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FACTORS INFLUENCING FOOT CONDITIONS AMONG PEOPLE WITH TYPE 2 DIABETES IN EAST THAILAND.

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ABSTRACT

Diabetes-related complications are costly non-communicable disease, the major complication being abnormal foot conditions afflicting 37% of type 2 diabetics treated in six governmental hospitals in eastern region of Thailand. This study found that among type 2 diabetics with abnormal foot conditions, peripheral neuropathy accounted for the majority of them (43 %), followed peripheral vascular disease (22 %). Cumulative foot conditions were most common between peripheral vascular disease and peripheral neuropathy, which were found in 14 patients (15 %). A significant correlation was found between self-management support and glycemic control behaviors ($r = 0.270$, $p < 0.001$). However, there were no significant correlation among self-management support and foot care behaviors, glycemic control behaviors and HbA1c. Probability of abnormal foot conditions is correlated directly with duration of diabetes. Those with the diabetes for over a year showed a higher chance of abnormal foot conditions than those with diabetes for shorter time (OR = 1.15, 95% CI = 1.09 - 1.21).

This finding provides fundamental information for health care providers to prevent foot conditions among diabetics. In addition, self-management by diabetics is beneficial to glycemic control. Finally, this study sheds some light on other factors affecting foot conditions, along with effective programs to prevent foot abnormality among type 2 diabetics.

Keywords: Foot conditions, self-management support, foot care behaviors, glycemic control behaviors, HbA1c, and type 2 diabetes mellitus.

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INTRODUCTION

Diabetes mellitus is the most common public health problem throughout the world with a prevalence of 171 million in 2000, and likely to be more than double by 2030 (International Diabetes Federation Atlas, 2009). Similarly, national prevalence in Thailand has been estimated at 3 million in 2000 and is predicted to reach 4.6 million by 2010 (Aekplakorn et al., 2003; Aekplakorn, 2010). With these rise chronic complications, such as nephropathy, cardiovascular disease, and retinopathy especially diabetic foot complication are also expected to increase (Wild et al., 2004; Khamseh et al., 2007; Forlee, 2010). Diabetic foot conditions are a common and costly complication of diabetes throughout the world.

Abnormal foot conditions occur as a consequence of poor glycemic control and inappropriate foot care behaviors among type 2 diabetics. These conditions include peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer (Jeffcoate and Harding, 2003; Searle et al., 2005; Perrin and Swerissen, 2008; Jordan et al., 2008). Moreover, one of the most common causes of foot ulceration is foot deformity (Forlee, 2010). The lifetime risk of diabetics developing foot ulceration has been estimated to be as high as 25 % in the USA (Singh et al., 2005). This condition imposes a tremendous medical and financial burden on the health care system in Thailand (Riewpaiboon et al., 2011).

Although there are standards of care or practical guidelines to prevent foot ulcers, the incidence of diabetic foot ulcers and amputations still occur in great numbers, and the evidence for their effectiveness is still scarce (Dorresteijn et al., 2010). Thus, health care providers have shifted their focus and attention to the promotion of health care, prediction, and prevention of diabetic foot conditions. People with diabetes mellitus must manage and practice their health condition on a day-to-day basis, manage specific behaviors in order to control glycemic level, and appropriate foot care behaviors to prevent or delay the progressive deterioration of foot conditions. Although, there are several previous studies related to foot ulcer, there has been no study related to some factors that influence foot conditions of people with type 2 diabetes in Thailand. Thus, this study focuses on those poorly understudied factors influencing foot conditions, in particular, pathophysiological factors and those related to self-management.

The purposes of this study were to identify foot conditions among people with type 2 diabetes in East Thailand, and to examine whether influencing factors including duration of diabetes mellitus, glycemic control behaviors, foot care behaviors, self-management support, and HbA1c that could predict foot conditions, peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer.

MATERIALS AND METHODS

In this study, in order to establish a prediction of type 2 diabetes with abnormal foot conditions, a research design was used to examine causal relationships among the duration of diabetes mellitus, gylcemic control behaviors, foot care behaviors, self-management support, and HbA1c with foot conditions, which include peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer. Subjects in this study were 254 type 2 diabetics who had been diagnosed for at least one year and had received diabetes treatment at tertiary care, secondary care, and primary care in governmental hospitals in East Thailand.

