


**FACTORS RELATED TO THE OCCURRENCE OF PERIPHERAL
ARTERIAL DISEASE IN PATIENTS WITH DIABETES TYPE 2**

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OF THE REQUIREMENTS FOR THE DEGREE OF
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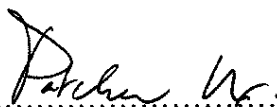
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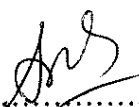


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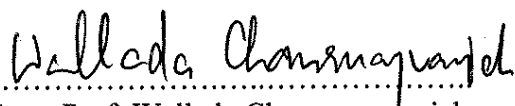
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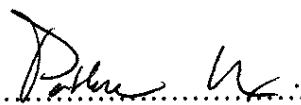
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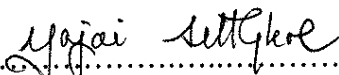
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FACTORS RELATED TO THE OCCURRENCE OF PERIPHERAL ARTERIAL DISEASE IN PATIENTS WITH DIABETES TYPE 2

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ABSTRACT

The number of people with type 2 diabetes in Vietnam have been increasing and peripheral artery disease (PAD) is the complication commonly found that leads to serious morbidity among these patients. This descriptive correlational research aimed to study the occurrence of PAD and the factors related to the occurrence of PAD among patients with type 2 diabetes. Self-efficacy theory was utilized as a framework for this study. The study was conducted among 136 adult patients with type 2 diabetes who were admitted in the endocrine department, Bach Mai hospital, Hanoi, Vietnam. Data were collected by using patients' hospital record and interviewing the patients with interviewing forms. The occurrence of PAD was measured by Ankle Brachial Index (ABI). Chi – Square test was employed to test the relationship among all variables. The results revealed that there was nearly equal distribution between males (52.2%) and females (47.8%). The age of patients ranged from 23 to 86 years with mean age of 59.62 years ($SD \pm 11.76$). A half of the patients lived in the rural area. The majority had experienced type 2 diabetes with the mean duration of 7.59 years ($SD \pm 6.83$ years). Almost all patients (82.2%) had level of HbA1C of over than 7.0 with the mean of 9.38 ($SD \pm 2.4$), there were 16.2 % of patients with PAD, majority of patients (61.8%) never heard about PAD and the knowledge regarding PAD early detection, complications and prevention was very low with the average total score of 2.31 ($SD \pm 3.49$). Majority of them had zero score on knowledge about PAD. The mean score of self-efficacy diabetes scale was 49.05 ($SD \pm 9.52$). This research showed that there was no significant correlation between PAD and knowledge about PAD ($p = .66$). Comorbidity and HbA1C had positive correlation with the occurrence of PAD ($p < .05$) while self-efficacy had negative correlation with PAD ($p < .05$). However, knowledge about PAD was not correlated with the occurrence of PAD ($p > .05$). It is recommended that patients with type 2 diabetes should receive routine examination on their ABI. Nurses should provide health information to patients with type 2 diabetes to control their diet in order to control the level of HbA1C and provide psychological support, find support resources to empower them which so as increase self -efficacy in diet control, proper exercise and foot care.

**KEY WORDS: PERIPHERAL ARTERIAL DISEASE/TYPE 2 DIABETES / HBA1C/
SELF EFFICACY**

86 pages

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LIST OF ABBREVIATIONS

Peripheral arterial disease	PAD
Type 2 Diabetes Melitus	T2DM
Haemoglobin A1C	HbA1c
Intermittent Claudication	IC
Ankle Brachial Index	ABI

CHAPTER I

INTRODUCTION

1.1 Background and significance of the study

In worldwide, there are 382 million people with diabetes, this includes both children and adult (Fowkes, et al, 2013). However, when consider only adult patients, there are 8.3% with diabetes and 80% of them are ones who are residing in low and middle income countries. If patients with diabetes mellitus (DM) cannot very well control their glycemic level, the consequence diseases such as heart disease or kidney diseases will occur (Fowkes, et al, 2013).

In 2013, DM led to 5.1 million deaths which affected the health care expense up to 548 billion USD. If the appropriate intervention is not taken place, numbers of DM patients will be dramatically increase in less than 25 years. Moreover, numbers of patients with DM will increase in low to middle incomes countries due to behavior and eating habit changed. In particular, countries in Southeast Asia, there are nearly 20% of the total population with DM (Fowkes, et al, 2013). These figures show the significance of DM as a major non communicable disease worldwide.

According to International Diabetes Federation atlas Sixth edition in 2014, in Vietnam the population age between 20 to 79 was 61,387,550 while people with DM was 3,299,110 made the national prevalence of 5.37% and the majority was type 2 diabetes mellitus (T2DM). Moreover, the report showed that diabetes related deaths was 53,953.

One important consequence disease of T2DM is Peripheral artery disease (PAD). It is the most common cause of death and disability among people with T2DM. Moreover, patients with T2DM who have PAD will increase the risk of mortality rate by 2 to 4 fold comparing with T2DM patients without PAD (McDermott, 2006 ; Marso & Hiatt, 2006).

In the United States, more than 5 million adults in 60 years and older have PAD (Bennett, Silverman, Gill, & Lip, 2009 ;Carter, Martinez, Purnell & Chesbro, 2013). The study reported that 9% of individuals aged 55 to 65 years have PAD; moreover, increases 47% to 57% in individuals older than 70 years (Bennett, Silverman et al. 2009). PAD causes indirect and direct functional impairments in older adults (Aronow 2006, Carter, et al. 2013). In Vietnam, follow the survey data of the National Heart Institute in 2007 found that the incidence of PAD was 3.4%. According to study about PAD in patient with T2DM in Endocrinology department, Bach Mai hospital, Vietnam in the year 2014, it revealed the high incidences of PAD which accounted for 7.7%.

PAD and T2DM are related to each other. People with T2DM show additional risk for developing PAD (Jude, et al. 2001; Dolan, et al. 2002). Previous studies demonstrated that 10.8% of T2DM experienced PAD in other words, they were 3 times to develop PAD comparing with ones without T2DM (Selvin & Erlinger , 2004). On the other way, when patients are diagnosed of PAD there is a 26.4 % of chance to be diagnosed as having T2DM. (Selvin & Erlinger 2004, Esteghamati, et al. 2015). Moreover, PAD in patients with T2DM is a major risk factor for lower extremity amputation (Jude, et al. 2001; Dolan, et al.,2002). Ankle-Brachial Index (ABI) is the measurement to confirm the presence of PAD. The survey in the year 2000 showed the incidence of 5.8% or 6.8 million people in the USA whose ages were over 40 years with the ABI less than 0.90 (Allison, et al. 2007, Carter, et al. 2013).

PAD is shown when fatty plaque builds up in the inner walls of the peripheral arteries, causing poor circulation. Blood circulation is compromised most popular in the arteries that supply the legs and feet (Hiatt, Armstrong et al. 2015). The most common cause of PAD is atherosclerotic vascular disease. Atherosclerosis related PAD is relatively common, affecting more than 200 million people worldwide (Fowkes et al. , 2013) including an estimated 8 to 10 million individuals in the United States alone (Allis et al., 2007). Because of the pathology of the peripheral vascular, patients with PAD show decline or impaired organ function. Previous studies found that people who are at risk of PAD include those with old age, DM, hyperlipidemia, chronic kidney disease and hypertension. People who have history of heavy smoking

as well as long term smoking are ones who also have high risk of PAD. (McDermott, 2006; Potier, et al., 2011; Carter, 2013).

It is widely accepted that PAD is classified into 4 stages from Stage 1 to Stage 4 according to Fontaine classification. While the first stage starts with minor sign and symptom and the 4th or the last stage is the most serious stage. The description in each stage is described below;

Stage 1 refers to the very minor stage of PAD. Patients in stage 1 usually do not experience any symptom. However, there are some sign that can be detected through physical examination include, paraesthesia, cold extremities, slightly diminished of dorsalis pedis pulses. ABI is lesser than 0.9

Stage 2 refers to the moderate stage. Patients with Stage 2 experience a very typical symptom called intermittent claudication (IC). It is also divided into Stage 2A and Stage 2B. In stage 2A, IC pain take place while the patients walk with the distance of greater than 200 meters. In stage 2B, IC will occur when patients walk with the distance of lesser than 200 meters.

Stage 3 refers to chronic advanced stage. In this stage patients experience pain at rest which is called “rest pain”. The severity of pain will be worst at night.

Stage 4 refers to chronic critical leg ischemic stage. In this stage patients suffer with rest pain and ulcerations. The ulcers range from small unhealed ulcers at toes, ankles to gangrene (Dormandy & Rutherford 2000).

According to literature review, there are many factors related to PAD in patients with T2DM. Self – efficacy is very important factor and plays an important role in successful treatment and prevent many chronic illnesses (Bandura, 1997) patient self-efficacy may affect choice behavior and the next results.

Knowledge about PAD including knowledge about symptom, effect and risk factors. According to study of Vasaroangrong and the others, 80% PAD of Thai patients did not know about their disease and symptoms of PAD (Vasaroangrong, Thosingha, Riegel, Ruangsetakit & Viwatwongkasem, 2016). So, knowledge about disease is very important factor that detect early and prevent risk factors related disease. (Vasaroangrong, Thosingha, Riegel, Ruangsetakit & Viwatwongkasem, 2016). Co-morbid diseases play a vital factor adding the risk of PAD among patients with T2DM. These include hypertension, hyperlipidemia and uncontrolled serum

glucose level because those aforementioned diseases lead to atherosclerosis (Tapp, Balkau, Shaw, Valensi, Cailleau, & Eschwege, 2007).

Now a day, the laboratory test confirming patients status of glycemic control is Haemoglobin A1C (HbA1c) because this parameter can represent 3-month average serum glucose level and better reflects the condition of patients with T2DM. Study in the United Kingdom Prospective Diabetes Study reported that when people show 1% increased HbA1c, they will be at risk of having PAD for 28% (Carter, Martinez et al. 2013).

PAD in patients with T2DM affects on people'health and socioeconomic of the countries. Thus, identifying some factors such as Knowledge about disease, self – efficacy, HbA1C, comorbidity related to PAD as well as providing nursing care program will assist Vietnamese people with diabetes to be able to detect early and reduce the rate of PAD.

1.2 Research questions

What are the factors that related to the occurrence of PAD in patients with T2DM?

1.3 Purpose of the study

To identify factors related to the occurrence of PAD in patients with T2DM.

1.4 Hypothesis

1.4.1 HbA1C is positively related to the occurrence of PAD.

1.4.2 Comorbidity is positively related to the occurrence of PAD.

1.4.3 Self efficacy is negatively related to the occurrence of PAD.

1.4.4 Knowledge about PAD is negatively related to the occurrence of PAD.

1.5 Conceptual Framework of the study

Self – efficacy theory (Bandura, 1986) is utilized as a framework. When patients with PAD has mastery experience, they will have a strong belief in their own capability with vicarious experience and external verbal persuasion from others (health care team, nurses, family members) so a person will response by any demonstration of the feedback. The feedback as proposed in self efficacy theory while applying in this study. There are some factors that correlated peripheral arterial disease among patients with type 2 diabetes. Those include knowledge about disease, self – efficacy, HbA1C and co-morbidity. Patients with peripheral arterial disease can lead to disability because lower limb amputation. When patients have the belief in their ability they can perform a successful special task or behaviors to get a desirable outcome. Similarly to comorbidity, patients who have underlining chronic illness such as heart diseases, chronic kidney diseases and hypertension.

The relationship between independent variables and a dependent variable are illustrated in the following conceptual framework.

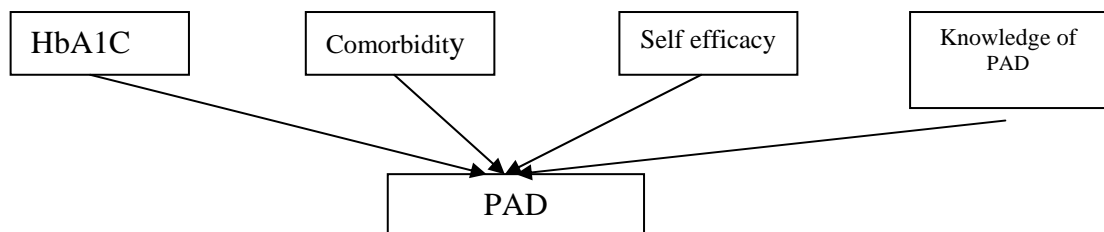


Figure 1.1: Framework of this study

1.6 Scope of the study

This study examines the relationship between factors related to the occurrence of PAD of 136 primary T2DM patients during hospital stays in the Endocrinology Department at Bach Mai hospital.

1.7 Definition of term

PAD is shown when fatty plaque builds up in the peripheral arteries, causing poor blood circulation (Carter et al., 2013). In advanced stages of PAD, ulcers or wounds on toes, feet, or legs that heal poorly and slowly; pain ischemic rest; and necrosis (Hirsch, et al., 2001). Other signs of PAD include differences in skin temperature between the lower extremities, pale skin and reduce and/or hair and nails grow poorly (Hirsch, et al., 2001)

HbA1c refers to a molecule of HbA with glucose bound of this N-terminal Valine (Carruthers 1990, Hare, Shaw et al. 2012) is known to correlate with average blood glucose levels over 3 months before (Nathan, et al. 2008; Hare, et al.,2012).

Comorbidity refers to the presence of one or more additional disorders (or diseases) with a disease or disorder. Other disorders may also be a behavioral disorder or mental.

Self-efficacy refers to people's perception toward their own believes on their own capabilities to perform targeted behaviors as they aim to attain their ultimate goals. People who possess self-efficacy have confidence, mastery behaviors, motivation and belief to control external environment to pursue their goals (Bandura 1997.). Eight item scales choose the number from 1 to 10 that corresponds to your confidence that you can do the tasks regularly at the present time. A higher number indicates higher self-efficacy.

Knowledge about PAD refer to factor driving PAD patients to find medical care (Vasaroangrong, et al. 2016). According to Tidarat Vasaroangrong, Orapan Thosingha et, al. at Faculty of Nursing, Mahidol University, Thailand developed questionnaire about knowledge of PAD questionnaire. This scale is comprised 15 true items relevant to PAD and 5 false items not relevant to PAD and force choice yes/no response format. Each item was binary 1, "yes" and 0, "no". The knowledge about PAD scored were calculated which ranged from 0 to 20 score, with higher scores indicating greater PAD knowledge (Vasaroangrong, et al., 2016).

1.8 Expected outcomes and benefits

1.8.1 The results from this study can be used among health care team to prevent the occurrence of PAD by controlling the associated factors.

1.8.2 Knowledge about independent variables from this study can be used the basic data to explain cause of PAD.

1.8.3 The results can be used to confirm the ideology of self-efficacy theory. Hence, it can be applied in nursing intervention among T2DM patients with PAD.

