

# Factors Associated with the Occurrence of Peripheral Arterial Disease in Patients with Type 2 Diabetes Mellitus\*

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## Abstract

**Purpose:** To study the occurrence of peripheral arterial disease (PAD) and factors associated with the occurrence of PAD among patients with type 2 diabetes mellitus (T2DM).

**Design:** Descriptive design.

**Methods:** The sample composed of 136 adult patients with T2DM who were treated at Bach Mai hospital, Hanoi, Vietnam. Data were collected using Ankle Brachial Index (ABI) to assess the occurrence of PAD, and 4 questionnaires: patients' demographic data, clinical information, the self-efficacy for diabetes, and knowledge about PAD. Chi-Square was employed to test association between studied variables.

**Main findings:** The findings revealed that 16.18% had PAD; 36.36% of those with PAD had stage 4-ulceration or gangrene; 63.64% had location of PAD at tibia-peroneal artery and 31.81% at femoro-popliteal artery. Co-morbid diseases, HbA1c, and self-efficacy were significantly associated with the occurrence of PAD ( $p < .05$ ). There was no association between the occurrence of PAD and knowledge about PAD ( $p > .05$ ).

**Conclusion and recommendations:** Nurses can empower patients with T2DM to increase self-efficacy as well as providing them with information to control the level of HbA1c and co-morbid diseases.

**Keywords:** type 2 diabetes mellitus, peripheral arterial disease, self-efficacy, HbA1c

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# ปัจจัยที่มีความสัมพันธ์กับการเกิดโรคหลอดเลือดแดงส่วนปลาย ในผู้ป่วยเบาหวานประเภทที่ 2

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## บทคัดย่อ

**วัตถุประสงค์:** เพื่อศึกษาการเกิดโรคหลอดเลือดแดงส่วนปลาย และปัจจัยที่มีความสัมพันธ์กับการเกิดโรคหลอดเลือดแดงส่วนปลาย ในผู้ป่วยเบาหวานประเภทที่ 2

**รูปแบบการวิจัย:** การวิจัยเชิงบรรยาย

**วิธีดำเนินการวิจัย:** กลุ่มตัวอย่างเป็นผู้ป่วยเบาหวานประเภทที่ 2 ที่มารับการรักษาตัวที่โรงพยาบาลบักมาย ประเทศเวียดนาม เก็บข้อมูลด้วยการประเมินการเกิดโรคหลอดเลือดแดงส่วนปลาย ด้วยการวัดดัชนีความดันเลือดเทียบหลอดเลือดแดงแขนกับขา และแบบสอบถาม จำนวน 4 ชุด: แบบสอบถามข้อมูลส่วนบุคคล แบบสอบถามข้อมูลทางคลินิกและโรคร่วม แบบสอบถามการรับรู้สมรรถนะในตนเองด้านการดูแลและควบคุมโรคเบาหวาน และแบบสอบถามความรู้เกี่ยวกับโรคหลอดเลือดแดงส่วนปลาย ใช้สถิติ ไคสแควร์เพื่อทดสอบความสัมพันธ์ระหว่างตัวแปร

**ผลการวิจัย:** กลุ่มตัวอย่างร้อยละ 16.18 เกิดโรคหลอดเลือดแดงส่วนปลาย ร้อยละ 36.36 ของผู้เกิดโรคหลอดเลือดแดงส่วนปลาย เป็นระยะที่ 4-ulceration or gangrene ร้อยละ 63.64 เกิดที่ตำแหน่ง tibia-peroneal artery และร้อยละ 31.81 เกิดที่ตำแหน่ง femoro-popliteal artery การมีโรคร่วม ระดับน้ำตาลสะสม และการรับรู้สมรรถนะในตนเองมีความสัมพันธ์กับการเกิดโรคหลอดเลือดแดงส่วนปลาย ( $p < .05$ ) แต่ความรู้เกี่ยวกับโรคหลอดเลือดแดงส่วนปลายไม่มีความสัมพันธ์กับการเกิดโรคหลอดเลือดแดงส่วนปลาย ( $p > .05$ )