Information collected was included personal and illness record forms. A questionnaire dealing with glycemic control self-management behaviors was developed, which was aimed to measure specific behaviors that could control blood glucose including diet, exercise, medication, and stress management. The questionnaire items were constructed as a 5-point Likert scale ranging from 0 to 4 points, in which 0 means almost never where 4 means almost always. The possible total scores ranged from 0 to 80 points. Higher scores indicated better glycemic control behaviors, while lower scores reflected poor glycemic control behaviors. It was found that the Cronbach's alpha coefficient of glycemic control self-management behaviors was 0.76. Questionnaires dealing with foot care behaviors were modified from the Nottingham Assessment of Functional Foot-care

Questionnaire (NAFF) (Lincoln et al., 2007). The final version of the constructed questionnaire was composed of 26 items. All items were rated using a 4-point Likert scale ranging from 1 to 4, in which 1 means never where 4 means always. It was found that possible total scores ranged from 26 to 104 points, where higher total scores indicated better foot care behaviors. There was no Thai version of this questionnaire; thus, this questionnaire was translated using forward and backward translation processes resulting in the Cronbach's alpha coefficient of the translated version of NAFF as 0.71. The questionnaires, dealing with self-management support were applied by using the Thai version of Patient Assessment of Chronic Illness (PACIC) (Wanikun et al, 2010). The Thai version was composed of 21 items and was used with permission from the author. Questionnaire items were arranged as a 5-point Likert scale ranging from 0 to 4 points, in which 0 means almost never where 4 means almost always. It was shown that the possible total scores were ranged from 0 to 84 points, where higher total scores indicated better support behaviors from health care providers resulting in the Cronbach's alpha coefficient of the Thai version of PACIC as 0.96.

Five Thai experts confirmed the content validity of the constructed questionnaires that included self-management support, chronic illness, a diabetic nurse, a podiatrist, and an endocrinologist. It was shown that content validity indexes (CVI) of foot care behaviors and glycemic control self-management behaviors were 0.93 and 0.90, respectively. The reliability of the foot assessment form that was used in a pilot study (n = 7) was 100 %.

The peripheral vascular disease was equated to the Ankle Brachial Index (ABI) (VeSera VS 1500) where indexes at < 0.40 = 2, 0.41- 0.90 = 1, and ≥ 0.91 = 0. The possible total scores for the peripheral vascular disease were ranged from 0 to 2 in each foot. Since the peripheral neuropathy involved sensory, motor, and autonomic nerves, thus sensory nerve response was checked with 5.07 monofilament. The monofilament was applied perpendicular to the plantar until it was bended from the pressure and left in place for approximately one second and then released. The patient with his or her eyes closed was responded as "yes" each time he/she sensed the monofilament on the foot. If the patient failed to sense the monofilament after it bended, the test site was considered to be insensate. The motor nerve was measured by the ability to spread the toes (abduct) and bring the toes together (adduct), and flexion-extension. Finally, the autonomic nerve was observed on the skin surface for dryness, cracks, fissures, and ingrown. Results were scored as follows: insensate = 1 point and sensate = 0 point, the inability of toes movement was scored as 1 point, whereas an active adduct-abduct toes-activity was scored as 0 point, the presence of dry skin and abnormal nails was scored as 1 point, whereas moisturized skin and normal nails was scored as 0 point. The possible total scores for peripheral neuropathy were ranged from 0 to 3 points in each foot. Foot deformity was classified according to the characteristic of the deformity appearance of the foot, i.e., those of foot with callus, claw toes, bunion, hammer toe, and Charcot foot were scored as 1 point, whereas those without foot deformity was scored as 0 point. In the absence or presence of a foot ulcer, it was scored as 0 or 1, respectively. Total possible scores for each foot were ranged from 0 to 7 points, while abnormal foot conditions were scored as ≥ 1.

The Research Ethics Committee of Faculty of Nursing, Burapha University, and Research Ethics Committee of the Hospital and the Board of Ethical Review of the six target hospitals approved this study project. Eligible subjects were approached and informed of the purpose, procedures, benefits, and risks of the study. All of the subjects were told to be assured of confidentiality and the freedom to withdraw from the study at any time. The subjects were free to ask any questions regarding the study and received a full explanation for all procedures. After the subjects explicitly understand all procedures and agreed to participate in the study, written consent was given.

The characteristics of the deformity appearance of the foot were presented as percentage, mean,

standard deviation (SD). The correlations among glycemic control behaviors, foot care behaviors, self-management support, and HbA1c were analyzed by using Pearson's correlation coefficient. Logistic regression analysis was used to test the significant relationship among abnormal foot conditions, peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer. Durations of diabetes mellitus, glycemic control behaviors, foot care behaviors, self-management support, and HbA1c were counted as the independent predictor variables. Stepwise backward selection was used as the method for variable selection, with p-value as > 0.001. Data were analyzed using the Statistical Package for Social Sciences software (SPSS for windows).