1.8.4 The results from this study can be used to guide the further study related to patients with PAD.

CHAPTER II

LITERATURE REVIEW

This chapter provides a literature review of factors related to the occurrence of PAD in patients with T2DM associated. The contents enhance the understanding of phenomena of PAD among patients with T2DM based on self-efficacy theory as follows 4 issues including the conclusion part:

2.1 Problems among patients with PAD

2.1.1 Incidence of PAD

2.1.2 Pathophysiology of PAD

2.1.3 Impact of PAD

2.1.3.1 Impact on physical

2.1.3.2 Impact on psychology of patients

2.1.3.3 Impact on patients' economic

2.1.3.4 Impact on patients' family

2.2 PAD in patients with type 2 diabetes

2.2.1 The definition of PAD

2.2.2 PAD in patients with T2DM

2.3 Self - efficacy theory as a conceptual framework to explain factors related to PAD among patients with T2DM.

2.3.1 Self efficacy theory

2.3.2 Self efficacy theory and the patients with PAD

2.4 Factors associated with PAD among patients with T2DM

2.4.1 HbA1C and its association with PAD among patient with T2DM.

2.4.2 Comorbidity and its association with PAD among patient with T2DM.

2.4.3 Knowledge about PAD and its association with PAD among patient with T2DM.

2.4.4 Self Efficacy and its association with PAD among patient with T2DM.

2.5. Conclusion

2.1 Problems among patients with peripheral artery disease

The normal characteristics of PAD is the gradually progressive stenosis of peripheral arteries leading to partial or totally occlusion of peripheral arteries. PAD normally is a consequence of atherosclerosis (Osthega, Paulose-Ram et al. 2007, Esteghamati, Aflatoonian et al. 2015). PAD is related with significant pain, loss of disability and function moreover, it was found that patients with PAD are at risk of cardiovascular and cerebrovascular diseases (Marso and Hiatt 2006).

A person is diagnosed of PAD when it is found that his or her peripheral arteries have occlusion. The diagnosis can be made by using vascular ultrasound and measuring patients' ankle brachial index (ABI). PAD is divided into 4 stages starting from the early stage in which there is little sign and symptom while in the advanced stage, patients would experience various signs and symptoms of ischemia. Those include chronic ulcers on any part of feet or legs. Gangrene is one of the most serious symptom in the advanced stage PAD (Hirsch, Criqui et al. 2001).

When patients with T2DM develop PAD, they are at risk of having lower limb amputation. Moreover, when the patients have PAD it can refer that they have systematic vascular pathology. Finally, it will lead to cerebrovascular diseases, cardiovascular disease, myocardial infarction and renal disease.

2.1.1 Incidence of PAD

In the United States, more than 5 million adults in 60 years and older have PAD (Bennett, Silverman et al. 2009). 9% of individuals aged 55 to 65 years have PAD and increases to 47% to 57% in individuals older than 70 years (Bennett, Silverman et al., 2009). This disease causes indirect and direct functional impairments in older adults. Moreover, the dramatically increased numbers of patients with PAD bring the burden of cost in health care (Aronow, 2006; Bak, et al, 2016; Dua & Lee, 2016).

Using an ABI of less than 0.9, Doppler ultrasound, MRI as the defining characteristic of PAD (Doobay & Anand, 2005). The National Health and Nutrition Examination Survey 1999- 2000 reported that incidence was 2.5% in patients aged 50 to 69 years and 14.5 to 29 % in persons older than 70 years (Hirsch, Criqui et al. 2001; Selvin & Erlinger, 2004). In Korea the incidence of PAD was 23.9% in patients over 70 years (Kim, Song et al. 2013). Indians found that incidence PAD in patient with T2DM only 6% (Premalatha and V , 2000). In China, the incidence of PAD is relatively similar, Foong reported that PAD incidence ranged from 6 to 10 % (Foong 2007; Thomas & Chan, 2003). 10% Asian Malay adults aged 40–80 years with diabetes in Singapore had pad (Tavintharan, Ning et al. 2009). Statistics at the Vietnam Heart institute indicates in patients who have the proportion of patients peripheral artery disease inpatient treatment at the Institute increased from 1.7% in the year 2003 to 2.5% in 2006) and 3.4% in the year 2007 (Phạm Việt Tuấn, 2008). The incidence would markedly increase with the advanced age, smoking, hypertension, chronic renal disease and dyslipidemia.

2.1.2 Pathophysiology of PAD

PAD can occur among patients with or without T2DM with the relatively similar pathological process (Marso and Hiatt 2006; Bak,et al., 2016). The different pathology between these 2 groups is that patients with T2DM tend to have pathology in the distal and tibial arteries (Haltmayer, Mueller et al. 2001). Patients with T2DM always have abnormal metabolism which can contribute to the occurrence of atherosclerosis. The process of proatherogenic alteration couple with impaired glucose tolerance lead to vascular endothelium inflammation. Consequently, pro-inflammatory cytokines and acute-phase proteins which include interleukin-6, tumor necrosis factor-alpha, C-reactive protein and fibrinogen increased. The action of C-reactive protein on the occurrence of PAD is very prominent. It inhibits endothelial cell nitric oxide synthase. This process causes alteration of vascular tone, induces the production of plasminogen activator inhibitor-1. Eventually, the formation of fibrinolytic plasmin is inhibited leading to athero-thrombosis (Signorelli, Fiore & Malaponte, 2014). It is importance to note that athero-thrombosis can easily induce PAD. The mechanism is relatively complex because it relates to changed of vascular endothelial cells, vascular

smooth muscle cells, fibroblast, platelets and inflammatory cells. Accordingly, the plaque is formed on the vascular wall makes the vascular become narrow and lead to ischemia of distal organs or so-call peripheral organs (Krishna, Moxon & Golledge, 2015). In patients with T2DM, high level of serum glucose also induce platelet aggregation. The higher the serum glucose level the more advanced plaque formation in the vascular cells (Suzuki, Pot, Gerrity & Bornfeldt, 2001).

Pathology of PAD can be explained by the other hypothesis, the hypothesis related to vascular calcification. In the past 2 decades, many researches support this pathological process. Calcification will be formed in vascular smooth muscle cells, macrophages and the necrotic lipid core and are associated with the occurrence of atherosclerosis. The explanation is that muscular smooth muscle cells become damaged so that they loss defensive mechanisms and functions allow crystallization of calcium or phosphate. The calcium plaques then occur making vascular become narrow (Ho & Shanahan, 2016).

Using the Fontaine staging system can be classified the clinical stage of symptomatic PAD (Marso and Hiatt 2006). In the Fontaine stage I represents, patients have PAD but are asymptomatic; stages II a and II b, patients with mild and moderate-to-severe intermittent claudication (IC). In Fontaine stage III with ischemic rest pain. In Fontaine stage IV, patients suffer with critical limb ischemia (CLI) so that they always experience distal ulceration and gangrene (Dua & Lee, 2016). According to Marso 2006, history of claudication has a low sensitivity, but a high specificity for PAD (Marso and Hiatt 2006). In advanced stages of PAD, a person may present with sores or wounds on the lower extremities including toes, feet, or legs that poorly and slowly heal. Patients also suffer from ischemic pain. This symptom lead to anxiety and depression due to sleep not enough. Skin discoloration, poor hair and toe nail growth was observed. Poor peripheral blood circulation will lead to gangrene and patients will receive lower limb amputation (Carter, Martinez et al. 2013).

Clinical experience with measure ABI and colour Doppler ultrasonography, and its high sensitivity (88%), specificity (95%) and accuracy (93%), have made this technique a valuable non-invasive screening tool (Esteghamati, et al., 2015). Patient with symptoms of PAD should be screening for diagnostic.

2.1.3 Impact of PAD

PAD has various impacts to patients and their families. Not only in the physical aspect, patients with PAD suffer with emotional alteration, economic problems and interaction with others. Details are described below.

2.1.3.1 Impact on physical symptoms

Patients with PAD experience various physical symptoms including pain, fatigue, and weakness. These symptoms alter their normal life. Many studies showed that patients with PAD who suffered with intermittent claudication or calf pain demonstrated difficulty in walking, their gaits are abnormal, they walked with instability so that it brought high risk for fall. They had difficulty when climbing up or down the stairs as well as the difficulty in walking in a long distance (Aronow, 2006). These lead to difficulty in commute and can deprive them from their routine social activities. Patients with PAD in the advanced stage have prominent or critical limb ischemia. Beside severe ischemic pain, they have to deal with chronic wounds on the toes, ankles, feet or legs and nail deformity. These will eventually lead to gangrene. Hence, patients have to receive limb amputation and become disable (Hirsch, et al., 2001; Dua & Lee, 2016).

2.1.3.2 Impact on psychological and emotional health

Patients in advanced stage of PAD always suffer with severe ischemic pain that would disturb their sleep quality. Pain at rest usually take place during the night time when patients sleep. Inadequate sleep will lead to the feeling of unpleasant, depression and anxiety. Moreover, with limited walking ability, patients would suffer with decreased work capability. They would have low self esteem, anxiety and low self confidence (Aronow 2006, Ostchega, Paulose-Ram et al. 2007, Bennett, Silverman et al. 2009). In particular, among the aged patients with PAD, they had to deal with feeling of dependency, loneliness and guilty because they have to receive extra assistance from their family members.

2.1.3.3 Impact on patients' economic

Patients with PAD have to deal with economic problems in 2 main tracks. The first track is related to the treatment expense. If PAD is detected in the very early stage, there are many treatment alternatives including pharmacological management in which the expense is relatively low. However, most of the patients

would get access to care while the disease is in its advanced stage in which there are less alternatives of treatment. In the late stage, patients with PAD require surgical treatment which include arterial by pass graft or interventional intravascular therapy and the treatment expenses are very high (Dua & Lee, 2016). Moreover, patients with chronic ulcers or gangrene require comprehensive wound treatment with high cost. The second track is related to decreased patients' capacity in their previous works. Most of patients with PAD become less active participate in their previous work due to chronic pain, hospitalization, and frequent hospital visit. This affects their usual work life and incomes. If the patients' incomes are the main family incomes, this would affect their family (Dua & Lee, 2016).

2.1.3.5 Impact on patients' family

The chronic physical symptoms in patients with PAD has direct impact on family members. In particular, the spouse, siblings or other close family members who residing in the same household. Patients' suffering from symptom make family members become stressful and anxious. Patients in advance stage who need assistance because of their limitation in movement become great burden for the family. The family members of these patients have to alter their life styles to comply with patients' need. They also have to deal with patients' emotional instability which make them become more stressful. In addition, if patients who have PAD have the other diseases such as T2DM, hypertension, heart disease or renal disease, family members would have more burden.

2.2 PAD in patients with T2DM

Although PAD can occur among patients without T2DM, in the past 3 decades there are evidences to support the occurrences of PAD among patients with metabolic disease as well as patients with T2DM.

A prospective cohort study with 5.7 years follow up of Veleacu and the others among 5,434 Mediterranean people whose ages are between 35 to 79 years reveled that people who had long-term uncontrolled diabetes showed the highest risk of the occurrence of PAD (OR 10.14; 95% CI 3.57-28.79). This study also compared diabetes with other factors such as hypertension, hyperlipidemia, BMI, smoking or

age. The authors summarized that level of HbA1c was the strongest risk among other risk factors (Velescu, et al., 2016). Moreover, it will lead to the diseases such as cardiovascular disease, stroke and renal disease if blood glucose can not be well controlled. Similar to the study of Torón and the others (Torón, Farré, Lliso & Diestro, 2016) among 131 patients who were diagnosed with PAD, it was found that T2DM was a major factor associated with PAD. Moreover, it was found that if patients were obesity, had high systolic blood pressure and hyperlipidemia, the severity of PAD was prominent. These group of patients were at risk for developing DFUs which led to lower limb amputation and sepsis.

The study of Sales and the others among patients with T2DM who came for a follow up visit at the endocrine clinic in the governmental hospital in North Brazil found that among 73 patients with T2DM there were 13.7% who had PAD. Among patients with PAD, most of them had symptomatic mild PAD so that the patients' quality of life and their physical activity were not affected (Sales, et al, 2015). From the above evidences, it can be concluded that the occurrence of PAD is associated with T2DM, duration of T2DM and the effectiveness in controlling T2DM.

2.3 Self - efficacy theory as a conceptual framework to explain factors related to PAD among patients with T2DM.

2.3.1 Self efficacy theory

There are various cognitive behavioral theories that have been used in researches among people with non communicable diseases. One of these is Self-efficacy theory (Bandura, 1997). The core concept of Self-efficacy theory is focusing on the believes of people in their own capabilities to obtain expected or desired outcomes. According to Bandura the desired outcomes can be achieved through specific performance attainments. People who have self- efficacy are confidence to perform health behaviors so that they can obtain expected health outcomes. The theories also belief in the influence of environment, it can interact with individual behavior (Bandura 1997.).

There are 4 components of the theory including: Mastery experience or so called- enactive attainment, vicarious experience, verbal persuasion and physiological feedback (Bandura 1997). Outcome expectation which can reflect goals of people interact with people characteristics and environment. All of components what are increasing patient self-efficacy should enable patient to be more successful at the control and prevention complication of disease which is they attempt. The patients' experience of mastery about disease is the most important behaviors because it can lead to the success of complication control. Beside, the patient who received encouragement from social persuasion will have ability to control the advancement of disease (Bandura 1997.).

Self efficacy theory provided the major concept, that I will use in my study. My interesting population is patients with T2DM. PAD is a condition that is manifested when fatty deposits of plaque accumulate in the inner walls of PAD, causing impaired blood circulation. This is most commonly compromised. They are patients who require good health behaviors and be confidence to perform self care in order to prevent and control complications from T2DM. PAD is the most complication in patients with T2DM. Self efficacy explains the clear concept of patients' own judgment on their activities to perform positive health practice. Accordingly, the expected outcome will be occurred.

2.3.2 Self efficacy theory and the patients with PAD: In this study, self efficacy is viewed as independent variable that will have an effect on the outcome which refer to the occurrence of PAD. Evidences from research findings revealed that self efficacy is related to the effectiveness to control glycemic level and the occurrence of DFUs and PAD in patients with T2DM. Moreover, T2DM patients who have high self-efficacy would be confidence to perform foot care, foot inspection and self monitoring so that they could early detect when some changes occur. This can prevent them from having severe occlusion of peripheral arteries (Collins, Lunos & Ahluwalia, 2010; Caldieraro-Bentley & Andrews, 2013; Adam & Folds, 2014).

