Underrecognition and Undertreatment for Peripheral Arterial Disease in Diabetic Patients in Thailand

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Objective: *Although several guidelines emphasized the importance of atherosclerotic risk factor management in peripheral arterial disease (PAD) in diabetic patients to reduce the cardiovascular mortality, authors do not know to what extent physicians follow these guidelines.*

Material and Method: *Between May 2014 and August 2014, consecutive eligible outpatients, aged ≥45 years with established DM, were invited to be involved in this study. History, physical exam and laboratory test were reviewed. Ankle brachial index ≤0.9 was considered PAD. Then patients were evaluated the percentage of risk factor control according to American Heart Association (AHA) criteria. The good control was defined that patients have adequate risk factor control between 3-5 factors.*

Results: *2,247 diabetic patients were recruited for the study. 286 patients out of 2,247 were diagnosed PAD (12.7%). 236 PAD patients (82.5%) did not have any symptom of intermittent claudication, rest pain, gangrene or ulcer. According to AHA criteria, the percentage of adequate control in low density lipoprotein, HbA1C and systolic blood pressure in PAD patients was 18.9, 30.1 and 33.2% respectively. 49.8% in PAD patients had met our good risk factor control criteria.*

Conclusion: *Most PAD in diabetic patients was asymptomatic. The atherosclerotic risk factor control was poor in this group.*

Keywords: *peripheral arterial disease, diabetes, risk factor, ankle brachial index*

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Peripheral arterial disease (PAD) in diabetic patients carry high morbidity and mortality from cardiovascular events, namely myocardial infarction and stroke[1,2]. In our previous study, the 3 year mortality of diabetic patients with ischemic ulcer (severe PAD) was 56.5%[3]. All causes of death in this study were due to myocardial infarction. Our series appear to be more aggressive than those diabetic patients with CLI in literatures, with whom the 5 years mortality in diabetic patients with critical limb ischemia is around 30%[4-7].

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Based on many trials and guidelines, including the American Heart Association (AHA) guidelines, the benefit of risk factors control in patients with PAD in terms of cardiovascular event, i.e. blood pressure, smoking, blood sugar, and obesity is well established[5-7]. Therefore, early detection of PAD is important because this can facilitate atherosclerotic risk factor modification and consequently reduce progression and improve outcome. However, authors do not know to what extent physicians follow these guidelines. In the prevalence of PAD in DM there is still uncertainty in Asia, which is range from 12-60%[8-13]. Therefore, this study aimed to investigate the prevalence of PAD in DM patients in our region of Northern Thailand. The authors also reviewed the extent of awareness of PAD diagnosis and the adherence to the guidelines in

risk factor control in this population. This study was determined to identify the risk factors associated with the adherence of guidelines in diabetic patients with PAD, which had not been previously explored.

Material and Method

The authors set a cross sectional study to recruit diabetic patients in 3 major provinces in the upper northern part of Thailand: Maharaj Nakorn Chiang Mai Hospital (a University hospital, Tertiary care), Lamphun Hospital (the general hospital in Lumphun province), and Chiangrai Prachanukroh Hospital (the general hospital in Chiangrai province). Based on the Leelawattana study[10] the sample size needed to study the prevalence of PAD in diabetic patients was 2,200 cases. Between May 2014 and August 2014, consecutive eligible outpatients, aged 45 years or over with established DM, were invited to be involved in this study. After agreement, patients signed an informed consent. First, patients were asked to give information about their demographic data. Then researchers asked if the patients had any symptoms of PAD, such as intermittent claudication, rest pain, gangrene, or ulcers. The questions also included smoking history, awareness of cerebrovascular disease, ischemic heart disease, and PAD. Patients were then examined to measure waist circumference, weight, and height. Patients rested for 20 minutes before blood pressure, cardio ankle value index (CAVI) and ankle brachial index (ABI) were measured by the VaSera CAVI instrument (Fukuda Denshi Ci Ltd, Tokyo, Japan)[14]. The authors then reviewed HbA1C and lipid profile (low density lipoprotein, high density lipoprotein).

