively. The prevalence of ulcers was 3.4%, and 2.2% of the patients had a history of amputation, and 9 (69.2%) of these 13 patients underwent amputation of a toe, which was the most common amputation location. Three patients (23.1%) had undergone above-knee amputation, and one patient (7.7%) had had a below-knee amputation. There was a higher prevalence of hypertension, nephropathy, cardiovascular disease (CVD), cerebrovascular disease (CVA), foot deformity, and loss of protective sensation in the intermediate- and high-risk groups than in the low-risk group. Factors that were significantly associated with risk of foot ulcer included age, duration of diabetes, eGFR, history of hypertension, dyslipidemia, nephropathy, CVA, deformity of foot, numbness, abnormal protective sensation, pulse deficit, ulcer and amputation ( $p < 0.05$ ), whereas FPG and HbA1c were not significantly associated.

The risk factors of CVD, CVA and amputation for abnormal ABI and CAVI patients are shown in Table 2. There was a significant association between CVA and ABI, but no significant association was found between any other cardiovascular risk factors or history of amputation and ABI and CAVI.

Table 3 shows the ABI and CAVI of type 2 patients at risk of developing foot ulcers. There was no abnormal ABI in the low-risk group, but it was at 7.1% in the moderate- and high-risk groups. In the low-risk

**Table 1.** Baseline characteristics of type 2 diabetes patients based on Thai guidelines 2014

	Low risk	Intermediate risk	High risk	Total
Number (%)	331 (55.8)	199 (33.6)	63 (10.6)	593 (100)
Age <sup>*#</sup>	61.32±14.20	66.90±10.60	67.00±16.60	63.80±13.70
Sex				
Male	124 (37.5)	60 (30.2)	22 (34.9)	206 (34.7)
Female	207 (63.5)	139 (68.8)	41 (65.1)	387 (65.3)
Duration (m) <sup>*#</sup>	140.50±98.90	181.20±105.30	178.80±111.40	158.00±104.20
FPG	142.10±47.40	137.20±48.00	146.50±46.30	141.00±47.50
HbA1c	7.70±4.10	8.50±9.40	7.80±1.40	8.00±6.30
eGFR <sup>*#</sup>	73.00±28.00	59.70±25.40	61.90±33.00	67.80±28.40
Smoking	27 (8.2)	23 (11.6)	5 (7.9)	55 (9.3)
HT <sup>*#</sup>	235 (71.0)	182 (91.5)	56 (88.9)	473 (79.8)
Dyslipidemia <sup>*</sup>	256 (77.3)	174 (87.4)	50 (79.4)	480 (80.9)
Nephropathy <sup>*#</sup>	24 (7.4)	36 (19.7)	14 (13.1)	75 (13.1)
CVD	56 (16.9)	46 (23.1)	13 (20.6)	115 (19.4)
CVA <sup>#</sup>	25 (7.6)	35 (17.6)	9 (14.3)	69 (11.6)
Deformity of foot <sup>#</sup>	2 (0.6)	7 (3.7)	39 (61.9)	48 (8.2)
Fungal infection	6 (1.8)	17 (9)	4 (6.6)	27 (4.7)
Numbness <sup>*#</sup>	78 (33.5)	121 (60.8)	34 (54.0)	233 (39.5)
Pulse deficit <sup>*</sup>	0 (0.0)	73 (36.7)	15 (23.8)	88 (14.8)
Abnormal protection sense <sup>*#</sup>	0 (0.0)	133 (67.2)	25 (40.3)	158 (30.2)
Ulcer <sup>#</sup>	0 (0.0)	0 (0.0)	20 (31.7)	20 (3.4)
Amputation <sup>#</sup>	0 (0.0)	0 (0.0)	13 (20.6)	13 (2.2)

Values are represented as n (%) and mean ± SD

\* significant risk factor  $p < 0.05$  between low risk group and intermediate risk group

# significant risk factor  $p < 0.05$  between low risk group and high risk group

+ significant risk factor  $p < 0.05$  between intermediate risk group and high risk group

group, the incidence of abnormal CAVI was 63%, while it was at 50% in the moderate-risk group, and 42.6% in the high-risk group. ABI is better than CAVI in classifying the risk of developing foot ulcers.

## Discussion

The results of the Thailand Diabetes Registry Project<sup>(17,18)</sup> indicated that the prevalence of diabetic foot ulcers in 11 tertiary hospitals was 5.9%. It was also found that 1.5% of diabetes patients had a history of amputation, and the most common location of amputation was the toe (32%).