2.4 Factors associated with PAD among patients with T2DM

As widely recognized, patients with T2DM are at risk of having PAD. Literature showed that T2DM increases the risk of PAD by 2 to 4 folds and exists in 12% to 20% of people with PAD (Carter, et al. 2013). However, there are many factors associated with the development of PAD in patients with T2DM. These factors can be divided into 2 main tracks; intrinsic factors and extrinsic factors (Dua & Lee, 2016).

Intrinsic risk factors refer to factors related with patients' characteristics. These factors are difficult or not possible to modify such as patients' age, gender or ethnic group. These factors are either have direct association with PAD or serve as a mediator to PAD. Extrinsic factors refer to factors that can be modified such as cigarette smoking, level of HbA1c, hypertension, hyperlipidemia, body mass index, and comorbid diseases (Dua & Lee, 2016). The other 2 extrinsic factors related to PAD are knowledge about PAD and self efficacy. These 2 later factors are factors that can be modified by nurses' roles.

In this present study, the researcher selected 4 factors include HbA1c, comorbidity, knowledge about PAD and self efficacy. All of aforementioned factors are extrinsic factors in which nurses can intervene to improve the patients' health outcomes. Details of each factor will be described as follow.

2.4.1 HbA1C and its association with PAD among patient with T2DM

In the past 2 decades, HbA1c had played a vital role in diagnose of diabetes and the follow up laboratory test for patients with T2DM. HbA1c is known as the average blood glucose concentration over the preceding 3 months. It is used as a biomarker in clinical practice for patients with T2DM (Nathan, Turgeon, Regan, 2007). Various cross sectional and prospective studies have supported the strong association between HbA1c and the occurrence of PAD. Dua & Lee (2016) stated that every one percentage of HbA1c rise there is an increase risk of 26% for PAD. The prospective cohort study conducted by Selvin and the others among 1,894 diabetic adults who attended diabetic clinic for 10 years found the very strong association between HbA1c and the development and severity of PAD (Selvin, Wattanakit, Steffes, Coresh & Sharrett, 2006).

This study also emphasized that diabetes patients who had poor glycemic control or had HbA1c level greater than 7.5% were more likely to experience critical ischemic lower limb with intermittent claudication by 5 times comparing with ones who had good glycemic control (HbA1c level lower than 6%). According to atherosclerosis in carotid artery, these patients who had poor glycemic control were at risk of developing coronary heart disease and stroke (Selvin, et al., 2006). Many studies also showed that HbA1c in patients with T2DM also related with DFUs and other chronic delayed healed wounds (Collins, Lunos & Ahluwalia, 2010; Caldieraro-Bentley & Andrews, 2013; Adam & Folds, 2014; Dua & Lee, 2016)

2.4.2 Comorbidity and its association with PAD among patient with T2DM

Patients with T2DM always have to deal with many underlying illnesses or so-called comorbidity. These comorbid diseases affect the development of PAD. The most common comorbid disease found are related with the pathology of atherosclerosis such as cardiovascular disease, coronary artery disease, hypertension, stroke or kidney disease. On the other ways, having these comorbid diseases reflect the abnormality of arteries. Accordingly, these patients are more likely to have risk of developing PAD. Hirsch and the others stated that 50 to 92% of patients with PAD showed that they had hypertension (Hirsch, et al. 2001; Madia, 2012). Patients with T2DM who have hypertension would have abnormality of the arterial walls leading to partial or near-totally occlusion (Mehler, et al. 2003; Carter, et al., 2013).

The other importance comorbid diseases is hyperlipidemia. It can easily lead to PAD because lipid abnormalities affect the endothelium cells in the vascular. Those lipid include low-density lipoprotein, cholesterol and triglyceride (Carter, et al. 2013). For each of 10 mg/dL rising of total cholesterol level, the risk of developing PAD increases by approximately 5% to 10% due to increased endothelial plaques. The higher the cholesterol level the patients have, the more severe occlusion or narrowing of the peripheral blood vessels and leading to critical limb ischemia (Dua & Lee, 2016).

It is very importance to note that, hypertension and hyperlipidemia in patients with T2DM can lead to many other comorbid diseases such as heart disease,

chronic renal disease or coronary heart diseases. The more co morbid diseases the patients have, the more risk of them to have PAD. Moreover, this group of patients are at risk of having high mortality rate (Mehler, et al, 2003; Carter, et al., 2013).

2.4.3 Knowledge about PAD and its association with PAD among patient with T2DM

Knowledge about PAD is the crucial factor driving PAD patients to seek medical care (Leventhal 1984). The majority of patients with PAD access medical care only after they have reached a catastrophic stage (Vasaroangrong, et al. 2015). However, knowledge about PAD in both general people and PAD patients is still low (Hirsch, Murphy et al. 2007). The public is poorly informed about PAD, with major knowledge gaps regarding the definition of PAD, risk factors that lead to PAD, and associated limb symptoms and amputation risk. At present, the knowledge regarding PAD is still very limited among lay persons. In particular, among patients who with T2DM. When the peripheral limb wounds or toe wounds occur, they would believe that these wounds come from high level of blood glucose but not related with the occlusion of peripheral arteries. The study of Vasaroangrong and the others found that some of them believed that the wounds came from in proper shoes wear and never relate them with the occlusion of the vessels (Vasaroangrong, et al. 2015). About 80% of PAD patients did not know about PAD disease and symptoms. Only 25% knew that PAD was an arterial disease. Moreover, there was evidence that only 14% of subjects who were familiar with PAD knew about the consequences of PAD (amputation and death). Most were unaware of important risk factors such as smoking and diabetes (Hirsch, Murphy et al. 2007, Lovell, Harris et al. 2009, Vasaroangrong, et al. 2015).

The ABI represents a simple, reliable method for diagnosing PAD. This method is very simple, cost effectiveness and not create any harm to patients. The ABI assessment process is relatively simple and can be performed by nurses so that it is very useful for any level of health care institutes in particular, in the very rural areas. (2003, Potier, Abi Khalil et al. 2011). ABI can be easily calculated by using the ratio of the systolic blood pressure in the patients' ankle divided by the systolic blood pressure at the arm. The diagnostic criteria for PAD based on the ABI are interpreted as follows at the time of this study: normal if 0.91 to 1.30; mild obstruction if 0.70 to

0.90, moderate obstruction if 0.40 to 0.69, severe obstruction if 0.40, and poorly compressible if greater than 1.30. An ABI value greater than 1.3 in the old value suggests poorly compressible arteries at the ankle level in the presence of medial arterial (Bak, et al, 2016) Measurement of the ankle-brachial index represents a noninvasive, objective way to diagnose PAD. ABI is the very simple reliability index, it owns a sensitivity above 90% and a specificity of 95% for the diagnosis of PAD (Bak, et al, 2016). There are more specific indicators of PAD that can be assessed by nurses. Those include the history of leg pain, pain at rest, pain after walking, calf pain, intermitten claudication, foot ulcers or gangrene (Gerhard-Herman, et al. 2006; Potier, et al. 2011).

2.4.4 Self Efficacy and its association with PAD among patient with T2DM

Self efficacy explains the clear concept of patients' own judgment on their activities to perform positive health practice. Accordingly, the expected outcome will be occurred. In my study, the conceptual framework will be based on self efficacy theory and a concept of self efficacy is also viewed as independent variable that will have an effect on the outcome which refers to the occurrence of PAD. Self efficacy and outcome expectation interact with characteristics of the individual and environment.

All of components what are increasing patient self-efficacy should enable patients to be more successful at the control and prevention complication of disease which is their attempt. The patients' experience of mastery about disease is the most important behaviours because it can lead to the success of complication control. Besides, the patient who received encouragement from social persuasion will have ability to control the advancement of disease.

There is a reciprocal relationship between self efficacy and outcome expectation with influence the performance is that these concepts are interacted with individual characteristic and the environment. It is a middle range theory and can be utilized from the descriptive, explanatory, predictive and prescriptive. Self efficacy of patient with PAD can be measured by standard scale with self-efficacy scale. The theory very easy to understand because it present the clear concepts. The most strength

of this theory is it described how to motivate or persuade patients to belief in their own capability to perform desired health behaviors. This theory have reality, utility, significance, discrimination, adequacy, consistency (Bandura 1997.)

Many studies have examined self efficacy for walking in the symptomatic patient with PAD (Collins, Lunos et al. 2010, Caldieraro-Bentley and Andrews 2013). A comprehensive review to explore measures for self-efficacy for walking in individual with PAD is necessary to guide descriptive and interventional research in this population. Instruments used to measure self-efficacy for walking in the population with PAD have a role in practice and research. Once reliability and validity of the instruments have been demonstrated in this specific population, the role of confidence and evaluation of social cognitive interventions can be appropriately explored.

2.5 Conclusion

According to the literature review it can be concluded that the incidence of PAD is gradually increasing among patients with T2DM. PAD has impacted on patients' physical health, severe symptoms, patient's emotion and psychology. Moreover PAD leads to the economic burden because it leads to patients' disability due to lower limb amputation. There are evidences to support that the occurrence of PAD is associated with many factors in particular patients' self efficacy, patients' knowledge about PAD, patients' Comorbidity and the level of HbA1C. Clearly understand this phenomena will assist the researcher to conduct research to confirm the relationship among these variables. It can be expected that knowledge gained from this study can be used to improve the quality of care among patients with T2DM.

CHAPTER III METHODOLOGY

3.1 Research design

The study was described correlation research aiming to study factors related to the occurrence of PAD in patients with T2DM.

3.2 Population and sample of the study

3.2.1 The population of this study

The population of this study included patients who were diagnosed with T2DM and admit to in a patient Endocrine department, Bachmai hospital, Hanoi.

3.2.2 The sample of the study

The sample was selected from the population, according to the following criteria:

Inclusion criteria

- The patients age 18 years old and above,
- Diagnosed with T2DM
- Able to verbally communicate with the researcher in Vietnamese

language.

Exclusion criteria

- Incomplete fill out questionnaire

Sample size:

The sample size in this study was calculated by G* power version 3.1.9.2 program to determine the minimum number of participants needed for co-relational design (Fall, Erdfeder, Buchner, & Lang, 2009). The researcher tested the relationship among HbA1C, self efficacy, Comorbidity, knowledge about PAD and the occurrence

of PAD in patients with T2DM. The level of significance $\alpha = 0.05$, the power of the statistical test (Power $1 - \beta = 0.8$). There are four independence variables in this study and effect size for this study ($p^2 = .099$). Base of G* power, sample size was 136 patients.

3.3 Setting

The research was conducted in Endocrinology Department, Bachmai hospital. It is one of the biggest hospitals in Vietnam. The Endocrinology department have 70 beds and have about 30 – 40 in patients with T2DM every day. Besides treating T2DM, patients have to treat some complications, such as PAD, foot uncle, cardiology disease, kidney disease. The patients come from different area, culture, socioeconomic.

Healthcare services were provided by the medical staff 24 hours per day. Nurses and a physician work two shift a day. Model of care assigned to groups in here. Two nurses take care about 20 – 25 patients. Every day patients were examined, evaluated, monitored, taken medicine, provided health information related disease by nurses. So, the researcher plans to collect data on Monday – Sunday, 7.00 am – 5.00 pm.

3.4 Instruments

The instruments used for data collection included 4 parts as follows:

Part I. Questionnaire demographic data of the patients: Patient name, Age, Gender, Weight, BMI, Province, Education level, Date of Admission to hospital, Mauritius status, occupation, location of residence, income, insurance,

Part II. Information related to illness and treatment: History of diseases: Duration of diabetes, Duration of PAD, comorbidity, Diagnosis, Blood pressure, Body Temperature, Laboratory, HbA_{1C}, ABI.

The ABI was a simple, inexpensive, and noninvasive tool that can be used to detect PAD (American Diabetes Association, 2013; Carter, 2013). It was defined as the ratio of the systolic blood pressure in the ankle divided by the systolic blood

pressure in the arm (American Diabetes Association, 2013). The tools required to perform the ABI measurement includes a handheld 5- to 10-MHz Doppler probe and a blood pressure cuff (American Diabetes Association, 2013). The ABI was measured by placing the patient in a supine position for 5 minutes (Association, 2003). Systolic blood pressure was measured in both arms, and the highest value was used as the denominator of the ABI. It was then measured in the dorsalis pedis and posterior tibial arteries by placing the cuff just proximal to the ankle. The higher value is the numerator of the ABI in each limb. The diagnostic criteria for PAD based on the ABI are interpreted as follows at the time of this study: normal if 0.91 to 1.30; mild obstruction if 0.70 to 0.90, moderate obstruction if 0.40 to 0.69, severe obstruction if 0.40 and poorly compressible if greater than 1.30 (American Diabetes Association, 2003; Carter, 2013; Potier, Abi Khalil, Mohammedi, & Roussel, 2011).

Part III. Self efficacy for diabetes score: Questionnaire the scale would like to know how confident you were in doing certain activities. This 8-item scale was originally developed and tested in Spanish for the Diabetes Self-Management study. The score for each item was the number circled. If two consecutive numbers were circled, code the lower number (less self-efficacy). If the numbers were not consecutive, do not score the item. The score for the scale was the mean of the six items. If more than two items are missing, do not score the scale. A higher number indicates higher self-efficacy. 8 items include: How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day? How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes? How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)? How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week? How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise? How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be? How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor? How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?

Part IV. The Knowledge about PAD scale Development of the knowledge about PAD by Tidarat Vasaroangrong, Orapan Thosingha et al in Faculty of Nursing, Mahidol University, Thailand. Questionnaire comprises 20 items presented in a forced choice, yes/no response format. The questionnaire begins with the question “Have you ever heard about peripheral arterial disease?” and follow by the questions of knowledge about PAD. The 20 items took 5-10 minutes to answer. The Knowledge about PAD scored was calculated which ranged from 0 to 20, with higher scores indicating greater PAD knowledge. Knowledge scores of patients with PAD, Knowledge about symptoms of PAD, Knowledge about risk factors of PAD, Knowledge about effects of PAD.

3.5 Instrument Reliability and Validity

3.5.1 Instrument Reliability

After obtaining the IRB approval the Numerical Rating scale, the Knowledge about PAD scale and Diabetes self efficacy scale were used in 30 patients with T2DM who had characteristic similar to the studied sample as aforementioned. The reliability by Cronbach’s alpha coefficient were employed to test each instrument reliability for 30 patients and for the whole sample (n = 136) (table 3.1).

Table 3.1 Reliability of scales (n= 17 and n=136)

Scale	N of Items	Cronbach's Alpha (n = 17)	Cronbach's Alpha(n= 136)
Knowledge about PAD scale	20	.831	.883
Diabetes self efficacy scale	8	.784	.910

3.5.2 Instrument Validity

Content validity was especially important for instruments that measure knowledge (Lynn 1986). Knowledge about PAD questionnaire was comprised 15 true items relevant to PAD and 5 false items not relevant to PAD (5 reverse items). The

overall content validity index of the Knowledge about PAD questionnaire when reverse items were deleted was 0.87 (Vasaroangrong, Thosingha et al. 2016).