RESULTS

A total number of participants was 254, consisting of 70.90 % female. Results are summarized in Table 1a and Table 1b. The prevalence of diabetes mellitus increased dramatically with age, with less than 1 % of them who had diabetes mellitus were under 30 years of age, where the average age was 59 years with SD = 11.67 years. The cumulative prevalence of diabetes mellitus was almost 82 % among patients of 60-69 years of age. It was shown that more than half of the subjects (51.20 %) had been diagnosed with type 2 diabetes mellitus for five to ten years, whereas more than one quarter (28.30%) had been diagnosed with type 2 diabetes mellitus for less than five years. Most of the subjects (79.90 %) were non-smoker and almost all of them (96.50 %) had no history of foot ulcer. Finally, more than half of the subjects (55.50%) had the level of HbA1c higher than 7%.

Table 1a. Frequency and percentage of demographic characteristics of the study (n = 254).

Demographic characteristics	*n*	Percent
Gender		
Female	180	70.90
Male	74	29.10
Smoking		
Never smoked	203	79.90
Past smoking	37	14.60
Current smoking	14	5.50
History of foot ulcer		
Not having	245	96.30
Having	9	3.50

Table 1b. Frequency, percentage, mean, and standard deviation of demographic characteristics of the study (n = 254).

Demographic characteristics	n	Percent	Mean	SD.
Age (years.)				
20 – 29	2	0.80	58.56	11.67
30 – 39	10	3.90		
40 – 49	40	15.70		
50 – 59	80	31.50		
60 – 69	76	29.90		
70 – 79	39	15.40		
80 – 89	7	2.80		
Duration of diabetes mellitus (years.)				
< 5	72	28.30	7.71	6.17
5 – 10	130	51.20		
≥ 10	52	20.50		
HbA1c				
< 7 %	113	44.50	7.73	1.85
7.00 - 7.99 %	56	22.00		
≥ 8 %	85	33.50		

It was found that most of the patients did not have abnormal foot conditions. However, 94 patients or about 37 % of the total population displayed one or more abnormal foot conditions (Table 2). The most common one among them was a peripheral neuropathy, which was found in 43 % of this population, followed by 22 % of a

peripheral vascular disease. Each of foot deformity and foot ulcer occurred in only 2 % of patients with abnormal foot conditions. Cumulative foot conditions were most common between peripheral vascular disease and peripheral neuropathy, which were found in 14 patients or about 15 % of patients. The combination of other abnormal foot conditions was rarely expected, where only 5 % of the patients developed peripheral neuropathy and foot deformity. All other combinations were found less than 4 % of the patients.

Table 2. Summary of the frequency and percentage of abnormal foot conditions, peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer found in the participants (n = 254).

Characteristics	Abnormal	
	n	percent
Foot conditions	94	37.00
Peripheral neuropathy	40	42.55
Peripheral vascular disease	21	22.34
Foot deformity	2	2.13
Peripheral neuropathy and peripheral vascular disease	14	14.89
Peripheral vascular disease and foot deformity	5	5.32
Peripheral neuropathy and foot deformity	1	1.06
Peripheral neuropathy and foot ulcer	1	1.06
Foot deformity and foot ulcer	1	1.06
Peripheral neuropathy and peripheral vascular disease and foot ulcer	4	4.26
Peripheral neuropathy and peripheral vascular disease and foot deformity	2	2.13

Diabetics' patients could take the benefit from services made available by health care providers. It was shown that diabetics' patients with guidance from health care provider were overwhelmingly adopting strategies to regulate blood glucose concentrations, as shown in Table 3 where r = 0.270 at $p < 0.001$. Those patients that apply some regulatory strategies to control blood glucose were also accepting recognized methods of foot care. The level of Hemoglobin A1c did not differ significantly from those recommended by health care provider ($p > 0.001$).

Table 3. The correlations among self-management support, glycemic control behaviors, foot care behaviors and HbA1c in the population.