The PAD was diagnosed when ABI ≤0.9. Alternatively, patients were diagnosed as PAD, and received treatments previously, such as medication, percutaneous angioplasty, or bypass grafting. The authors classified each risk factor as "controlled" if they were at the target goal of the AHA guideline[5]. These consisted of systolic pressure <130 mmHg, Diastolic BP <80 mmHg, low density lipoprotein(LDL) <70 mg/dL, HbA1C <7% and stop smoking. They also classified a discriminating boundary between "good" and "poor" risk factor control similar to a previously established study[15]. The definition of good control was defined as 3 to 5 risk factors at target values, and "poor control" was defined when 0 to 2 risk factors were at target. Independent predictive factors of "good control" of 5 major cardiovascular risk factors were evaluated by multivariate analysis.

Statistical analysis

Categorical variables were presented as frequency and percentages. The authors compared categorical variables by using the Chi-squared test. Multivariate analysis using logistic regression with backward elimination was performed to determine the risk factors of a good control. The iterative process of variable selection, covariates are removed from the model if they are non-significant and not a confounder. Significance is evaluated at the 0.05 alpha level. The protocol was approved by our local ethics committee in each hospital and signed informed consent was obtained for all patients. Analysis was performed by STATA for Windows version 13.0.

Results

2,247 diabetic patients were recruited for the study. There were 874 (38.9%) males and 1373 (61.1%) females (Table 1). The mean age was 62.7±9.4 years. 23.3% were aged 70 years or older. 286 patients out of 2,247 were diagnosed PAD, so the prevalence was 12.7%. The prevalence in Chiang Mai University hospital, Lamphun Hospital, Chiangrai Prachanukroh Hospital was 16.3% (154/947), 10.7% (98/914), and 8.8% (34/386) respectively. When physicians asked patients for any symptom of PAD, i.e. intermittent claudication, rest pain, or gangrene, 80 patients had such symptoms. Fifty patients of this group met the diagnostic criteria In contrast, the remaining 30 cases did not meet PAD criteria. The remaining 236 PAD patients (82.5%) did not have any symptom before. The value of ABI and CAVI was statistically correlation both leg (Fig 1).

Diabetic patients with PAD had histories of cardiovascular events (angina pectoralis, myocardial infarction, unstable angina, stroke and transient ischemic attack), than those without PAD, as shown in Table 1. According to AHA criteria, 18.9% of PAD patients had controlled in LDL level, whereas 93.7% of PAD patients had stopped smoking (Table 2). There was 49.8% % of PAD patients had met our good risk factor control criteria. The predictive factors of good control of major risk factors were analyzed by multivariate analysis, which pointed out an independent association of good risk factor control with age over

70 years old, odds ratio (OR) 3.07; 95% confidence interval (95% CI 1.1-8.3); $p = 0.03$); a high plasma level of high density lipoprotein (OR 1.03; 95%CI 1.0-1.1; $p = 0.03$); and diabetic treatment without insulin (OR 2.37; 95%CI 1.1-5.3; $p = 0.03$) (Table 3). Following drug chart reviews, 68.2% of PAD cases were on anti-platelet medication. This percentage in non-PAD cases was 58.5%. This difference was significant ($p = 0.01$).

Discussion

The prevalence of PAD in 2247 DM patients was 12.7%. It is interesting to note that this figure is much higher in University hospitals than those in the other two general hospitals. This information stressing the difference of prevalence figures is due to different settings. 286 PAD cases had symptoms of only 17.5% (50/286), namely intermittent claudication, rest pain, gangrene, and ulcer. In other words, most PAD in diabetic patients was asymptomatic cases. This discrepancy might partially be explained for several reasons. Diabetic patients usually have peripheral neuropathy, which can mask symptoms like intermittent claudication or rest pain[16]. Also some chronic foot ulcers can originate from insensate foot (neuropathic ulcer), rather than ischemia. The majority of diabetic patients with PAD were asymptomatic (76.2%) (218/286). Therefore, this supports the screening of PAD in DM patients, otherwise the diagnosis would be delayed, possibly causing inappropriate treatment. Also based on the association study between CAVI and CT coronary angiogram, CAVI is an independent risk factors for coronary artery disease[14]. Our study also showed significant correlation between CAVI and ABI. Further studies are necessary to assess whether higher CAVI adds predictive value to ABI, which may be another way to seek early PAD cases.