In contrast, the result of this study shows that the prevalence of diabetic foot ulcers was 3.4% and 2.2% of patients had a history of amputation. In line with the results of the Thailand Diabetes Registry Project, we found that the toe was the most common site of amputation (69.2%).

With regard to the clinical application of this study, our results showed that the proportion of patients at intermediate and high risk of foot ulceration was as

high as 44.2%. The recommendations for follow-up and education in accordance with the 2014 Thai guidelines are different for each group and relate to the frequency of foot examination, foot education, and advice about proper footwear in order to reduce the risk of amputation. The team approach for wound care prevents limb amputation, and the recommendations are foot examination every year for patients at low risk of developing foot ulcers, every 1-6 months for those at intermediate risk, and at each visit for patients at high risk. The American Diabetes Association (ADA) also recommends foot examination at each visit for patients at high risk of developing foot ulcers<sup>(19)</sup>.

The strength of this study is that it is the first one performed to determine the prevalence of diabetic foot ulcer in patients in the three risk groups defined by the guidelines of the Diabetes Association of Thailand issued in 2014.

A limitation of this study is that the authors could not measure ABI and CAVI for every case of type 2 diabetes, and patients whose ABI and CAVI

**Table 2.** Comparing cardiovascular risk factors between ABI and CAVI

Risk factor	ABI test			CAVI test		
	Normal	Abnormal	p-value	Normal	Abnormal	p-value
Hypertension						
No	10 (100.0)	0 (0.0)	0.470	4 (80.0)	1 (20.0)	0.074
Yes	116 (95.1)	6 (4.9)		38 (39.6)	58 (60.4)	
Dyslipidemia						
No	12 (100.0)	0 (0.0)	0.430	1 (33.3)	2 (66.7)	0.768
Yes	114 (95.0)	6 (5.0)		41 (41.8)	57 (58.2)	
Smoking						
No	116 (95.1)	6 (4.9)	0.470	38 (41.3)	54 (58.7)	0.855
Yes	10 (100.0)	0 (0.0)		4 (44.4)	5 (55.6)	
Nephropathy						
No	83 (95.6)	3 (3.5)	0.990	27 (46.6)	31 (53.4)	0.151
Yes	35 (92.1)	3 (7.9)		11 (31.4)	24 (68.6)	
CVD						
No	109 (95.6)	5 (4.4)	0.830	40 (43.5)	52 (56.5)	0.217
Yes	17 (94.4)	1 (5.6)		2 (22.2)	7 (77.8)	
CVA						
No	120 (96.8)	4 (3.2)	0.004	40 (41.2)	57 (58.8)	0.727
Yes	6 (75.0)	2 (25.0)		2 (50.0)	2 (50.0)	
Loss of protective sensation						
No	90 (96.8)	3 (3.2)	0.260	30 (43.5)	39 (56.5)	0.571
Yes	36 (92.3)	3 (7.7)		12 (37.5)	20 (62.5)	
Foot ulcer						
No	120 (95.2)	6 (4.8)	0.699	38 (40.0)	57 (60.0)	0.355
Yes	3 (100.0)	0 (0.0)		2 (33.3)	1 (66.7)	
Amputation						
No	124 (95.4)	6 (4.6)	0.760	41 (41.4)	58 (58.6)	0.807
Yes	2 (100.0)	0 (0.0)		1 (50.0)	1 (50.0)	

\* significant risk factor  $p < 0.05$ , values are represented as n (%) and mean  $\pm$  SD

**Table 3.** Comparing the ABI and CAVI of type 2 diabetes patients at different levels of risk of developing foot ulcers

Group of foot ulcer risk	ABI test (n = 132)		CAVI test (n = 101)	
	Normal	Abnormal	Normal	Abnormal
Low	48 (100.0)	0 (0.0)	11 (36.7)	19 (63.3)
Moderate	65 (92.9)	5 (7.1)	29 (50.0)	29 (50.0)
High	13 (92.9)	1 (7.1)	7 (53.8)	6 (42.6)
Total	126 (95.5)	6 (4.5)	47 (46.9)	54 (53.5)

Values are presented as n (%)

were measured were mostly over 60 years old. If we had been able to take measurements from younger patients, the results of ABI and CAVI might have been closer to the normal range; however, comparison of

ABI and CAVI was not the primary objective of this study.

Further studies comparing ABI and CAVI with cardiovascular disease should be done in the future to

determine which test has the highest sensitivity and specificity for diabetes patients.