3.6 Data collection

Research was conducted by after the consent of the director of Bachmai hospital, head of Endocrinology unit. The study also was approved by the Ethical Committee of Mahidol University and IRB of Vietnam National University, Vietnam.

In this study, the researcher collected by herself according to doing a letter to request for data collection cooperation from the dean of the Graduate School, Mahidol University to propose the director of Bachmai Hospital and the director of the Endocrine unit in Bach Mai hospital in order to ask for an approval of collecting data in the same time the researcher propose the research project to make a consideration from Mahidol University. When the approval was approved and received permission to data collection, the researcher met the director of the hospital, head of department and head nurse of the Endocrinology ward at the data resource. This was done in order to explain the purposes for data collection. Head nurse introduced researcher to target population. Then, the researcher self introduced, make a relationship with the patients, then informs sample about the objective of the study, data collection procedure and asked for the research cooperation. In addition, the researcher asked patient signed consent form. Then, the researcher used the questionnaire and assessment form for data collection. The questionnaires (1) demographic data question, (2) Information related to illness and treatment (3) Self efficacy Scale, (4) The knowledge of PAD scale. Participants could free to withdraw from the study at any time without explaining; confidentiality was maintained by not collecting data that could identify any one individual and also through employing unique study codes. The first, the researcher selected information about patients in record such as: Diagnosis, laboratory, treatment, medication. And then the patients answered the questions in the context of an interview, the researcher examined for patients which lasted for about 30 minutes.

3.7 Protection of human rights

This study was conducted based on the protection of human rights. The participants were asked to participate in the study. The researcher explained the purpose of the study, the research procedure, benefits, risks, type of questionnaire length of time for completing the questionnaire, and the right to refuse participation in the study anytime. The participants who agreed to participate were informed and assured that the data would be kept confidential and would be reported only as a group data. Informed consent was by all participants.

In this research, the researcher was strictly a concern for human rights and ethical issued throughout the research process by:

3.7.1 Submitting the research proposal to get approval from the Ethical Committee of Mahidol University and IRB of Vietnam National University, Vietnam and started the data collection process after receiving approval from director of Bachmai hospital, head of Endocrinology unit.

3.7.2 The researcher introduced herself or himself to the participants, inform the patients about the research objective and all data collection process. The patients were informed that they had a right to refuse to join in the research process. During anytime throughout the research process, patients had their own right to withdraw from the research project at any time and were not affected their treatment or curing process. If patients agreed to join in the research process, they were invited to sign their name in the consent form.

3.7.3 This research was caused any risk to the patient physical health. The data collection process might take time about 30 minutes. Although the patients were not getting any benefit from this research but the results were not benefited for other patients who had the same health care problem as the sample.

3.7.4 All contents were kept confidential, only the researcher and the research team were able to get access to the data. Any content related to data that were presented in the thesis or any publicity were anonymous. In case of the ones who withdrawn themselves from the research, all data were deleted from the database and were not used as any part of the research.

3.7.5 If the participants had further questions or require more explanation in regard to the research, they were informed to feel free to ask the researcher at any time throughout the research process.

3.7.6 After the participants were clearly understood the research process and agreed to join in the research, they were invited to sign their name in the consent form.

3.8 Data analysis

Using a computer program to test the ability on each aspect of PAD with T2DM.

All intervals or continuous data were analyzed using statistical analysis in term of frequency, percentage, range, mean and standard deviation.

The nominal and ordinal data were reported with a frequency and percentage.

The relationships between age, HbA1C, self-efficacy, Comorbidity, duration of diabetes and PAD were analyzed by Chi – Square test.

CHAPTER IV

RESULTS

This descriptive correlational study was conducted to examine the relationship between HbA₁C, Comorbidity, Self efficacy, knowledge about PAD and PAD among patients with T2DM, who aged above 18 years old in an Endocrinology unit at the Bach Mai hospital from August to October, 2016. The findings were presented in the descriptive statistic as follows:

1. The demographic data of patients with T2DM.
2. The information related to illness and treatment
3. The correlation between HbA₁C, Comorbidity, Self efficacy, knowledge about PAD and PAD among patients with T2DM.

4.1 General characteristics of the sample

The sample includes 136 patients with T2DM. The demographic data were collected, including age, gender, BMI, marital status, educational level, occupation and income. It can be seen from the Table 4.1 the findings illustrated that a nearly equal distribution between males (52.2%) and females (47.8%). The age of patients with type 2 diabetes ranged from 23 to 86 years with the mean age of 59.62 years (SD = 11.76). The samples with overweight were 20.6% and obesity was 18.4%, mean of BMI were 22.07 (SD = 3.27). Most of them were married (71.3%), finished secondary school (44.9%), retired from their work (33.1%) and farmer (34.6%), living in the rural (50%). 75% samples had health insurance. The majority of the samples never smoked (52.9%), 52.2% never alcohol, 13.2% have never exercised, 26% never stress (table 4.1).

Table 4.1 Characteristic of the individual (n = 136)

Characteristics	Number	Percentage
Gender		
Male	71	52,2
Female	65	47,8
Age (years)		
18-39	9	6,6
40-59	57	41,9
>=60	70	51,5
Min: 23		
Max: 86		
Mean \pm SD: 59,62 \pm 11,763		
BMI		
<18.5	20	14.7
18.5-22.9	63	46.3
23-24.9	28	20.6
>=25	25	18.4
Min: 15.56		
Max: 35.16		
Mean \pm SD: 22.07 \pm 3.27		
Marital status		
Married	97	71.3
Single	14	10.3
Divorced	4	2.9
Widowed	21	15.4

Table 4.1 Characteristic of the individual (n = 136) (cont.)

Characteristics	Number	Percentage
Educational Level		
Elementary school	22	16.2
Secondary school	61	44.9
High school	31	22.8
Two years certificate	7	5.1
College	6	4.4
Bachelor	7	5.1
Other	2	1.5
Occupation		
Professional	3	2.2
Farmer	47	34.6
Industrial worker	12	8.8
Salesperson	14	10.3
Home worker	11	8.1
Retired	45	33.1
Other job	4	2.9
Location of residence		
City	66	48.5
Rural	68	50
Mountain	2	1.5
Income per month(USD)		
<100	53	39
101-200	52	38.2
201-300	21	15.4
>300	10	7.4
Min: 0		
Max: 750 USD		
Mean ± SD = 164,58		

Table 4.1 Characteristic of the individual (n = 136) (cont.)

Characteristics	Number	Percentage
Insurance		
Yes	102	75
No	34	25
Percentage		
100%	8	5.9
95%	8	5.9
80%	74	54.4
40%	11	8.1
0%	35	25.7
Number of people live together		
0	8	5.9
1-5	124	91.2
>=5	4	2.9
Min: 0		
Max: 8		
Smoking		
Never	72	52.9
Occasional	14	10.3
Sometime	29	21.3
Often	14	10.3
Always	7	5.1
Alcohol		
Never	71	52.2
Occasional	16	11.8
Sometime	27	19.9
Often	13	9.6
Always	9	6.6

Table 4.1 Characteristic of the individual (n = 136) (cont.)

Characteristics	Number	Percentage
Exercise		
Never	18	13.2
Occasional	24	17.6
Sometime	40	29.4
Often	44	32.4
Always	10	7.4
Stress		
Never	26	19.1
Occasional	64	47.1
Sometime	39	28.7
Often	7	5.1
Always	0	0

4.2 The sample information related to illness and treatment

The majority of samples had experienced T2DM with the mean duration of 7.59 years (SD=6.83), 11.8% their no treatment. 52.2% samples have hypertension with the mean duration of 3.12 years (SD = 4.89), 18.3% no treatment. In addition, the samples also suffer from conditions such as: heart disease, kidney disease. COPD with the ratio 7.4%; 14.7%; 1.5% and the mean duration were 0.29 (SD = 1.96); 0.46 (SD = 1.83); 0.04 (SD = 0.429). Many of them do not treat diseases with the ratio 20%; 30%; 50%. All most they do not control HbA1C, and men of HbA1C were 9.38 (SD=2.4).The samples have an ABI right value and ABI left value less than 0.9 were 7.4% and 3.4% (Table 4.2).

Table 4.2 Characteristic of information related to illness and treatment (n = 136)

Characteristics	Number	Percentage
Duration of DM(years)		
Less than 5year	60	44.1
6-10 year	25	18.4
>10 year	51	37.5
Min: 0		
Max: 28		
Mean \pm SD: 7.59 \pm 6.83		
Treatment of diabetes disease		
No	16	11.8
Sometime	26	19.1
Always	94	69.1
Hypertension		
Yes	71	52.2
No	65	47.8
Duration of hypertension (n = 71)		
\leq 5 years	40	56.35
6-10 years	22	30.98
>10 years	9	12.67
Min: 0		
Max: 26		
Mean \pm SD: 3.12 \pm 4.89		
Hypertension treatment (n = 71)		
No	13	18.3
Sometime	9	12.7
Always	49	69.0
Heart disease		
No	126	92.6
Yes	10	7.4

Table 4.2 Characteristic of information related to illness and treatment (n = 136)
(cont.)

Characteristics	Number	Percentage
Duration of Heart disease (n = 10)		
<=5 years	9	90.0
6-10 years	0	0
>10 years	1	10.0
Min: 0		
Max: 22		
Mean ± SD: 0.29± 1.96		
Heart disease treatment (n = 10)		
No	2	20
Sometime	2	20
Always	6	60
Kidney disease		
No	116	85.3
Yes	20	14.7
Duration of Kidney disease (n-20)		
<=5 years	18	90
6-10 years	1	5
>10 years	1	5
Min: 0		
Max: 16		
Mean ± SD: 0.46± 1.83		
Kidney disease treatment (n= 20)		
No	6	30
Sometime	2	10
Always	12	60
COPD		
No	134	98.5
Yes	2	1.5

Table 4.2 Characteristic of information related to illness and treatment (n = 136)
(cont.)

Characteristics	Number	Percentage
Duration of COPD (n = 2)		
<=5 years	2	100
Min: 0		
Max: 5		
Mean ± SD: 0.04± 0.429		
COPD treatment		
No	1	50
Always	1	50
HbA1C (mg/dl)		
<=7	16	11.8
>7	120	88.2
Min: 5.2		
Max: 18.6		
Mean ± SD: 9.38± 2.4		
ABI Left		
<=0.9	5	3.7
>0.9	131	96.3
Min: 0.79		
Max: 1.31		
Mean ± SD: 1.17 ± 0.19		
ABI Right		
<=0.9	10	7.4
>0.9	126	92.6
Min: 0.61		
Max: 1.3		
Mean ± SD: 1.18 ± 0.23		
Temperature		
Normal	134	98.5
High	2	1.5

Table 4.3 Range, mean and standard deviation of laboratory values, weight, height and vital signs

Preclinical characteristics	Minimum scores	Maximum scores	Mean scores	SD
Cholesterol	1.31	23.4	5.464	2.16
Triglyceride	0.56	9.95	2.35	1.64
Weight (Kg)	30	90	56.88	9.928
Height (cm)	145	176	160.35	7.239
Systolic	90	170	125.04	14.501
Diastolic	60	100	77.21	7.924
BMI	15.56	35.16	22.07	3.27

The meanings of cholesterol and triglycerides were 5.464 (SD=2. 26) and 2.35 (SD=1.64)(table 4.3).

Table 4.4 The number of Comorbidity of patients with T2DM (n=136)

Comorbidity	Number	Percentage
0 comorbidity	33	24.3
1 comorbidity	56	41.2
2 comorbidities	31	22.8
3 comorbidities	12	8.8
4 comorbidities	3	2.2
5 comorbidites	1	0.7

Most of patients have 1 comorbidities (n=56) and 2 comorbidities (n=31). 24.3% (n = 33) without comorbidity from (table 4.5).

4.3 The sample information related to PAD

In total 136 patients participated in the study, 22 people with PAD (16.2%). The majority of stage I Asymptomatic (40.9%) and stage IV Ulceration or gangrene (36.4%). The main location of the occlusion was Tibio-Peroneal artery (63.6%) and Femero-Popliteal artery (31.8%) (Table 4.5).

Table 4.5 Characteristics of PAD

Characteristics	Number	Percentage
PAD		
No	114	83.8
Yes	22	16.2
Stage of disease (n = 22)		
Stage I Asymptomatic	9	40.9
Stage II Intermittent claudication	2	9.1
Stage III Rest pain	3	13.6
Stage IV Ulceration or gangrene	8	36.4
Location of occlusion (n = 22)		
Tibia-Peroneal artery	14	63.6
Femero-Popliteal artery	7	31.8
Aorto-Iliac artery	0	0
Ilio-femoral artery	1	4.6

4.4 Knowledge scores of patients with PAD

A lot of patients do not know about the PAD complication of type 2 diabetes (61.8%). 38.2% patients have ever heard about PAD, but do not understand clearly about the symptom, risk factor, effect of PAD. Almost source of heard about PAD from Broadcast media (26.5%) (Table 4.6).

The average of the total score of knowledge about PAD was 2.31 (SD = 3.49). The knowledge score about PAD is show in table 4.6

Table 4.6 Knowledge scores of patients with PAD

	N (%)	Possible range	Mean	SD
Did you ever hear about PAOD				
No	84 (61.8%)			
Yes	52 (38.2%)			
Source of hearing about PAD (n = 52)				
Family	8 (15.4%)			
Health care provider	17 (32.7%)			
Friend	19 (36.5%)			
Broadcast media	36 (69.2%)			
Knowledge about Symptoms of PAD		0 – 7	0.56	1.05
Knowledge about risk factors of PAD		0 – 7	0.89	1.45
Knowledge about effect of PAD		0 - 6	0.86	1.49
Total score of knowledge about PAD		0 - 20	2.31	3.49

4.5 Self- efficacy diabetes scale

The mean score of self-efficacy diabetes scale was 49.05 (SD = 9.52).

Table 4.7 Mean and Standard Variation of Self- efficacy diabetes scale

Variable	Min	Max	Mean	Std. Deviation
Self- efficacy diabetes scale	18	67	48.98	8.91
Item 1	2	10	5.95	1.395
Item 2	2	10	6.13	1.437
Item 3	2	9	6.10	1.290
Item 4	2	10	6.24	1.560
Item 5	2	10	6.16	1.357
Item 6	2	9	5.99	1.417
Item 7	3	9	6.16	1.415
Item 8	2	10	6.26	1.491

4.6 Correlation between HbA₁C, Comorbidity, Self efficacy, knowledge about PAD and PAD.

All variables in this study were tested for Chi-Square to test the correlation among variables. Results of table 4.8 indicated that there was not any significant correlation between PAD and knowledge about PAD ($p = .66$). Comorbidity has positive correlated with PAD (Sig (2-sided); $p = 0.00$). HbA₁C has positive correlated with PAD (Sig (2-sided); $p = 0.047$). Self efficacy has negative correlated with PAD Sig (2-sided); $p = 0.02$).