An ABI ≤0.9 has been used as a criterion for the diagnosis of PAD because of its simplicity and non-invasiveness. However, resting ABI might be in error because the diabetic patient may have medial arterial calcification (Monckeberg's sclerosis) as high as 47% in diabetic patients with DM type 1[17]. This can lead to false elevation of ankle pressure, and consequently false ABI elevation. In our study the prevalence of ABI ≤0.9 is 12.7. When taking false elevation into account, the real prevalence might be higher. A study found sensitivity and specificity of resting ABI was 70.6% and 88.5%, respectively, in patients with PAD investigated by color duplex scan[1]. AHA guidelines suggest that in cases where ABI is more than 1.3 (non compressible artery), toe brachial pressure index is more reliable[5].

Other concerning issues, such as risk factor management in blood pressure, blood sugar control, and lipids are inadequate mainly in PAD patients. 49.8% of PAD patients had met the criteria of good control in the cardiovascular risk factors. This low rate of good control may be explained by non-recognition of PAD, consequently ignoring the benefit of intensive risk control, which can reduce cardiovascular event. For example, the Heart Protection Study reported that lowering LDL cholesterol in diabetic patients by using simvastatin can reduce cardiovascular events by approximately 25%[18]. Moreover, the collaborative atorvastatin diabetes study indicated that intensive treatment with atorvastatin in diabetic patients reduced cardiovascular events approximately 37%[19]. In the UKPDS study, tight control of blood pressure can reduce the risk of PAD by 50% in diabetic patients[20]. The Hope study reported that Ramipril reduced the rate of cardiovascular events by 25% in diabetic patients[21]. Although there is no direct evidence to indicate that optimal glycemic control reduces the risk of PAD[22], such controls are known to reduce the risk for microscopic events, such as nephropathy and retinopathy[23, 24].

Based on REACH registry, at 3 years, mortality was significantly lower in patients with good risk factor control, than those with poor risk factor control[15]. The mortality in PAD with good risk factor control was statistically significantly lower than those with poor risk factor control throughout the 3 year study (1 yr: 4.2% vs 6.3%; 2 yr: 6.4% vs 9.6%; 3 yr 10.4% vs 16.8%). However, in our study, the majority of PAD patients with atherosclerotic disease received under-treatment for major cardiovascular risk factors. There were several reasons to explain this undertreatment. Firstly, there was low perception of PAD in clinical practice. One survey in the USA found a lack of physician knowledge and a bad attitude about PAD[25]. Some general practitioners treated hyperlipidemia intensively in patients with PAD, and some did not. Some vascular surgeons did not treat it because of the expense, and ask general practitioners to handle it instead, which made this matter more complicated if general practitioners did not understand the importance of risk factor management in these PAD patients. Some clinicians