#### **What is already known on this topic ?**

Prevalence of foot ulcer classification in type 2 diabetic patients.

Risk factors of foot ulcers in type 2 diabetes.

#### **What this study adds ?**

Data on the prevalence of foot ulcers in the risk groups defined by the 2014 guidelines issued by the Diabetes Association of Thailand for foot care and management. A comparison of ankle brachial index (ABI) and cardio-ankle vascular index (CAVI) in these different risk groups, and CVD risk factors.

#### **Acknowledgement**

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#### **Potential conflict of interest**

None.

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## ความชุกของการเกิดแผลที่เท้าและการแบ่งตามกลุ่มความเสี่ยงต่อการเกิดแผลในผู้ป่วยโรคเบาหวานชนิดที่ 2 ในโรงพยาบาลราชวิถี

วีระศักดิ์ ศรีนภากร, ทองคำ สุนทรเทพวรากล, ชัยชาญ ดีโรจนวงศ์, สติชัย นิรมิตรมหาปัญญา, นวพร นภาทิ้วอำนวย

ภูมิหลัง: แผลที่เท้าในผู้ป่วยโรคเบาหวานชนิดที่ 2 เป็นสาเหตุสำคัญในการถูกตัดส่วนของขาที่ไม่ได้มีสาเหตุจากอุบัติเหตุ ได้มีการแบ่งกลุ่มความเสี่ยงของการเกิดแผลที่เท้าตามแนวทางของประเทศไทยปี พ.ศ. 2557 แต่ยังไม่มีการศึกษาถึงความชุกของผู้ป่วยตามความเสี่ยงต่อการเกิดแผลตามแนวทางดังกล่าว

วัตถุประสงค์: เพื่อศึกษาความชุกของการเกิดแผลที่เท้าและการแบ่งกลุ่มตามความเสี่ยงในผู้ป่วยโรคเบาหวานชนิดที่ 2 ที่โรงพยาบาลราชวิถี และศึกษาความสัมพันธ์ระหว่าง ankle brachial index (ABI) และ cardio-ankle vascular index (CAVI) กับปัจจัยเสี่ยงตามกลุ่มความเสี่ยง

วัสดุและวิธีการ: ศึกษาผู้ป่วยโรคเบาหวานชนิดที่ 2 จำนวน 593 ราย ที่โรงพยาบาลราชวิถีและได้แบ่งความเสี่ยงผู้ป่วยตามแนวทางการรักษาของประเทศไทย ปี พ.ศ. 2557 ผู้ป่วยโรคเบาหวานชนิดที่ 2 ได้รับการตรวจ ankle brachial index (ABI) จำนวน 132 ราย และ cardio-ankle vascular index (CAVI) 101 ราย

ผลการศึกษา: ความชุกของการมีแผลที่เท้าเป็น 3.4% มีผู้ป่วย 2.2% มีประวัติตัดส่วนของเท้า ความชุกของกลุ่มที่มีความเสี่ยงต่อการเกิดแผลที่เท้าต่ำ, ปานกลางและสูงเป็น 55.8%, 33.6% และ 10.6% ตามลำดับ ปัจจัย อายุ, ระยะเวลาที่เป็นโรคเบาหวาน, eGFR, ความดันโลหิตสูง, ไขมันสูง, โรคไต, โรคหลอดเลือดสมอง, ความผิดปกติของเท้า, การเสียความรู้สึกที่เท้า, คล้ำซีพอร์ไม่ได้, การมีแผลและประวัติการถูกตัดส่วนของเท้ามีความสัมพันธ์กับกลุ่มความเสี่ยงของการเกิดแผลที่เท้าสูงอย่างมีนัยสำคัญ ( $p < 0.05$ ) แต่ค่าน้ำตาลก่อนอาหารและระดับ HbA1c ไม่สัมพันธ์กับความเสี่ยงต่อการเกิดแผลที่เท้าและพบว่าความผิดปกติของ ABI มีความสัมพันธ์กับโรคหลอดเลือดสมอง

สรุป: ผู้ป่วยประมาณเกือบครึ่งหนึ่งของผู้ป่วยโรคเบาหวานชนิดที่ 2 เป็นกลุ่มที่มีความเสี่ยงต่อการเกิดแผลที่เท้าปานกลางและสูง การคัดกรองความเสี่ยงของการเกิดแผลเป็นสิ่งจำเป็นและการแบ่งกลุ่มตามความเสี่ยงเพื่อให้ความรู้ การติดตามและการรักษาอย่างเหมาะสม

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