Table 4.8 Correlation between HbA₁C, Comorbidity, Self efficacy, knowledge about PAD and PAD.

	HbA ₁ C	Comorbidity	Self-efficacy	Knowledge about PAD
PAD p- value	.047	.000	.02	.66

CHAPTER V

DISCUSSION

In this chapter, the discussion will be focused on 2 main streams; the incidence of PAD among patients with T2DM and factors associated with the occurrence of PAD. Details are presented below.

5.1 The Incidence of PAD in patients with T2DM.

In this study, the researcher considered the value of the ABI and confidence that is worth to identify PAD diagnosis combination a few other laboratory tests such as Doppler ultrasound, MRI circuit. The validity of the ABI as a diagnostic marker of clinical arterial vascular disease. It has afterward been shown to be an accurate and reliable marker of atherosclerosis. The ABI test has been reported to have a sensitivity above 90% and a specificity of 95% for the diagnosis of PAD (Grenon, et al. 2009; Potier, et al., 2011). Result from the research found that normal ABI right value is 92.6% and mean ABI value is 1.18 (SD = 0.23). Normal ABI left is 96.3% and mean ABI left value is 1.17 (SD = 0.19). In total of 136 patients participated in the study with the mean age of 59.62 years (SD = 11.76 years) it reported that there were 22 patients with PAD complication (prevalence of PAD was 16.2%). Similarly to the study Medical treatment of PAD and claudication of (Marso & Hiatt, 2006) lower-extremity PAD is common and affecting up to 12% to 29% of the elderly and study of (Carter. et al 2013) shown that mellitus increases the risk of PAD by 2 to 4 folds and exists in 12% to 20% of people with PAD. However, this prevalence was lower than that of other countries. For example, in the UK, the incidence of PAD is 23.5% in the T2DM population (Fowkes et.al., 2013). In the US T2DM population who are cigarette smokers, the incidence of PAD is 29% (Hirsch, et.al., 2007) and in Asian T2DM patients the incidence of PAD is 17.7% (Foong et.al., 2007). In Thailand, the incidence of PAD among T2DM patients was 33.3% (Wongkongkam et al, 2012).

This present studied result is higher than the study of (Thomas, et al, 2003; Foong 2007; Tavintharan,et al., 2009) among Chinese persons with diabetes, the incidence of PAD has been reported to range from 6% to 10% and study about Asian Malay adults with aged 40–80 years with diabetes in Singapore had 10% PAD. It can be explained, the first, this research was conducted in Bach Mai hospital, one of the biggest hospitals in Vietnam, where are concentrated in critically ill patients who were referred from the other hospitals in the provinces of the Northern region of Vietnam. Patients have various complications and should receive other treatments be such as kidney disease, heart disease, PAD. Second, the majority of samples had experienced T2DM with the mean duration of 7.59 years (SD=6. 83 years). Similarly to the previous studies in that the occurrence of PAD was associated with duration of T2DM, the patients ages and level of serum glucose as well as HbA1c. Moreover, these patients visited the hospital with many consequence illnesses such as coronary artery disease, renal disease and hypertension (Vasaroangrong, et al., 2016; Velescu et al., 2016; Bak, et al, 2016)

Among those with PAD (22 patients), only 10% of demonstrated a classic symptom of claudication while 40% do not complain of leg pain. Likewise the previous studies which reported that 10% of PAD patients present with the classic symptoms of the disease. Affected PAD individuals include 50% with atypical leg symptoms and 40% with no lower extremity symptoms present. All most location of occlusion were Tibio-Peroneal artery (63.6%) and Femero-Popliteal artery (31.8%) (Hiatt, Armstrong, Larson, & Brass, 2015; Guzman, Bian, Shintani, Stein, 2013).

Total 22 patients with PAD, the majority of Stage 1 Asymptomatic (40.9%) and Stage 4 Ulceration or gangrene (36.4%). Similar to the study of Vasaroangrong and the others indicated that Thai patients with T2DM are admitted to hospital with advanced stages of PAD, ischemic ulcer or gangrene. And the majority of patients with PAD access medical care only after they have reached a catastrophic stage (Vasaroangrong, et al., 2016). Most patients do not know their disease, they go to hospital only when there is a critical expression as leg ulcers or gangrene. According to Arown (2006) in the research about drug treatment of PAD in the elderly, reported that 50% of older adults who have PAD do not experience any symptoms of disease, because they did not recognize that those were symptoms related

to lower limb ischemia. On the other way, they perceived that those symptoms were from their chronic illnesses that they experienced for long time. Moreover, the aged patients with many chronic illnesses are more likely to be bound in their residences or spend most of their time in bed or armed chair. They are less likely to walk in a long distance so that the leg pain is not noticeable and if it is noticed, they understand that it is a normal process of aging (Ostchega, Paulose-Ram, Dillon, Gu & Hughes, 2007).

5.2 The relationship between Comorbidity, HbA1C, self efficacy, knowledge about PAD and PAD

The relationship between Comorbidity and PAD

Accordingly, Chi - Square was employed to test the correlation among variables. Results indicated that Comorbidity has positive correlated with PAD ($p = 0.00$). The result supported the study hypothesis. This research, 24.3% samples without Comorbidity ($n = 33$) and 75.7% samples have Comorbidity ($n = 103$). Patients with 1 Comorbidity was 41.2% ($n = 56$), 2 Comorbidity was 22.8% ($n = 31$), 3 Comorbidity was 8.8% ($n = 12$), 4 Comorbidity was 2.2% ($n = 3$), 5 Comorbidity was 0.7% ($n = 1$). Similar study of (Wongkongkam, et al., 2012) about Factors influencing the presence of PAD among Thai patients with type 2 diabetes indicated almost patients PAD in type 2 diabetes had Comorbidity (94.8%) and patients have 5 Comorbidity was 0.8%.

This research result shows that the prevalence of hypertension is 69%, heart disease is 9.7% kidney disease is 19.4%. Similar to the study of (Hirsch, Criqui et al. 2001, Madia 2012) reported that hypertension is defined by a blood pressure of 140/90 mm Hg and is found in 50% to 92% of patients with PAD.

In this research results indicated Comorbidity has positive correlated with PAD. This is the same result as a number of studies of (McDermott, 2006; Potier et al. ,2011; Carter et al., 2013): Incidence also is elevated in patients with hyperlipidemia, hypertension, or chronic kidney disease. Persons with PAD have significantly

increased functional impairment and elevated rates of functional decline relative to those without PAD (Olin & Sealove 2010; Madia 2012).

The relationship between HbA1C and PAD

HbA1C be used to quantify average blood glucose levels over a 3-month period. Many studies have reported that high levels of HbA1c are strongly associated with an increased risk of cardiovascular disease (Selvin, et al., 2004; Choi, et al., 2011). In this research, 136 patients were attended, all most they do not control HbA1C, and mean of HbA1C were 9.38 (SD=2.4), the highest HbA1C value is 18.6% and lowest is 5.2%, have 16 patients with HbA1c value less than 7 (11.8%) and 120 patients with HbA1c values greater than 7 (88.2%). Most of them finished secondary school (44.9%), retired from their work (33.1%) and farmer (34.6%), living in the rural (50%), 39% income below 100 USD/month. May be this is one of the factors related to the control level of HbA1C as medication adherence, diet, routine blood sugar test.

This result research indicated that HbA1C has positive correlated with PAD ($p=.047$). Similar to previous researches which reported that HbA1C were related to PAD (Carter, Martinez et al. 2013), which are found that with every 1% increase in glycosylated haemoglobin there was a 28% increase in the risk of PAD in the United Kingdom Prospective Diabetes Study. Many research support for result of this research. According to study of (Choi, Shin et al. 2011) about the association between HbA1c, carotid atherosclerosis, arterial stiffness, and PAD in Korean type 2 diabetic patients indicated there was a significant association between HbA1c and carotid plaque [OR 2.66, 95% confidence interval (CI) 1.01 to 5.67 for the highest. The lowest terrible of HbA1c], and PAD (OR 3.75, 5% CI 1.30 to 10.81). Study of (Tavintharan et al., 2009) supported that a higher HbA1c was associated with an increased incidence of PAD, (OR 1.12;95%CI:1.00–1.29; $p=0.05$).

The relationship between self efficacy and PAD

In this study, the researcher used the Self efficacy scale to assess how confident the patients in doing certain activities. The score for each item was evaluated from 1 to 10. Code the lower number indicates less self-efficacy. A higher mean score indicated a higher self-efficacy. The reliability by Cronbach's alpha coefficient were

employed to test for the whole sample ($n = 136$) equal 0.91. Total 8 questions refer to the ability to care about nutrition, exercise, prevent acute complications and the ability to assess the health status, including: question 1 “How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?” mean score is 5.95 ($SD = 1.395$). Question 2 “How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?” mean score is 6.13 ($SD = 1.437$). Question 3 “How confident do you feel that you can choose the appropriate foods to eat when you are hungry, for example, snacks” mean score is 6.1 ($SD = 1.29$). According to (Franz, Horton et al. 1994) reported that medical nutrition therapy plays a role to prevent and treatment of the acute complications of insulin-treated T2DM such as hypoglycemia, hyperglycemia. Nutrition therapy is also important in the treatment of long-term complications of diabetes mellitus such as renal disease, hypertension, and cardiovascular disease. Adhere to diet in patients with T2DM keep an extremely important role in controlling blood sugar. That involves increasing the proportion HbA1C and PAD complication. Research results indicate that many patients do not adhere to the diet as directed. Similar study (Cheng, et al., 2013) community T2DM patients had a low self-efficacy and diabetes knowledge, awareness are factors that influence patients' self efficacy. Question 4 “How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week” mean score is 6.24 ($SD = 1.56$). In this research result, 13.2% patients have never exercised, only 7.4% of patients always exercise. According to study of (Duvivier, Schaper et al. 2016) show that breaking sitting to standing and light-intensity walking may be an alternative to structured exercise to promote glycemic control in patient with T2DM. Exercise has the effect of limiting complications, reduce blood glucose levels, reduce stress and increase insulin sensitivity. Similar reported American Diabetes Association: Diabetes mellitus and exercise (Position statement) (American Diabetes Association, 2003). People with diabetes was encouraged to participate in either recreational or competitive physical activities because of potential to improve cardiovascular fitness and psychological well-being and for social interaction and recreation. However, physical activity is not without risks. Hypoglycemia, hyperglycemia, ketosis, cardiovascular ischemia and arrhythmia, exacerbation of proliferative retinopathy, and lower-extremity injury are

potential complications of exercise. Question 5 “How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?” mean score is 6.16 (SD = 1.357). Question 6 “How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?” mean score is 5.99 (SD = 1.417). Diabetes causes acute complications such as hyperglycemia or hypoglycemia. The proper management of emergencies is very important to help and rescued patients. In this study, the average duration of diabetes disease is 7.9 years, but when the researchers asked about the level of management of the situation, it is only at points on average. Question 7 “How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?” mean score is 6.16 (SD = 1.415). Question 8 “How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?” mean score is 6.26 (SD = 1.419). Understanding the disease and self-assess changes in health status is necessary for people with chronic diseases. The total mean score was 48.99 (SD = 8.9) (0 to 80 scores) it means score 6.1 (0 – 10 score). Similar study (Jamie Adam 2014) about Self-efficacy, and adherence in patients with T2DM in the mid westem United States reported that the mean level of self-efficacy was 6.6 (SD = 2.3) (0 to 10 score). From these results indicate that self efficacy average level. So patients should be nursing guidance and counselling necessary knowledge to take care of themselves when the patient come back home. For elderly patients or patient confusion doesn't take care of themselves have to guidance counselling for their' family.

In this research, self efficacy has negative correlate with PAD ($p = .02$). That means, when the score of self efficacy high, it means the patients can control diabetes and evaluate the risk factors. They will come to the hospital to use medication under the guidance and receive advices on their health. If patients able to take care of themselves poorly, they were not aware of the serious complications can occur, they are easy to overlook the symptoms of the disease. Especially for complications of PAD, assessment of pain is easy to mistake for the other diseases that the patient subjectively, not go to the hospital soon, and when the hospital is almost already in advanced stages.

The relationship between knowledge about PAD and PAD

In this research, researchers used the knowledge about the PAD scale, this scale was developed with the knowledge about PAD by Tidarat Vasaroangrong, Orapan Thosingha in Faculty of Nursing, Mahidol University, Thailand. The overall content validity index of the Knowledge about PAD Questionnaire when reverse items were deleted was 0.883.

The result of research found that almost patients do not know about the PAD complication of T2DM (61.8%). 38.2% patients have ever heard about PAD, but do not understand clearly about the symptom, risk factor, effect of PAD. They do not know the name of this disease PAD, they just know that complications ultimately cause pain and lower limb amputations. Understanding the symptoms, risks and effects of the disease are extremely important information for early detection and prevention of complications. Similar study (Vasaroangrong, et al, 2016) reported 80% of PAD patients did not know about their disease and symptoms of PAD and only 25% knew that PAD was an arterial disease. And study of (Hirsch, et al. 2007) show knowledge about PAD in both general people and PAD patients is still low (Hirsch, et al. 2007).

The number of items in the initial pool was 20 items. The symptom domain comprised 7 items and mean score about was 0.558 (SD = 1.05). The risk factor domain of PAD had 7 items and the mean score was 0.897 (SD = 1.44). The effects domain of PAD had 6 items and the mean score was 0.85 (SD = 1.49). All most patients know very little information about diseases, over 85% patients do not know the symptoms, risk factors, the effect of the disease. Special, 32.4% patients know that risk factors of PAD are T2DM.

About 38.2% of patients have ever heard about PAD almost a source of heard about PAD from Broadcast media (26.5%), heard from provider is 12.5%, from friends is 14% and family is 5.9%. Similar research of (Hirsch, Murphy et al. 2007) demonstrate that only a relatively small fraction of individuals received information on PAD from a physician (14%), nurse (2%). This can be explained, the first, today with the development of information and communications technology, patients easily identify disease-related information on the electronic pages of information. The second, Bachmai Hospital is a tertiary hospital, where many patients, each nurse must

care for over 15 patients per day, so nurses have less time to counsel patients. In research result, 20.6% patients know that, in the severe stage of disease, it can lead to amputation. Similar (Alan, et al., 2007) show that 14% patients were aware that PAD could lead to amputation. The average of the total score of knowledge about PAD in this research was 2.31 (SD = 3.49). Similar conclusion of study (Hirsch, Murphy et al. 2007) the knowledge score about PAD and the public is poorly informed about PAD, with major knowledge gaps regarding the definition of PAD, risk factors that lead to PAD, and associated limb symptoms and amputation risk. Most were unaware of important risk factors such as diabetes (Hirsch, Murphy et al. 2007, Lovell Harris et al. 2009, Vasaroangrong, et al. 2016).