Table 1. Baseline clinical data of participants

Characteristics	Total (2247 patients) n (%)	PAD (286 patients) n (%)	Non-PAD (1961patients) n (%)
Age (years)			
45 – 49	151 (6.7)	11 (3.9)	140 (7.1)
50 – 59	759 (33.8)	63 (22.0)	696 (35.5)
60 – 69	813 (36.2)	97 (33.9)	716 (36.5)
70 – 79	400 (17.8)	81 (28.3)	319 (16.3)
≥ 80	124 (5.5)	34 (11.9)	90 (4.6)
Previous history of cardiovascular events			
Chronic stable angina	8 (0.4)	3 (1.1)	5 (0.3)
Myocardial infarction	73 (3.3)	19 (6.6)	54 (2.8)
Unstable angina	35 (1.6)	9 (3.2)	26 (1.3)
Stroke (ischemic)	55 (2.5)	15 (5.2)	40 (2.0)
Transient ischemic attack	3 (0.1)	1 (0.35)	2 (0.10)
Current medications			
Antithrombotic / anti-platelet			
Aspirin	1277 (56.9)	177 (61.9)	1100 (56.2)
Ticlopidine	3 (0.1)	1 (0.4)	2 (0.1)
Clopidogrel	60 (2.7)	17 (5.9)	43 (2.2)
Warfarin	31 (1.4)	11 (3.9)	20 (1.0)
Ticagrelor	1 (0.04)	1 (0.35)	-
Prasugrel	-	-	-
Dabigatran	-	-	-
Other	14 (0.6)	7 (2.5)	7 (0.4)
Beta – blockers	540 (24.1)	83 (29.0)	457 (23.3)
Angiotensin converting enzyme inhibitors	671 (29.9)	85 (29.7)	586 (29.9)
Angiotensin receptor blockers	641 (28.6)	97 (33.9)	544 (27.8)
Calcium channel blockers	871 (38.8)	126 (44.1)	745 (38.0)
Nitrates	64 (2.9)	18 (6.3)	46 (2.4)
Diuretics	548 (24.4)	111 (38.8)	437 (22.3)
Lipid management agents			
Statin	1544 (68.8)	200 (69.9)	1344 (68.6)
Fibrates	261 (11.6)	36 (12.6)	225 (11.5)
Nincin	16 (0.71)	2 (0.70)	14 (0.71)
Others	70 (3.1)	7 (2.5)	63 (3.2)
Antidibetic agents			
Insulin	638 (28.4)	112 (39.2)	526 (26.8)
Sulfonylureas	1174 (52.3)	131 (45.8)	1043 (53.2)
Biguanides	1414 (63.0)	142 (49.6)	1272 (64.9)
Thiazolidinediones	423 (18.8)	53 (18.5)	370 (18.9)
DDP4-intibitors	159 (7.1)	19 (6.6)	140 (7.2)
Others	73 (3.2)	11 (3.8)	62 (3.2)

PAD = peripheral arterial disease, DDP4 = dipeptidyl peptidase 4

Table 2. the percentage of "controlled" or "not controlled" according to AHA recommended criteria between PAD and non-PAD

Items	PAD (286 patients)	Non- PAD (1961patients)	*p*-value
Blood pressure (BP)			
Systolic BP <130 mmHg*	33.2	38.4	<0.0001
Systolic BP 130 - 150 mmHg	41.3	45.6	
Systolic BP >150 mmHg	25.5	16.1	
Blood pressure (BP)			
Diastolic BP <80 mmHg*	55.9	48.1	0.046
Diastolic BP 80 - 100 mmHg	41.3	48.9	
Diastolic BP >100 mmHg	2.8	3.0	
LDL			
<70 mg/dL*	18.9	18.7	0.993
70 - 90 mg/dL	27.0	26.8	
>90 mg/dL	54.1	54.6	
HbA1C (%)			
<7 %*	30.1	25.8	0.089
7 - 8 %	23.6	30.7	
>8%	46.3	43.5	
Smoking			
Never*	65.7	76.6	<0.0001
Former*	28.0	20.2	
Current	6.3	3.2	

* These classified as "controlled" according to AHA guideline, PAD = peripheral arterial disease, BP = blood pressure, LDL = low density lipoprotein

may have been concerned about the cost-effectiveness of lipid-lowering treatment, more specifically about its cost-effectiveness for patients with PAD. Lastly, this may have come from confusion about the correct values for good control. There are several guidelines in clinical practice. For example, in the USA the National Cholesterol Education Program used LDL100 mg/dl as the desirable blood cholesterol level[26]. However, for PAD in diabetic patients who have a high risk of developing associated ischaemic heart disease, the recommendation for LDL levels is 70 mg/dl, rather than 100 mg/dl (AHA guidelines)[5,7]. Therefore, it is important to educate all clinicians who treat vascular patients about good risk factor control. Interestingly, our study indicated higher rates of good control when patients were age over 75 years old. Perhaps this might reflect good cooperation in such patients. 68.2% of PAD cases in our study was on a type of antiplatelet medication, while AHA guidelines recommended all PAD patients should have at least one antiplatelet to reduce the risk of cardiovascular death[5]. Aspirin is the first choice, but clopidogrel is an effective alternative medication to aspirin. The Anti-platelet Trialist's collaboration has reported that aspirin can lower mortality due to cardiovascular events by 25% in patients with symptomatic atherosclerotic disease[27]. Especially, in the subset of intermittent claudication, aspirin can reduce the death rate by 18%[27]. The CAPRIE study compared the effectiveness between aspirin and clopidrogrel. In a PAD subgroup, patients with clopidrogrel had a 24% lower rate of composite endpoint (myocardial infarction, stroke, vascular death) when compared with patients with aspirin alone[28]. However, no study for particular diabetic patients was available.