**สรุปและข้อเสนอแนะ:** พยาบาลสามารถใช้วิธีการสร้างความมั่นใจและสร้างพลังเพื่อส่งเสริมให้ผู้ป่วยเบาหวานประเภทที่ 2 รับรู้สมรรถนะในตนเองเพิ่มขึ้น ร่วมกับการให้ข้อมูลความรู้ในการควบคุมระดับน้ำตาลสะสม และควบคุมภาวะโรคร่วม ทั้งนี้เพื่อลดอัตราการเกิดโรคหลอดเลือดแดงส่วนปลาย

**คำสำคัญ:** ผู้ป่วยเบาหวานประเภท 2 โรคหลอดเลือดแดงส่วนปลาย การรับรู้สมรรถนะในตนเอง ระดับน้ำตาลสะสม

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## Background and Significance

Currently, there were 382 million people with diabetes mellitus (DM) worldwide; this included children and adult<sup>1</sup>. According to the International Diabetes Federation; the survey in the year 2014 among Vietnamese population aged between 20 to 79, revealed that there were 3,299,110 people with diabetes mellitus in total population of 61,387,550 made the national prevalence of 5.37%; the majority was type 2 diabetes mellitus (T2DM).

One important consequence of T2DM was peripheral arterial disease (PAD). Previous studies demonstrated that 10.8% of T2DM experienced PAD; which was 3 times to develop PAD comparing with ones without T2DM<sup>2</sup>. PAD was the most common cause of disability and death among people with T2DM. Patients with T2DM who have PAD will increase the risk of mortality rate by 2 to 4 folds comparing with T2DM patients without PAD<sup>3,4</sup>.

PAD was shown when fatty plaque builds up in the inner wall of the peripheral arteries caused poor circulation, especially in the arteries that supplied legs and feet<sup>5</sup>. PAD was classified into 4 stages from Stage 1 to Stage 4 according to Fontaine classification. While the first stage started with minor signs and symptoms of peripheral arterial occlusion and the 4<sup>th</sup> or the last stage was the most serious stage with severe signs and symptoms due to peripheral limbs ischemia. To detect the occurrence of PAD the very simple test was measuring ankle brachial index (ABI); which was a simple, inexpensive, and noninvasive tool that could be used to detect PAD<sup>6,7</sup>. According to a study in 2014 about PAD in patients with T2DM in Endocrinology department, Bach Mai hospital, Vietnam, revealed the high incidence of PAD which accounted for 7.7%<sup>8</sup>.

There were many factors related to PAD in patients with T2DM. Among those factors, self-efficacy was the important factor because it affected patients health behaviors. Patients with high self-efficacy showed high confidence in complying with the treatment and be able to

perform self-care, self-assessment, and early detection of complications from chronic illnesses<sup>9,10</sup>. Knowledge about PAD including knowledge about symptom and risk factors influenced the occurrence of PAD<sup>11</sup>. According to study of Vasaroangrong, et al. 80% of Thai patients who had PAD did not know about their disease and symptoms of PAD, knowledge about disease was very important factor that detected early and prevented risk factors related disease<sup>11</sup>. Co-morbid diseases also played a vital factor adding the risk of PAD among patients with T2DM.

Haemoglobin A1c (HbA1c) was a preferred parameter to assess serum glucose level in patients with T2DM because it could represent 3-month average serum glucose level and better reflected the condition of patients with T2DM. The United Kingdom Prospective Diabetes Study reported that when people showed 1% increased of HbA1c, they will be at risk of having PAD for 28%<sup>7</sup>. PAD affected people's health and socioeconomic of the countries. Therefore, identifying some factors such as knowledge about PAD, self-efficacy, glycemic control, co-morbid diseases, related to PAD as well as providing nursing care program will assist Vietnamese people with T2DM to be able to detect early and reduce the rate of PAD.