CHAPTER VI

CONCLUSION

6.1 Conclusion of the study

This descriptive research was based on self efficacy theory. The research aimed to study the incidence of PAD gradually increasing among patients with DM type 2 and factors related to the occurrence of PAD in patients with DM type 2. The relationship between HbA1c, self efficacy, Comorbidity, knowledge about PAD and PAD. Data collection was conducted during August to October, 2016 in the Endocrinology department in the Bach Mai hospital with 136 T2DM inpatients.

The instrument of the research consisted of four parts as follows: Questionnaire demographic data of the patients. Information related to illness and treatment. Self efficacy for diabetes scale. The Knowledge about PAD scale. All instruments were tested for their validity and reliability as clearly explained in chapter 3. Self efficacy for diabetes was .91 and knowledge about PAD scale was .88.

The 136 patients were selected according to the inclusion criteria. The researcher collected data by herself from 8.00 am to 4.00 pm every day until the sample reached the target of the studied sample size. For each patient, the researcher spent about 30 minutes on interviewing, examine and collected some data from their patients' records. During data collection, there was no adverse event among the patients. All sample recruited in the study remained throughout the study process with no attrition.

Data analysis was conducted by using SPSS computer program. The descriptive statistics were used to describe general information and study variables, including HbA1C, comorbidity, self – efficacy and knowledge about PAD. Accordingly, Chi - Square was used to examine correlation between HbA1C, comorbidity, self – efficacy and knowledge about PAD and PAD in patients with T2DM.

The findings are summarized as follows:

Total 136 inpatients with T2DM were attend this research, the findings a nearly equal distribution between males (52.2%) and females (47.8%). The age of patients with type 2 diabetes ranged from 23 to 86 years with the mean age of 59.62 years (SD = 11.76). The samples with overweight were 20.6% and obesity was 18.4%, mean of BMI were 22.07 (SD = 3.27). Most of them were married (71.3%), finished secondary school (44.9%), retired from their work (33.1%) and farmer (34.6%), living in the rural (50%). 75% samples had health insurance. The majority of the samples never smoked (52.9%), 52.2% never alcohol, 13.2% have never exercised, 26% never stress.

The majority of samples had experienced type 2 diabetes with the mean duration of 7.59 years (SD=6. 83 years), 11.8% their no treatment. 52.2% samples have hypertension with the mean duration of 3.12 years (SD = 4.89), 18.3% no treatment. In addition, the samples also suffer from conditions such as: heart disease, kidney disease. COPD with the ratio 7. 4%; 14.7%; 1.5% and the mean duration were 0.29 (SD = 1.96); 0.46 (SD = 1.83); 0.04 (SD = 0.429). Many of them do not treat diseases with the ratio 20%; 30%; 50%. All most they do not control HbA1C, and the means of HbA1C were 9.38 (SD=2. 4). The samples have an Ankle Brachial Index (ABI) right value and ABI left value less than 0.9 were 7.4% and 3.4%. The meanings of cholesterol and triglyceride were 5.464 (SD=2. 26) and 2.35 (SD=1. 64). Most of patients have 1 commodities (n=56) and 2 comorbidity (n=31). 24.3% samples (n = 33) without comorbidity from. In total 136 patients participated in the study, 22 people with PAD (16.2%). The majority of stage 1 asymptomatic (40.9%) and stage 4 ulceration or gangrene (36.4%). The main location of occlusion were Tibio-Peroneal artery (63.6%) and Femoro-Popliteal artery (31.8%). A lot of patients do not know about the PAD complication of T2DM (61.8%). 38.2% patients have ever heard about PAD, but do not understand clearly about the symptom, risk factor, effect of PAD. Almost source of heard about PAD from Broadcast media (26.5%). The average of the total score of knowledge about PAD was 2.31 (SD = 3.49). The knowledge score about PAD is low. The mean score of self-efficacy diabetes scale was 49.05 (SD = 9.52).

All variables in this study were tested for Chi-Square to test the correlation among variables. Results this research indicated that there was not any significant correlation between PAD and knowledge about PAD ($p = .66$). Comorbidity has positive correlated with PAD (Sig (2-sided); $p = 0.00$). HbA1C has positive correlated with PAD (Sig (2-sided); $p = 0.047$). Self efficacy has negative correlated with PAD Sig (2-sided); $p = 0.02$).

The result of this research supported the ideology of self efficacy in that. When patients have self confidence in performing proper health behaviors, they can achieve good health outcomes. So that nurses should develop strategies to improve self efficacy by giving support, persuasion and providing good model for learning.

6.2 Implications of research findings

6.2.1 Implications for nursing practice

1) Patients with T2DM should receive routinely examined on their ABI because it is a non invasive procedure and nurses can be trained to perform this ABI examination.

2) There should be a strategy to promote T2DM patients to get early access to specialist in particular the vascular physicians because PAD can be early detected and properly receive proper treatment.

3) Nurses should provide health information to patients with T2DM to control their diet in order to control level of HbA1C.

4) Nurses should perform psychological support and find support resources for patients with T2DM to empower them, which will lead to increased self efficacy in diet control, proper exercise and foot care.

5) Knowledge in regard to PAD should be given to all patients with T2DM because in this study the level of knowledge among patients was relatively low.

6.2.2 Implications for further study

- 1) Self efficacy improvement program should be developed and tested for its effectiveness by using quasi experimental study.
- 2) Multi sites research should be conducted to represent the broad picture of the problem of PAD in patients with T2DM in Vietnam.
- 3) An education program on knowledge should be developed and tested for its effectiveness using quasi experimental research.
- 4) The demographic variables or other related variables should be analyzed for their correlation to PAD.

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APPENDICES

APPENDIX A
LIST OF THE EXPERTS

1 Prof.Dr. Truong Viet Dung, MD, PhD

Chairman of Independent Ethic Committee, Ministry of Health, Vietnam

Dean of School of Medicine and Pharmacy, Vietnam National University, Vietnam.

2 MSC. Dr. Le Ba Ngoc

Endocrinology, Department of Bach Mai Hospital

3 BA. Nguyen Tien Hong

Head nurse at Endocrinology, Department of Bach Mai Hospital

4 BA. Chu ThiThao

Endocrinology, Department of Bach Mai Hospital

5 MSC. Đam Minh Ngoc

Nursing Instructor at Hanoi Medical University

APPENDIX B

CERTIFICATE OF APPROVAL



MAHIDOL UNIVERSITY
Since 1888

The Institutional Review Board
Faculty of Nursing, Mahidol University
Tel 0-2441-5333 Ext 2531-32

Document No. 0517.0510/IRB-NS *456*
Date May 3, 2016
Subject Result of research project considerations after the revision
Dear Chair, Master of Nursing Science Program in Adult Nursing (for Vietnamese Nurses)

According to the student named Mrs. Nguyen Thi Anh has submitted the research project entitled Factors related to the occurrence of peripheral artery disease in patients with diabetes type 2 protocol no. IRB-NS2016/24.0703 at the Institutional Review Board, Faculty of Nursing, Mahidol University on the (date) May 2, 2016 the IRB committee have examined and found the research protocol and all the research documents are revised according to the suggestions of the IRB. The IRB committee have made the decision and the results are as follows:

Approve.

On the date May 2, 2016

Please look at the guideline for the research conduct post approval.

The document is attached together with the COA

A handwritten signature in cursive script, reading "Fongcum Tilokkulchai".

(Associate Professor Dr. Fongcum Tilokkulchai)
Chair, Institutional Review Board

Copy to Assistant Professor Dr. Orapan Thosingha
Mrs. Nguyen Thi Anh

APPENDIX C

PATICIPANT INFORMATION SHEET

(English version)

- 2 MAY 2016
99.C7C3

IRB-NS Form No. 3.1

Participant Information Sheet

In this document, there may be some statements that you do not understand. Please ask the principal investigator or his/her representative to give you explanations until they are well understood. To help your decision making in participating the research, you may bring this document home to read and consult your relatives, intimates, personal doctor or other doctor.

Title of Research Project: Factors related to the occurrence of peripheral artery disease in patients with diabetes type 2

Name of Researcher: Nguyen Thi Anh

Research Site-Office and its telephone number available for contact both in and out of the office hours:

Work address : Nursing Department, Bach Mai Hospital, 78 Giai Phong Street, Dong Da District, Ha Noi capital, Vietnam Code: 100.000. Telephone number: + (84).435765015

Telephone number (conveniently accessible): +84.0904718680

E-mail address: lyanh1981@gmail.com

IRB office of VNU: 144 Xuan Thuy street, Cau giay district, Hanoi city, Vietnam. Code: 100.000. Phone number: (+84)437450118, Fax: +84-4-37450146.

Phone number of IRB: (+84)98397654 (contact with Associate Professor Le Thi Luyen, MD, PhD)

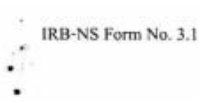
Source of Fund: No research funding

This research project aims to study the relationship among HbA1C, self efficacy, co morbidity, knowledge about peripheral arterial disease and the occurrence of peripheral arterial disease in patients with diabetes type 2.

It expects the following benefits:

1) Providing basic data about factors related to the occurrence of peripheral arterial disease patients with DM type 2.

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/29 07C3
Date of Approval 2 MAY 2016



2) In the future, nurses can develop relevant program by using this data to prevent the occurrence of peripheral arterial disease patients with DM type 2.

You are invited to participate in this research project because you are patients with DM type 2. You don't directly receive profit from this study but the information from you will provide the guidance to nurses and other health care workers in developing high quality care in patients with DM type 2. There will be 136 patients who participate in this study.

After you are agreed to participate the research project, you will be invited to perform the following procedures:

- 1.The researcher will ask you to sign a consent form.
- 2.The researcher will collect some demographic data from medical record form.

3.You will be invited to answer the questionnaires or the researcher will interview you in a private room. There are four questionnaires for data collection. The Questionnaires (1) demographic data (10 questions), (2) Information related to illness and treatment (12 questions) (3) Self efficacy Scale (8 questions), (4) The knowledge of peripheral arterial disease scale (20 questions). The overall items in the questionnaires are 50 questions, the time using to answer the questionnaire is about 30 minutes. During you answer questionnaires, if there are any questions that are unpleasant or discomfort you have the rights not reply the question.

4.During interview or use questionnaire, if you feel uncomfortable. You can stop to participate in this study or ask the researcher to discontinue the study at anytime. You are also invited to ask any questions or ask the researcher to explain to you more about the participation on this study.

During interview or use questionnaire, if you don't want to participate in this study they can stop in any conditions. You will get the same standard care after withdraw from the study. There are no any effects for caring. In process of collecting data, the if you develop some unexpected events due to the stage of illness such as severe hypertension (systolic blood pressure higher than 200 mmHg), uncontrolled hyperglycemic ketoacidosis or any symptoms, which influence vital sign (heart rate

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Project Number IRB-NS 99.16/29.0703
Date of Approval 2 MAY 2016

IRB-NS Form No. 3.1

higher than 120 beats/min or lower than 60 beat per minute, systolic blood pressure higher than 200 mmHg or lower than 90 mmHg, respiratory rate lower than 14 per minute, or more than 30 per minute.) , the research will stop collecting data and will immediately contact with doctors who have response to take care of you. The researcher will take care until you are stable.

If you have any questions about this research please feel free to contact the researcher, Mrs Nguyen Thi Anh via telephone: +84.0904718680.

You don't get any money or payment for participating in this research.

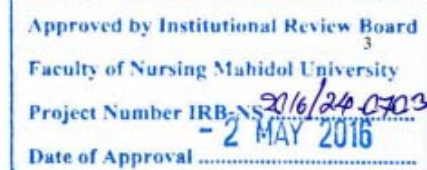
If relevant information arises about benefits and risks of the research project, the researcher will inform you immediately and without concealment.

Your information will be kept confidential, it will not be subject to an individual disclosure, but will be included in the research report as part of the overall results. Individual information may be examined by a researcher, the ethics committee, etc. You have the right to withdraw from the project at anytime without prior notice. And the refusal to participate or the withdrawal from the research project will not at all affect the proper service or treatment that he/she will receive.

This research project is approved by The Institutional Reviews Boards, Faculty of Nursing (IRB-NS) at the office of IRB-NS room 503 5th floor, Faculty of Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom 73170 Thailand Tel 0066 2 441 5333 ext 2531, 2532 Fax: 006624415333 ext 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Then submit document and the result to SMP- IRB institutional review board of Vietnam National University, Associate Professor Le Thi Luyen, MD, PhD. Tel: +84913597423. Y1 Building, 144 Xuan Thuy Street, Cau Giay District, Hanoi city, Vietnam. Code: 100000. Phone number of VNU: +84437450118, Fax: +84437450146. Email: smp@vnu.edu.vn

On the condition that you are not treated as indicated in the information sheet distributed to the subjects, you can contact the chair, or the representative of the IRB-NS at the contact address presenting above.



IRB-NS Form No. 3.1

I thoroughly read the details in this document.

Signature..... Participant

(.....)

Date.....

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 216/24-0703
Date of Approval: 2 MAY 2016

(Vietnamese)

Thông tin dành cho đối tượng nghiên cứu

Phiên bản 02 / ngày 08 tháng 08 năm 2016

THÔNG TIN DÀNH CHO ĐỐI TƯỢNG NGHIÊN CỨU

Trong tài liệu này sẽ có một số vấn đề mà ông (bà) có thể không hiểu. Hãy hỏi người nghiên cứu và đại diện của cô ấy để đưa cho ông (bà) lời giải thích cho đến khi ông (bà) hiểu rõ ràng vấn đề. Để giúp cho việc quyết định có tham gia vào chương trình nghiên cứu hay không, ông (bà) có thể mang tài liệu này về nhà để đọc hoặc hỏi ý kiến người thân và các bác sĩ.

Tên đề tài nghiên cứu: Các yếu tố liên quan đến bệnh động mạch ngoại vi trên người bệnh đái tháo đường type 2.

Tên người nghiên cứu: Nguyễn Thị Anh

Nơi nghiên cứu và số điện thoại liên lạc trong và ngoài giờ hành chính: (Đại diện của người nghiên cứu)

Bệnh viện Bạch Mai: 78 Đường Giải Phóng, Quận đông Đa, Hà Nội, Việt Nam. Mã: 100000.

Số điện thoại: (+84) 438683731 Fax: (+84). 438691607

Nguồn hỗ trợ: Không có

Mục đích của nghiên cứu: Nghiên cứu đánh giá được các yếu tố liên quan đến bệnh động mạch ngoại vi trên người bệnh đái tháo đường type 2.