Table 3. The risk factors that associated with good control

Characteristics	Univariate Analysis			Logistic Regression Analysis		
	OR	95% CI	*p*-value	AOR	95% CI	*p*-value
Demographic data						
Age (years)						
45 – 59	Ref.					
60 – 69	1.27	0.61 to 2.64	0.490	1.48	0.57 to 3.84	0.426
≥70	2.16	1.03 to 4.56	0.027	3.07	1.13 to 8.32	0.027
Education						
None / Primary school	2.48	0.82 to 8.31	0.073			
Secondary school	2.21	0.61 to 8.53	0.174			
Vocational	Ref.					
University or higher	3.27	0.80 to 14.01	0.060			
Physical examination						
Body weight (kg)	1.02	1.01 to 1.04	0.009			
BMI (kg/m^2)	1.06	1.01 to 1.11	0.015			
Waist circumference (cm)	1.03	1.01 to 1.05	0.010			
Heart rate (bpm)	1.02	1.00 to 1.04	0.072	0.98	0.95 to 1.01	0.128
Cardiovascular risk factor						
Chronic kidney disease stage I-V	1.68	0.89 to 3.22	0.088			
Previous history of cardio- vascular intervention						
Percutaneous coronary intervention	4.28	0.82 to 42.10	0.050			
Laboratory						
Fasting blood sugar(mg/dl)	1.01	1.00 to 1.01	0.015			
Total Cholesterol (mg/dl)	1.01	1.00 to 1.02	0.075			
HDL-C (mg/dl)	0.98	0.96 to 1.00	0.103	1.03	1.00 to 1.05	0.031
Current medications						
Warfarin	6.36	0.75 to 295.01	0.053	7.03	0.47 to 104.97	0.158
Calcium channel blockers	1.96	1.09 to 3.51	0.016	2.02	0.95 to 4.31	0.069
Insulin	1.83	1.02 to 3.30	0.031	2.37	1.07 to 5.26	0.034

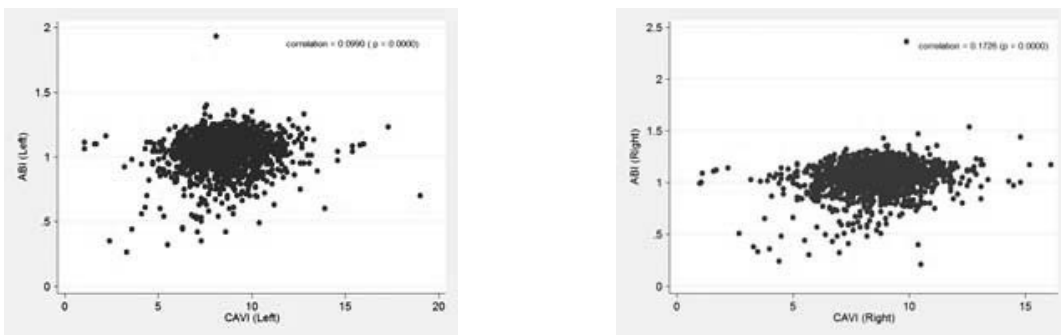

Fig. 1 the correlation between value of ABI and CAVI on left leg (left diagram) and right leg (right diagram).

Limitation

In the treatment of PAD in diabetic patients, apart from risk factor control and antiplatelet, there are several other treatments, such as exercise, medication, revascularization procedure, and amputation. In this review authors did not focus on those issues.

Conclusion

The treatment for PAD in diabetic patients is critical. Not only they carry the high risk of cardiovascular morbidity and mortality, but in actual practice, this condition appeared to be underrecognition and undertreatment for the risk factor control.