## Objective

To study the occurrence of peripheral arterial disease (PAD) and factors associated to the occurrence of PAD among patients with type 2 diabetes mellitus (T2DM).

## Hypothesis

Co-morbid diseases, HbA1c, self-efficacy, and knowledge about PAD were associated with the occurrence of PAD.

## Methodology

### Population and Sample

The population included patients who were diagnosed with T2DM and admitted to the Endocrine Department, Bach Mai Hospital,

Hanoi, Vietnam.

Sample was selected from the population with inclusion criteria: 1) age 18 years and older, 2) able to communicate in Vietnamese language.

The sample size was calculated by G\* power program to determine the minimum number of participants needed for Chi Square Test<sup>12</sup>. The level of significance  $\alpha = .05$ , the power of the statistical test ( $\text{Power } 1 - \beta = .85$ ). The maximum category groups in this study was three (degree of freedom =  $3 - 1 = 2$ ) and medium effect size for this study ( $w = .3$ )<sup>13</sup>. Based on G\* power, sample size was 122 patients, plus 10% for missing value and attrition, so the final sample size was 136 patients.

### **Research Instruments**

The instruments used for data collection were as follows:

1. Demographic data included age, gender, BMI, education level, marital status, occupation, location of residence, income, and type of health insurance.

2. Clinical characteristics included duration of T2DM, HbA1c level, and co-morbid diseases. Co-morbid diseases were collected by asking the patients along with obtaining the data from patients' hospital records. It referred to any disease the patients had before the time of data collection. One disease was assigned for 1 score.

3. The Self-efficacy for diabetes score. This questionnaire contained 8 items with 1 to 10 response scales. Each item referred to the question related to level of confidence the patient perceived in performing self-care to control diabetes. The response of 1 was the lowest confidence, while the response of 10 referred to the highest confidence. This scale originally developed and tested in Spanish for the Diabetes Self-Management study<sup>14</sup>. The range of total score was 10 to 80. This scale was offered to use publicly. The psychometric property of this scale was tested through the research of Lorig, et al. in the year 2009<sup>15</sup>.

4. Knowledge about PAD. This questionnaire was developed by Vasaroangrong,

et al. The questionnaire comprised 20 items presented in a dichotomous choice, yes or no response format. The scale was divided into 3 domains, knowledge about PAD symptoms, knowledge about risk factors of PAD, and knowledge about the effects of PAD. The total score of knowledge about PAD ranged from 0 to 20, with higher score indicating greater PAD knowledge<sup>11</sup>.

5. The diagnostic criteria for PAD, the Ankle Brachial Index (ABI). The ABI in each patient was assessed and recorded in patients' chart by endocrinologist on the first day of hospital admission. Level of ABI was interpreted as follows: ABI = .91 to 1.30 = normal; ABI = .70 to .90 = mild obstruction, ABI = .40 to .69 = moderate obstruction, ABI < .40 = severe obstruction<sup>6,7</sup>.

All questionnaires were translated into Vietnamese by Vietnamese English instructor and validated by 5 experts in the field of endocrine.

Reliability of the self-efficacy for diabetes scale and knowledge about PAD scale were tested by Cronbach's alpha coefficient among 17 patients with T2DM and yielded .78 and .83 respectively. The reliability for the studied sample ( $n = 136$ ) of the self-efficacy for diabetes scale was .91 and knowledge about PAD scale was .88.

### **Protection of Human Subject**

This project was approved by the Institutional Review Board of the Faculty of Nursing, Mahidol University, Thailand (COA No.IRB-NS 2016/349.0205) and the IRB of Vietnam National University, Vietnam. The researcher recruited sample as standard process specified by the IRB. The issues of independently to make decision to consent, anonymity, and confidentiality were warranted.

### **Data Collection**

Data were collected as the following sequences:

1. After getting permission to collect data from the director of the hospital, the researcher informed head of Endocrine department, and

head nurse of endocrine ward in regard to details of the research project and asked permission to select the subjects according to the inclusion criteria.