Khía cạnh lợi ích:

1) Việc nghiên cứu này cung cấp dữ liệu cơ bản về các yếu tố liên quan đến bệnh động mạch ngoại vi trên người bệnh đái tháo đường type 2.

2) Trong tương lai, chương trình này phát triển để phòng ngừa và phát hiện sớm bệnh động mạch ngoại vi. Tuy nghiên cứu này không mang lợi ích ngay bệnh nhân đái tháo đường type 2 nhưng sẽ mang lại nhiều lợi ích cho những người mắc bệnh tương tự trong tương lai.

3) Ông (bà) được mời tham gia chương trình nghiên cứu bởi vì Ông (bà) được chẩn đoán đái tháo đường type 2 và trên 18 tuổi.

4) Sẽ có 136 người tham gia, và buổi nghiên cứu sẽ có phần hỏi - đáp diễn ra trong vòng 30-40 phút

5) Việc tham gia của Ông (bà) vào nghiên cứu này là hoàn toàn TỰ NGUYỆN..

Nếu Ông (bà) quyết định tham gia đề tài nghiên cứu, Ông (bà) sẽ phải tuân theo các bước như sau:

1) Người nghiên cứu sẽ yêu cầu Ông (bà) ký tên vào **Bản chấp thuận tham gia nghiên cứu**

2) Người nghiên cứu sẽ thu thập thông tin của Ông (bà) từ hồ sơ bệnh án

3) Người nghiên cứu sẽ sắp xếp một phòng riêng để phỏng vấn Ông (bà). Sau đó, người nghiên cứu sẽ thu thập số liệu bằng bộ câu hỏi gồm 4 phần với tổng số câu hỏi là 52 câu và thời gian thu thập số liệu là khoảng 30 – 40 phút. Cụ thể như sau: 1) thông tin chung với 10 câu hỏi. 2) Thông tin về bệnh và điều trị 12 câu hỏi. 3) Đánh giá kiến thức về bệnh động mạch chi dưới với 22 câu hỏi. 4) Thang đo tự chăm sóc hiệu quả với 8 câu hỏi

4) Sau khi thu thập số liệu, người nghiên cứu sẽ kiểm tra lại toàn bộ dữ liệu nghiên cứu.

5) Trong suốt quá trình phỏng vấn, nếu Ông (bà) không muốn tham gia nghiên cứu, ông (bà) có thể yêu cầu dừng lại. Việc dừng này không ảnh hưởng đến quá trình chăm sóc và điều trị thông thường ở bệnh viện. Ông (bà) vẫn nhận được sự chăm sóc theo đúng tiêu chuẩn chăm sóc thường quy sau khi rút khỏi nghiên cứu.



Thông tin dành cho đối tượng nghiên cứu

Phiên bản 02 /ngày 08 tháng 08 năm 2016

- 6) Nếu Ông (bà) xuất hiện tình trạng sức khỏe không tốt như mệt mỏi, khó chịu trong quá trình phỏng vấn, hãy nói với người nghiên cứu. Cô ấy sẽ tạm dừng phỏng vấn ngay lập tức và kết nối liên lạc với bác sỹ để chăm sóc Ông (bà) đến khi ổn định.
- 7) Nếu Ông (bà) không tham gia nghiên cứu này, Ông (bà) sẽ nhận được sự thăm định và điều trị như bình thường
- 8) Nếu Ông (bà) có bất kỳ câu hỏi nào về dự án, hãy gọi điện tới Bà: Nguyễn Thị Anh ;Số điện thoại: +84 904718680.

Ông (bà) sẽ không được nhận, cũng như không phải trả bất cứ một khoản tiền nào cho việc tham gia vào nghiên cứu này.

Nếu có thông tin về lợi ích cũng như rủi ro của nghiên cứu này, người nghiên cứu sẽ thông tin cho Ông (bà) ngay lập tức mà không được che giấu bất cứ thông tin nào.

Thông tin của Ông (bà) sẽ được bảo mật tuyệt đối, và không được tiết lộ dưới dạng thông tin cá nhân, tuy nhiên nó sẽ được thể hiện trong báo cáo tổng thể như là kết quả của một đề tài nghiên cứu khoa học. Thông tin cá nhân của Ông (bà) sẽ được kiểm tra bởi người nghiên cứu, và Hội đồng đạo đức trong nghiên cứu y sinh học.

Ông (bà) có quyền rút khỏi nghiên cứu bất cứ lúc nào mà không cần báo trước và điều này sẽ không ảnh hưởng tới các dịch vụ chăm sóc và điều trị mà Ông (bà) nhận được.

Đề tài nghiên cứu này được chấp thuận bởi Hội đồng đạo đức, Khoa Điều Dưỡng, Đại học Mahidol Thái Lan, đặt văn phòng tại tầng 5 phòng 504, Đại học Mahidol, đường Phuttamonthon 4, Salaya, Nakhon Pathom 73170, Thái Lan. Điện thoại: 66 2 441 5333 số máy lẻ 2531, 2532. Fax 0066 2 441 5333 số máy lẻ 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Đề tài nghiên cứu này cũng được chấp thuận bởi Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội. Địa chỉ: tòa nhà Y1, số 144 phố Xuân Thủy, quận Cầu Giấy, Hà Nội, Việt Nam; điện thoại: 04-37450188; fax: +84437450146; email: smp@vnu.edu.vn.

Nếu tôi không được hưởng sự điều trị như trong bản thông tin đưa ra, tôi có thể liên lạc với Hội đồng đạo đức, Khoa Điều Dưỡng, Đại học Mahidol Thái Lan, hoặc Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội với các thông tin liên lạc như đã nêu ở trên.

Tôi đã đọc kỹ và hiểu toàn bộ chi tiết nêu trong bản thông tin này.

Ngày..... thángnăm.....

Họ tên, Chữ kí của người tham gia nghiên cứu

APPENDIX D INFORMED CONSENT

(English version)

IRB-NS Form No. 4

- 2 MAY 2016
24.0703

Informed Consent Form

Date...../...../.....
My name is....., aged.....years old,
now living at the address no.....road/street.....
sub-district.....
District.....Province.....
Postal code.....Tel.No.....

I give my consent to participate as a subject in the research project entitled
“Factors related to the occurrence of peripheral artery disease in patients with diabetes
type 2.”

In so doing, I am informed of the background and purpose of research project;
its procedural details to carry out or to be carried out; its expected benefits and risks
that may occur to me, including methods to prevent and handle harmful consequences;
and payment/ incentives, and expense. I thoroughly read the detailed statements in the
information sheet given to the research subjects, I was also given explanations and my
questions were answered by the head of the research project. I was explained that the
researcher will collect some demographic data from my medical record form. I was
explained that during answering, if I feel uncomfortable. I can stop to participate in
this study. During the research process, if I feel discomfort during interviewing or
answering questionnaire. The researcher will stop the process until I feel comfort to
continue or I can make decision to withdraw myself from the study.

I consent to participate as a subject in this research project.

On the condition that I have any questions about the research procedures,
or on the condition that I suffer from an undesirable side effect from this research, I
can contact Mrs. Nguyen Thi Anh at the mobile phone number +84.0904718680, E-
mail address: lyanh1981@gmail.com.

On the condition that I am not treated as indicated in the information sheet
distributed to the subjects, I can contact the Chair of The Institutional Reviews Boards,
Faculty of Nursing (IRB-NS) at the office of IRB-NS room 503 5th floor, Faculty of
Nursing, Mahidol University, 999 Phuttamonthon 4 Road, Salaya, Nakhon Pathom

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 9116 / 248-0703
Date of Approval 2 MAY 2016

IRB-NS Form No. 4

73170 Thailand Tel 66 2 441 5333 ext 2531, 2532 Fax 66 2 441 5333 ext 2531 ,
Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

I also can contact SMP- IRB institutional review board of Vietnam
National University, Associate Professor Le Thi Luyen, MD, PhD. Tel:
+84913597423. Y1 Building, 144 Xuan Thuy Street, Cau Giay District, Hanoi city,
Vietnam. Code: 100000. Phone number of VNU: +84437450118, Fax: +84437450146.
Email: smp@vnu.edu.vn

I am aware of my right to further information concerning benefits and risks
from the participation in the research project and my right to withdraw or refrain from
the participation anytime without any consequence on the service or health care I am
to receive in the future, I consent to the researcher's use of my private information
obtained in this research, but do not consent to an individual disclosure of private
information. The information must be presented as part of the research results as a
whole.

I thoroughly understand the statement in the information sheet for the
research subjects and in this consent form. I thereby give my signature.

Signature.....Participants/Proxy/
(.....) Date.....

Signature.....Person in Charge of Informing and
Requesting a Consent/Head of (Mrs. Nguyen Thi Anh) Research Project/Date.....

In case that the participant is not literate, the reader of all the statements
for the participant is (Mr./Mrs./Ms.....), who gives his/her
signature as a witness.

Signature.....Witness
(.....) Date.....

Approved by Institutional Review Board
Faculty of Nursing Mahidol University
Project Number IRB-NS 2016/24-034

(Vietnamese version)

Thông tin dành cho đối tượng nghiên cứu

Phiên bản 02 / ngày 08 tháng 08 năm 2016



BẢN CHẤP THUẬN THAM GIA NGHIÊN CỨU

Ngày...../...../.....

Tên tôi là, tuổi.....

Mã ID (người nghiên cứu ghi):

Địa chỉ:

Mã vùng: Số điện thoại:

Trước tiên, tôi xin bày tỏ sự đồng ý tham gia vào đề tài nghiên cứu có tên là **“Các yếu tố liên quan đến bệnh động mạch ngoại vi trên người bệnh đái tháo đường type 2”**.

Trong quá trình trước khi tham gia nghiên cứu, tôi đã được thông báo về nội dung cũng như mục đích của nghiên cứu, chi tiết quá trình được thực hiện, những lợi ích và rủi ro có thể xảy ra đối với người tham gia nghiên cứu, các phương pháp ngăn ngừa và giải quyết các tác dụng không mong muốn có thể xảy ra cho người tham gia nghiên cứu và cả về chi phí tham gia nghiên cứu. Tôi đã đọc kỹ toàn bộ thông tin trong bản thông tin dành cho đối tượng nghiên cứu. Bên cạnh đó, các câu hỏi của tôi cũng đã được giải đáp bởi người thực hiện nghiên cứu.

Tôi đồng ý tham gia vào nghiên cứu này như một đối tượng nghiên cứu

Nếu có bất cứ câu hỏi nào về nghiên cứu hoặc có vấn đề mới phát sinh trong quá trình nghiên cứu, tôi có thể liên hệ với chị Nguyễn Thị Anh số điện thoại: +84904718680 email: lyanh1981@gmail.com (Số điện thoại liên lạc trên được kết nối 24/24 h).

Nếu tôi không được điều trị và chăm sóc như những gì đề cập đến trong bản thông tin dành cho đối tượng nghiên cứu, tôi có thể liên hệ với Hội đồng đạo đức, Khoa Điều Dưỡng, Đại học Mahidol Thái Lan, đặt văn phòng tại tầng 5 phòng 504, Đại học Mahidol, đường Phuttamonthon 4, Salaya, Nakhon Pathom 73170, Thái Lan. Điện thoại: 66 2 441 5333 số máy lẻ 2531, 2532. Fax 0066 2 441 5333 số máy kè 2531, Email: nsirbnursing@mahidol.ac.th, ns.irbnursing@gmail.com

Tôi cũng có thể liên lạc với Hội đồng đạo đức trong nghiên cứu Y sinh học, Khoa Y Dược, Đại học Quốc Gia Hà Nội. Địa chỉ: tòa nhà Y1, số 144 phố Xuân Thủy, quận Cầu Giấy, Hà Nội, Việt Nam; điện thoại: 04-37450188; fax: +84437450146; email: smp@vnu.edu.vn.

Tôi nhận thức được quyền thông tin liên quan tới lợi ích và rủi ro của người tham gia nghiên cứu và quyền được rút khỏi nghiên cứu bất cứ lúc nào mà không gặp vấn đề gì về dịch vụ cũng như việc chăm sóc sức khỏe mà tôi sẽ nhận được trong tương lai. Tôi đồng ý cho bên nghiên cứu sử dụng thông tin cá nhân cho việc nghiên cứu, nhưng không đồng ý việc tiết lộ thông tin cá nhân. Các thông tin phải được trình bày như là một phần của kết quả nghiên cứu.

Tôi hoàn toàn hiểu những tuyên bố đã nêu trong bản thông tin dành cho đối tượng nghiên cứu và trong phiếu chấp thuận tham gia nghiên cứu này. Sau đây là chữ ký của tôi.

Ngày..... tháng..... năm.....

CHỦ NHIỆM ĐỀ TÀI NGHIÊN CỨU
(Ký và ghi rõ họ tên)

NGƯỜI THAM GIA NGHIÊN CỨU
(Ký và ghi rõ họ tên)

Part 2 Information related to illness and treatment (12 questions)

11 Diagnosis:

12 How long do you have diabetes?.....

Treatment: Always ; Sometime ; No

13 Which co morbidity do you have?

13.1 Hypertension O no O yesfor how long?

Treatment: Always ; Sometime ; No

13.2 Heart disease O no O yesfor how long?

Treatment: Always ; Sometime ; No

13.3 COPD O no O yesfor how long?

Treatment: Always ; Sometime ; No

13.4 Renal disease O no O yesfor how long?

Treatment: Always ; Sometime ; No

13.5 Others please describe:.....

.....

14 What do you have current and past treatment method?

15 Which trauma or surgery do you have in the past?

16 Which medicines do you use in the past and now?

17 Do you have any habits such as

Smoking: Always ; Often ; Sometime ; Occasional ; Never

Alcohol: Always ; Often ; Sometime ; Occasional ; Never

Exercise: Always ; Often ; Sometime ; Occasional ; Never

18 Do you have any stress or anxiety?

Always ; Often ; Sometime ; Occasional ; Never

19 Laboratory: HbA1C:..... Cholesterol:.....;Lipid:

Other:.....