What is already known on this topic?

There has been underdiagnosis and undertreatment for PAD in diabetic patients in Western patients.

What this study adds?

This study investigated the status of diagnosis and management PAD in diabetic patients in Thailand. Also this study was determined to identify the risk factors associated with the adherence of guidelines in diabetic patients with PAD, which had not been previously explored.

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Potential conflicts of interest

None.

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การวินิจฉัยและการรักษาโรคหลอดเลือดส่วนปลายในผู้ป่วยเบาหวานในประเทศไทยต่ำกว่ามาตราฐานที่ควรจะเป็น

ศุภพงษ์ อาวรณ์, ณัฐพงศ์ โฆษชุณหนันท์, กิเริ่น โซนี่, นิมิตร อินปั๋นแก้ว, ปิยะมิตร ศรีธรา, อรินทยา พรหมินธิกุล, ชลลิสา จริยาเลิศศักดิ์, อันธิกา วงษ์ธานี, อัมพิกา มังคละพฤกษ์, กิตติพันธุ์ ฤกษ์เกษม

ภูมิหลัง: *การศึกษานี้จุดประสงค์เพื่อประเมินอัตราการควบคุมปัจจัยเสี่ยงต่อการเกิดภาวะหลอดเลือดแข็งในผู้ป่วยเบาหวานที่มีภาวะโรคหลอดเลือดส่วนปลาย (peripheral arterial disease-PAD)*

วัสดุและวิธีการ: *การศึกษาได้ดำเนินการคัดกรองผู้ป่วยที่เป็นโรค PAD ในผู้ป่วยเบาหวานที่มีอายุตั้งแต่ 45 ปี ในระหว่างเดือนพฤษภาคม พ.ศ. 2557-สิงหาคม พ.ศ. 2557 ภาวะโรค PAD จะวินิจฉัยเมื่อผู้ป่วยมีผลการตรวจ ankle brachial index น้อยกว่า 0.9 หลังจากนั้นการศึกษานี้จะประเมินว่าผู้ป่วยได้รับการปฏิบัติตามแนวเวชปฏิบัติมากน้อยเพียงใดในการควบคุมปัจจัยเสี่ยง 5 ปัจจัย ผู้ใดที่สามารถควบคุมปัจจัยเสี่ยงบรรลุตามเป้าหมายได้อย่างน้อย 3 ใน 5 ปัจจัย ถือว่าควบคุมปัจจัยเสี่ยงได้ดี*

ผลการศึกษา: *ผู้ป่วยเบาหวานจำนวน 2247 คนมาเข้าร่วมการศึกษา 286 คนพบว่าเป็นโรค PAD ความชุกของ PAD ในผู้ป่วยเบาหวานการศึกษานี้คือร้อยละ 12.7 โดยในผู้ป่วยกลุ่มนี้มีเพียง 50 คนเท่านั้นที่มีอาการแสดงขาขาดเลือดมาก่อนเช่นอาการเดินแล้วเมื่อยน่อง นิ้วเท้าดำเน่า หรือมีแผลเรื้อรัง นอกนั้น 236 คนไม่มีอาการใดๆ จากการประเมินการควบคุมปัจจัยเสี่ยงพบว่าอัตราที่ควบคุมปัจจัยเสี่ยงที่เป้าลุตามเป้าหมายตามเกณฑ์เวชปฏิบัติพบเพียงร้อยละ 18.9 ในด้าน low density lipoprotein ร้อยละ 30.1 สำหรับ HbA1C และร้อยละ 33.2 สำหรับความดัน systolic และโดยรวมเมื่อพิจารณาทั้ง 5 ปัจจัยร่วมกันพบว่ามีเพียงร้อยละ 49.8 ที่เข้าเกณฑ์ว่าควบคุมปัจจัยเสี่ยงได้ดี*

สรุป: *ผู้ป่วย PAD ในผู้ป่วยเบาหวานส่วนมากไม่มีอาการ การควบคุมปัจจัยเสี่ยงในกลุ่มนี้ทำต่ำกว่ามาตราฐาน*