2. On the day of hospital admission, the researcher self-introduced, made relationship with the patients, read and explained details of data collection process using the participation information sheet. After they volunteered to join the study, they were asked to sign the consent form.

3. The researcher collected data from patients' hospital record including demographic data, clinical information including HbA1c, ABI, duration of T2DM, characteristics of PAD including stage of PAD, location of arterial occlusion.

4. The researcher interviewed all subjects using the self-efficacy for diabetes scale and knowledge about PAD scale. The interview process for each subject lasted for 30 to 45 minutes.

#### **Data Analysis**

The data analysis was performed using the computer statistical package with the significant level at .05. Descriptive statistics were used to analyze frequency, percentage, range, mean, and standard deviation. The association between age, HbA1c, self-efficacy, co-morbid disease, and PAD were analyzed by Chi – Square test.

#### **Findings**

The findings showed that 52.21% of subjects were males and 47.79% were females, age ranged from 23 to 86 years with the mean age of 59.62 years (SD = 11.76), 71.32% were married, 44.85% finished secondary school, 34.56% were farmer while 33.09% were retired from their work, 50.00% resided in the rural, 75.00% had health insurance, 47.06% had history of smoking, 47.79% had history of drinking, and 80.88% experienced stress.

Regarding health information, 55.88% had history of T2DM longer than 6 years with the average of 7.59 years (SD = 6.83), 88.24% had HbA1c greater than 7 mg/dl with the average of 9.38 mg/dl (SD = 2.4), 75.74% had one or more co-morbid diseases. Hypertension and hyperlipidemia were the first 2 co-morbid diseases found among these subjects. The average level of cholesterol and triglyceride were 246.40 and 235.0 mg/dl.

#### **The occurrence and characteristics of PAD**

The findings revealed that 16.18% had PAD (ABI < .9); 8.82% had PAD of the left leg, 7.35% had PAD on the right leg; 36.36% of those with PAD had stage 4-ulceration or gangrene; 63.64% had location of PAD at tibia-peroneal artery and 31.81% at femoro-popliteal artery. (Table 1)

**Table 1:** Level of ABI (n = 136) and characteristics of PAD (n = 22)

Characteristics	Number	Percentage
<b>Level of ABI of either left or right leg (n = 136)</b>		
≥ .9	114	83.82
< .9	22	16.18
.70 - .89 mild occlusion	18	13.24
.59 - .69 moderate occlusion	4	2.94
Min = .59, Max = 1.30, Mean = 1.17, SD = .21		
<b>Level of ABI of the left leg (n = 136)</b>		
≥ .9	121	91.18
< .9 (.70 - .89) mild occlusion	12	8.82
Min = .79, Max = 1.30, Mean = 1.17, SD = .19		
<b>Level of ABI of the right leg (n = 136)</b>		
≥ .9	126	92.65
< .9	10	7.35
.70 - .89 mild occlusion	6	4.41
.59 - .69 moderate occlusion	4	2.94
Min = .59, Max = 1.30, Mean = 1.18, SD = .23		
<b>Stage of disease (n = 22)</b>		
Stage I Asymptomatic	9	40.91
Stage II Intermittent claudication	2	9.09
Stage III Rest pain	3	13.64
Stage IV Ulceration or gangrene	8	36.36
<b>Location of occlusion (n = 22)</b>		
Tibia-peroneal artery	14	63.64
Femoral-popliteal artery	7	31.81
Iliofemoral artery	1	4.55

#### Knowledge and source of knowledge about PAD

Only 38.24% (52 out of 136) of subjects have heard about PAD. Among these, only 32.69% of them (17 out of 52) had heard about PAD from health care providers. According to knowledge about PAD, the overall score was relatively low with the mean of 2.31 (range 0-20). Similarly, score in each dimension was relatively low with the mean of .56 in knowledge about symptoms, .89 in knowledge about risk factors, .86 in knowledge about effect of PAD.