20 ABI: Right:.....Left:.....

21 Vital sign: Blood pressure:.....; Temperature:.....; Pulse:.....; Breath:...

22 Fontaine’s Stage of disease:

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- 22.1 Stage I Asymptomatic
- 22.2 Stage II Intermittent claudication
- 22.3 Stage III Rest pain
- 22.4 Stage IV Ulceration or gangrene

23. Location of occlusion:

- 23.1 Tibio-Peroneal artery
- 23.2 Femero-Popliteal artery
- 23.3 Aorto-Iliac artery
- 23.4 Ilio-Femoral artery

Part 3 The knowledge about Peripheral Arterial Occlusive Disease

- 1) Did you ever heard about PAOD? Yes ; No
- 2) Source of information about PAOD:
 - Family Health care provider
 - Friend Broadcast media

Item	Yes	No
Symptoms of PAOD		
1 Leg pain during walking that disappears when resting or stopping walking		
2 Loss of skin hair		
3 Pain radiated down leg and induced by sitting, standing or walking (false item)		
4 Pain at night, relieved by dangling the leg or standing		
5 Pain and weakness, which take a long time for recovery		
6 Toe color changes to a dark color		
7 Hip or Knee joint pain (false item)		
Risk factors of PAOD		
8 Diabetes Mellitus		
9 Old age		
10 Hypertension		

Instrument ENG 19 June 2016

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 Project Number IRB-NS 2016/20-0703
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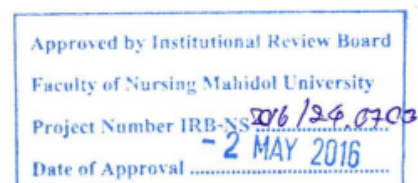
11 Lack of exercise (false item)		
12 Lipids or fats in the blood		
13 Smoking		
14 Low bone density and low bone mass (false item)		
Effects of PAOD		
15 High risk for coronary artery disease or ischemic heart disease		
16 High risk for stroke		
17 It can lead to diminished walking ability.		
18 In the severe stage of disease, the vein will collapse(false item).		
19 In the severe stage of disease, it can lead to amputation.		
20 In the severe stage of disease, it can lead to death.		

Part 4: The Self efficacy Diabetes Scale

We would like to know how confident you are in doing certain activities. For each of the following questions, please choose the number that corresponds to your confidence that you can do the tasks regularly at the present time. Number 1 refers to the least confident, number 10 refers to the most confident.

Item	1	2	3	4	5	6	7	8	9	10
1 How confident do you feel that you can eat your meals every 4 to 5 hours every day, including breakfast every day?										
2 How confident do you feel that you can follow your diet when you have to prepare or share food with other people who do not have diabetes?										
3 How confident do you feel that you can choose the appropriate foods to eat when you are hungry (for example, snacks)?										

Instrument ENG 19 June 2016



Item	1	2	3	4	5	6	7	8	9	10
4 How confident do you feel that you can exercise 15 to 30 minutes, 4 to 5 times a week?										
5 How confident do you feel that you can do something to prevent your blood sugar level from dropping when you exercise?										
6 How confident do you feel that you know what to do when your blood sugar level goes higher or lower than it should be?										
7 How confident do you feel that you can judge when the changes in your illness mean you should visit the doctor?										
8 How confident do you feel that you can control your diabetes so that it does not interfere with the things you want to do?										

Instrument ENG 19 June 2016

Approved by Institutional Review Board
 Faculty of Nursing Mahidol University
 Project Number IRB-NS 2016/29-0203
 Date of Approval 2 MAY 2016

(Vietnamese version)

BỘ CÂU HỎI NGHIÊN CỨU

Số thứ tự: **KHOA** Mã bệnh án:

Mã ID: **Y DƯỢC**

Xin vui lòng cho biết ý kiến của các Ông/bà bằng cách trả lời các câu hỏi sau:

Phần 1: Thông tin chung của người bệnh

1 Giới: Nam Nữ

2 Tuổi

3 Cân nặng (Kg) ; Chiều cao (m) ; BMI (kg/m²).....

4 Tình trạng hôn nhân

- Đã lập gia đình Độc thân
 Ly hôn Góa (chồng hoặc vợ)

5 Trình độ học vấn

- Tiểu học Trung học cơ sở Trung học phổ thông
 Trung cấp Cao đẳng (3 năm) Cử nhân Đại học
 Khác (ghi cụ thể)

6 Nghề nghiệp

- Chuyên gia Nông dân Công nhân
 Buôn bán Nội trợ Nghỉ hưu
 Công việc khác (ghi cụ thể).....

7 Nơi ở: Thành thị Nông thôn Miền núi

8 Thu nhập

- Thu nhập của gia đình là bao nhiêu trong một tháng:.....USD
 - Thu nhập của bản thân bao nhiêu một tháng:USD

9 Bản thân có thể bảo hiểm y tế không? Có ; Không ; ?..... (%)

10 Có bao nhiêu người sống cùng với bạn?



Phần 2: Những thông tin liên quan đến bệnh và điều trị.

11 Chân đoán:

12 Bị bệnh đái tháo đường thời gian bao lâu?.....

Điều trị: Thường xuyên ; Không thường xuyên : Không điều trị

13 Những bệnh lý kèm theo nào mà bản thân đang mắc phải?

13.1 Tăng huyết áp: Có ;Không; Thời gian mắc bệnh:.....

Điều trị: Thường xuyên ; Không thường xuyên : Không điều trị

13.2 Bệnh tim:Có ;Không; Thời gian mắc bệnh:.....

Điều trị: Thường xuyên ; Không thường xuyên : Không điều trị

13.3 Bệnh thận: Có ; Không; Thời gian mắc bệnh:.....

Điều trị: Thường xuyên ; Không thường xuyên : Không điều trị

13.4 COPD: Có ; Không ; Thời gian mắc bệnh:.....

Điều trị: Thường xuyên ; Không thường xuyên : Không điều trị

13.5 Bệnh khác (Miêu tả chi tiết):.....

14 Những thuốc đã dùng trước đây và hiện tại là thuốc nào?.....

15 Bản thân có thói quen:

Tập thể dục: Luôn luôn; Thường xuyên ; Thỉnh thoảng ; Hiếm khi ; Không bao giờ

Hút thuốc: Luôn luôn ; Thường xuyên ; Thỉnh thoảng ; Hiếm khi ; Không bao giờ

Uống rượu: Luôn luôn ; Thường xuyên ; Thỉnh thoảng ; Hiếm khi ; Không bao giờ

16 Bản thân có bị stress hoặc lo lắng nào không?

Luôn luôn ; Thường xuyên ; Thỉnh thoảng ; Hiếm khi ; Không bao giờ

17 Xét nghiệm: HbA_{1c}:.....; Cholesterol:.....; Lipid:.....;

Khác:.....

18 ABI: Phải:.....Trái:.....

19 Dấu hiệu sống: Huyết áp:; Nhiệt độ cơ thể:.....;Mạch:.....Nhịp thở:.....

20 Có biến chứng PAD: Có Không

21 Giai đoạn của bệnh :

Giai đoạn I không có triệu chứng Giai đoạn III đau khi nghỉ ngơi

Giai đoạn II đau cách hồi Giai đoạn IV loét hoặc hoại tử

22 Vị trí của tắc:

Động mạch chày-mác Động mạch chậu

Động mạch đùi-khoeo Động mạch chủ bụng

23 Điểm kiến thức của bệnh nhân với PAD

Bạn đã bao giờ nghe nói về bệnh ĐM ngoại vi ? Có Không

Nguồn nghe về bệnh động mạch ngoại vi:

- + Gia đình + Người Cung cấp dịch vụ chăm sóc sức khỏe (bác sỹ, ĐD)
 + Bạn bè + Phương tiện truyền thông

Nội dung	Có	Không
Các triệu chứng của PAD		
1 Đau chân khi đi và biến mất khi nghỉ ngơi hay dừng lại		
2 Rụng lông, móng da		
3 Đau tỏa xuống chân khi ngồi, đứng hoặc đi bộ (Mục sai)		
4 Đau vào ban đêm, đỡ đau khi dùng đũa chân hoặc đứng dậy		
5 Đau và yếu mà phải mất một thời gian dài để hồi phục		
6 Ngón chân đổi màu thành màu đen sẫm		
7 Đau khớp xương chậu hoặc đầu gối (Mục sai)		
Yếu tố nguy cơ của PAD		
8 Đái tháo đường		
9 Tuổi già		
10 Tăng huyết áp		
11 Thiếu tập thể dục (Mục sai)		
12 Lipid hoặc mỡ trong máu		
13 Hút thuốc		
14 Mật độ xương thấp và khối lượng xương thấp (Mục sai)		
Anh hưởng của PAD		
15 Nguy cơ cao đối với bệnh mạch vành hay bệnh tim thiếu máu cục bộ		
16 Nguy cơ cao đối với đột quỵ.		
17 Có thể dẫn đến khả năng đi bộ bị suy giảm.		
18 Trong giai đoạn nặng của bệnh, các tĩnh mạch sẽ tắc (Mục sai)		
19 Trong giai đoạn nặng của bệnh, có thể dẫn đến cắt cụt chi.		
20 Trong giai đoạn nặng của bệnh, có thể dẫn đến tử vong.		

APPENDIX F

PERMISSION FOR USING INSTRUMENTS

1/17/2016

Gmail - Ask your permission about using the Self-Efficacy for Diabetes scale



anh nguyen <lyanh1981@gmail.com>

Ask your permission about using the Self-Efficacy for Diabetes scale

5 thu

anh nguyen <lyanh1981@gmail.com>
 Từ: self-management@stanford.edu

11:08 Ngày 26 tháng 12 năm 2015

Dear **Stanford Patient Education Research Center**

My name is Nguyen Thi Anh. I'm working at Nursing department in Bach Mai Hospital, Hanoi, Vietnam. I am participating second year Master nursing at Mahidol, Thai lan. I'm going to do a study about " Factors related to peripheral arterial disease in patients with diabetes type 2 ". Self efficacy is one of factors that I want to focus among patient with DM type 2. I just read about your 'Self efficacy for diabetes scale that measure self efficacy very effectively and I am really exciting its content. So, I want to ask your permission about using this instrument. Please, help me ! I promise that I only use it for reference, not for any commercial purposes.

Extremely grateful for your support! Wish you have a happy time!

Best regards,

Nguyen Thi Anh

Kate R Lorig <lorig@stanford.edu>
 Từ: anh nguyen <lyanh1981@gmail.com>

14:57 Ngày 26 tháng 12 năm 2015

This scale is free for anyone to use and you have my permission. We would love a PDF of your translation.
 Kate lorig

Sent from my iPad
 [Ấn văn bản trích dẫn]

anh nguyen <lyanh1981@gmail.com>
 Từ: Kate R Lorig <lorig@stanford.edu>

17:06 Ngày 26 tháng 12 năm 2015

Thank you so much
 [Ấn văn bản trích dẫn]

Vietnamses version.pdf
 89K

anh nguyen <lyanh1981@gmail.com>
 Từ: hong nguyen tien <hongntbm@gmail.com>

14:44 Ngày 05 tháng 01 năm 2016

[Ấn văn bản trích dẫn]

anh nguyen <lyanh1981@gmail.com>
 Từ: Tran Bich <tranbich1405@gmail.com>

04:17 Ngày 17 tháng 01 năm 2016

----- Forwarded message -----
 From: anh nguyen <lyanh1981@gmail.com>
 Date: 2015-12-26 11:08 GMT+07:00
 Subject: Ask your permission about using the Self-Efficacy for Diabetes scale
 To: self-management@stanford.edu

1/17/2016

Gmail - giving permission to use the scale



anh nguyen <lyanh1981@gmail.com>

giving permission to use the scale

1 thư

Orapan Thosingha <orapan.tho@mahidol.ac.th>
Tới: anh nguyen <lyanh1981@gmail.com>

17:12 Ngày 16 tháng 01 năm 2016

Dear Nguyen Thi Anh,

I am very glad to give you the permission to use the scale and please see the full scale attached to this mail.

If you have any other questions please do not hesitate to ask me.

Good luck for your study

Orapan Thosingha

Dr.Orapan Thosingha,RN,DNS
Head of Surgical Nursing Department,
Faculty of Nursing, Mahidol University,
Bangkok, Thailand
e mail : orapan.tho@mahidol.ac.th

From: anh nguyen [lyanh1981@gmail.com]
Sent: Saturday, January 16, 2016 5:03 PM
To: Orapan Thosingha
Subject: The letter

Dear Dr. Orapan Thosingha

My name is Nguyen Thi Anh. I'm working at Nursing department in Bach Mai Hospital, Hanoi, Vietnam. I am participating in the second year of Master of nursing program at Mahidol University, Thailand.

I'm going to do a study about " Factors related to the occurrence of peripheral arterial disease in patients with diabetes type 2 ". Knowledge about peripheral arterial disease is one of factors that I want to focus among patients with DM type 2. I just read about your research entitled "Factors influencing pre hospital delayed time among patients with peripheral arterial occlusive disease" published in European Journal of Cardiovascular Nursing in the year 2015. I found that the scale you used for evaluate The Knowledge about peripheral arterial disease scale that measure Knowledge about peripheral arterial disease is very useful for my research. Accordingly, I would like to ask the permission from you to use this scale in my research. Would you please

1/17/2016

Gmail - The letter



anh nguyen <lyanh1981@gmail.com>

The letter

1 thư

anh nguyen <lyanh1981@gmail.com>
Từ: orapan.tho@mahidol.ac.th

17:03 Ngày 16 tháng 01 năm 2016

Dear Dr. Orapan Thosingha

My name is Nguyen Thi Anh. I'm working at Nursing department in Bach Mai Hospital, Hanoi, Vietnam. I am participating in the second year of Master of nursing program at Mahidol University, Thailand.

I'm going to do a study about " Factors related to the occurrence of peripheral arterial disease in patients with diabetes type 2 ". Knowledge about peripheral arterial disease is one of factors that I want to focus among patients with DM type 2. I just read about your research entitled "Factors influencing pre hospital delayed time among patients with peripheral arterial occlusive disease" published in European Journal of Cardiovascular Nursing in the year 2015. I found that the scale you used for evaluate The Knowledge about peripheral arterial disease scale that measure Knowledge about peripheral arterial disease is very useful for my research. Accordingly, I would like to ask the permission from you to use this scale in my research. Would you please kindly send me the complete scale and the direction to use the scale at your most convenience.

I am looking forward to hearing from you at your most convenience.

Sincerely yours,

Nguyen Thi Anh

BIOGRAPHY

NAME	Mrs. Nguyen Thi Anh
DATE OF BIRTH	19 November 1981
PLACE OF BIRTH	Hanoi, Vietnam
INSTITUTE ATTENDED	Bach Mai Medical, nursing school, 2000 - 2003 Hanoi, Medical University, 2008 – 2012 Bachelor of Nursing Mahidol University, 2015-2016 Master of Nursing Science (Adult Nursing)
POSITION AND OFFICE	2004 – May, 2012: Ophthalmology June, 2012 – Present: Nursing department Bach Mai Hospital, Hanoi, Vietnam
EMPLOYMENT ADDRESS	No. 78 Giai Phong street, Dong Da ward, Hanoi city, Vietnam Workplace Telephone number: + 84- 8693731 Email: Website: http:// www.bachmai.gov.vn
HOME ADDRESS	Tuong Chuc village – Ngu Hiep - Thanh Tri ward – Ha Noi city – Vietnam Email: lyanh1981@gmail.com Mobile phone number: +84 904718680