The overall self-efficacy for diabetes scale was low with the average score of 48.98 (SD = 8.91) from the total score of 80.

#### Factors associated with the occurrence of PAD

The proposed hypothesis: Co-morbid diseases, HbA1c, self-efficacy, and knowledge about PAD were associated with the occurrence of PAD.

The findings were partially supported the proposed hypothesis that co-morbid diseases, HbA1c, and self-efficacy were significantly associated with the occurrence of PAD ( $p < .05$ ). However, there was no association between the occurrence of PAD and knowledge about PAD ( $p > .05$ ). (Table 2)



**Table 2:** Association between HbA1c, co-morbid diseases, self-efficacy for diabetes, knowledge about PAD and the occurrence of PAD (n = 136)

Factors	Occurrence of PAD				X <sup>2</sup>	p-value
	Yes		No			
	n = 22		n = 114			
	No	%	No.	%		
<b>HbA1c</b>						
5.2 – 7.0	0	0	16	14.04	6.10 <sup>a</sup>	.04*
7.1 – 11.6	15	68.18	81	71.05		
11.7 – 18.6	7	31.82	17	14.91		
<b>Self- efficacy for diabetes scores</b>						
18 - 49	15	68.18	47	41.23	5.40 <sup>a</sup>	.02*
50 - 67	7	31.82	67	58.77		
<b>PAD knowledge scores</b>						
Less than 1 scores	13	59.09	73	64.04	.19 <sup>a</sup>	.66
1 - 13 scores	9	40.91	41	35.96		
<b>Co-morbid diseases scores</b>						
no co-morbid disease	1	4.55	32	28.07	5.55 <sup>a</sup>	< .01*
1 to 5 co-morbid diseases	21	95.45	82	71.93		

\* p &lt; .05

## Discussion

The occurrence of PAD among subjects with T2DM in this study was 16.18%; similar to the study of Carter, et al. which shown that T2DM increased the risk of PAD by 2 to 4 folds comparing with people without T2DM<sup>16</sup>.

However, the occurrence found in this study was lower than that of other countries. For example; in the UK, the occurrence of PAD is 23.5% in T2DM population<sup>1,17</sup>. The explanation might be that this study was conducted in only one hospital within the very limited time frame. Among those with PAD (22 subjects), only 10% demonstrated a classic symptom of claudication while 40% did not complain of leg pain. Likewise, the previous reports which indicated that 10% of PAD patients present with the classic symptoms of the disease<sup>5,18,19</sup>. Affected PAD individuals included 50% with atypical leg symptoms and 40% with no lower extremity symptoms present<sup>5,18-20</sup>. Most location of occlusion was Tibia-Peroneal artery. A total of 22 subjects with PAD, 40.91% had Stage I

Asymptomatic and 36.36% had Stage IV Ulceration or gangrene. Similar to the study of Vasaroangrong, et al. which indicated that Thai patients with T2DM were admitted to hospital with advanced stages of PAD, ischemic ulcer or gangrene. The majority of patients with PAD accessed medical care only after they have reached a catastrophic stage<sup>11</sup>. Subjects in this study did not have knowledge about PAD or risk factors for PAD so that they came to the hospital only when there was a critical expression as leg ulcers or gangrene.

The results indicated that co-morbid disease was associated with the occurrence of PAD (p < .05). The majority of subjects (75.7%) in this study had co-morbid diseases whereas hypertension and hyperlipidemia accounted for 68.93% and 48.54% of these patients. The level of cholesterol and triglycerides were above normal value with the average of 246.40 and 235.00 respectively. Similar to the study of Wongkongkam, et al. indicated that 94.8% of T2DM with PAD had co-morbid diseases<sup>17</sup>.

Patients with hypertension and hyperlipidemia always developed atherosclerosis leading to narrow vascular lumen eventually the occlusion would take place<sup>18-20</sup>.

The mean of HbA1c was 9.38 mg/dl (SD = 2.4), the highest HbA1c value was 18.6 mg/dl, 88.24% had HbA1c greater than 7 mg/dl. The finding also indicated that HbA1c was associated with the occurrence of PAD ( $p < .05$ ); similar to previous research which reported that HbA1c was related to the occurrence of PAD; and also found that with every 1% increase in glycosylated hemoglobin there was a 28% increased the risk of PAD<sup>16</sup>. High level of HbA1c could induce vascular calcification, prolonged level of HbA1c, initiated crystallization of calcium/phosphate in the form of hydroxyapatite in both the intima and the media of the arterial wall. Intravascular calcification was also associated with atherosclerosis, vascular smooth muscle cells, macrophages, and the necrotic lipid core. Atherosclerotic plaques can break leading to obstruction in blood flow and suboptimal organ perfusion and is the major event precipitating ischemia in PAD<sup>21</sup>.

The mean of self-efficacy for diabetes score was 48.98 out of the total score of 80 which was considered to be low. The finding indicated that the subjects were not confident in their abilities related to diabetes management; similar to the study of Adam and Folds about self-efficacy and medical adherence in patients with T2DM in the Mid Western United States which reported the similar level of self-efficacy score in average level<sup>22</sup>. In this study, self-efficacy was associated with the occurrence of PAD ( $p < .05$ ); reflecting that subjects with T2DM who had low confidence in self-care practice are more likely to develop PAD. More than half of the subjects did not know that PAD was a consequence of T2DM; 38.24% had heard about PAD but did not understand clearly about the symptom, risk factors, and effects of PAD. They did not know the name of this disease, they just knew that complications ultimately cause pain and lower limb amputations; similar to the study of

Vasaroangrong, et al. reported that 80% of PAD patients did not know about their disease and symptoms of PAD and only 25% knew that PAD was an arterial disease<sup>11</sup>. Although, there was no association between knowledge of PAD and the occurrence of PAD in this study, knowledge and information related to risk factors, effects of diabetes on the development of PAD as well as prevention of PAD should be provided to the patients. There were evidences to support that only a relatively small fraction of individuals received information on PAD from a physicians, nurses, and other health care providers. Moreover, public knowledge about PAD was relatively limited with major knowledge gaps regarding the definition of PAD, risk factors that lead to PAD, associated limb symptoms and amputation risk<sup>18,23-25</sup>. In this regard, nurses can play a vital role on providing patients with comprehensive but simple information in order to increase awareness and prevention of PAD.

### **Conclusion and Implication for Nursing Practice and Further Research**

In this study, it was found that co-morbid diseases, self-efficacy for diabetes, and HbA1c were major factors associated to the occurrence of PAD among T2DM patients. Therefore, patients should receive routine examination on their ABI. There should be a strategy to promote T2DM patients to get early access to specialist in particular the vascular physicians to early detect and properly provide treatment. Nurses should empower patients with T2DM to improve their confidence in diabetic management, provide them with health information related to glycemic control. These nursing interventions would increase patients' self-efficacy for diabetic management leading to proper control of HbA1c level. Moreover, patients should be properly informed about the right methods to deal with common co-morbid diseases such as hypertension and hyperlipidemia. Appropriate food pattern, regular exercise, sleep hygiene, and stress management are vital message for patients with T2DM. The results of this study



supports the concept of self-efficacy theory in that while patients with T2DM gain experience of mastery over their health behaviors related to diabetic control, they would be able to control the occurrence of undesired health outcomes. Nurses can perform vital roles in persuading patients, giving support to encourage them to obtain their optimum health outcomes.

For further studies, empowering program to improve self-efficacy for diabetes, glycemic control as well as controlling the common co-morbid diseases should be developed and tested for its effectiveness by research. Multi sites research should be conducted to represent the broad picture of the problem of PAD in patients with T2DM in Vietnam.

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