Factors	Glycemic control behaviors	Foot care behaviors	HbA1c
Self-management support	0.270**	0.032	-0.006
Glycemic control behaviors		0.363**	0.020
Foot care behaviors			0.090

** $p < 0.001$

The prevalence of abnormal foot conditions increased with duration of diabetes mellitus among the patients in this study with a significant logistic regression, as shown in Table 4. It was shown that if the duration of diabetes mellitus was increased one year, the chance of having abnormal foot conditions increased 1.15 times with the value of *OR* = 1.15, 95% CI = 1.09 - 1.21. In the similar fashion, the duration of diabetes mellitus could be used to predict peripheral vascular disease, where the value of *Nagelkerke* R^2 = 0.138, $p < 0.001$. The risk of having peripheral vascular disease was shown to increase 1.12 times with the value of *OR* = 1.12, 95% CI = 1.06 - 1.17, when the duration of diabetes mellitus was increased one year. Thus, the duration of diabetes mellitus could be used to predict peripheral neuropathy with the value of *Nagelkerke* R^2 = 0.132, $p < 0.001$. The risk of having

peripheral neuropathy was shown to increase 1.11 times with the value of *OR* = 1.11, 95%CI = 1.06 - 1.17, when the duration of diabetes mellitus was increased one year. The duration of diabetes mellitus could be used to predict the development of foot deformity where the value of *Nagelkerke* R^2 = 0.102, $p < 0.001$. The risk of developing foot deformity, was shown to increase 1.11 times with the value of *OR* = 1.11, 95%CI = 1.05 - 1.18, when the duration of diabetes mellitus was increased one year. In the similar fashion, the risk of developing foot ulcer was shown to increase 1.13 times with the value of *OR* = 1.13, 95%CI = 1.05 - 1.22, when the duration of diabetes mellitus was increased one year.

Table 4. A summary of logistic regression for factors association to foot conditions, peripheral vascular disease, peripheral neuropathy, foot deformityand foot ulcer (n=254).

Factors	β	S.E.	Odd ratio	95% CI (Lower - Upper)	Nagelkerke R^2
Foot conditions					
Duration of DM	0.14	0.03	1.15††	1.09 - 1.21	0.173**
Constant	-1.61	0.25			
Peripheral vascular disease					
Self-management support	-0.32	0.18	0.07	0.51 - 1.02	
Duration of DM	0.11	0.03	1.12††	1.06 - 1.17	0.138**
Constant	-1.91	0.45			
Peripheral neuropathy					
Duration of DM	0.11	0.02	1.11††	1.06 - 1.17	0.132**
Constant	-1.92	0.26			
Foot deformity					
Duration of DM	0.10	0.03	1.11††	1.05 - 1.18	0.102**
Constant	-3.51	0.43			
Foot ulcer					
Duration of DM	0.13	0.04	1.13††	1.05 - 1.22	0.139**
Constant	4 - 4.65	0.65			

††p < 0.001 significant of coefficients, ** P < 0.001 significant of model

The development of peripheral neuropathy could be used to predict the occurrence of foot ulcer. People with peripheral neuropathy showed higher risk of foot ulcer 16 times greater than those people who did not have peripheral neuropathy, where the value of *OR* = 16.12, 95% CI = 1.18 - 141.43, $p < 0.05$, Nagelkerke R^2 = 0.277, as shown in Table 5.

Table 5. The parameter estimates of risk factor and foot ulcer by using Backward Wald logistic regression.

Factors	β	S.E.	Odd ratio	95% CI (Lower - Upper)	Nagelkerke R^2
Peripheral neuropathy	2.78	11.10	16.12††	1.18 - 141.43	0.277*
Foot deformity	1.46	0.76	4.31	0.97 - 19.27	
Constant	-5.28	1.00	0.005		

$^{\dagger\dagger}p < 0.001$ significance of coefficients, *$P < 0.05$ significance of model

DISCUSION

Type 2 diabetes mellitus is characterized by insulin resistance, which may be combined with relatively reduced insulin secretion. The defective responsiveness of body tissues to insulin is believed to involve the insulin receptor. However, the specific defects are not known. It has been shown that abnormal foot conditions occur as a consequence of poor glycemic control and inappropriate foot care behaviors among type 2 diabetics, and it has been reported that several conditions are contributed to the abnormal foot conditions, i.e., peripheral vascular disease, peripheral neuropathy, foot deformity, and foot ulcer (Jeffcoate and Harding, 2003; Searle et al., 2005; Perrin and Swerissen, 2008; Jordan et al., 2008). It has been demonstrated that one of the most common causes of foot ulceration is foot deformity (Forlee, 2010), with the lifetime risk of diabetics developing foot ulceration has been estimated to be as high as 25 % in the USA in 2005 (Singh et al., 2005). **Therefore,** these conditions impose a tremendous medical and financial burden on the health care system in Thailand.

It has been observed that normal foot conditions are very common among type 2 diabetes mellitus patients in Thailand. This is probably attributed in part to the relatively short time during which the subjects had been diagnosed with diabetes mellitus, which is quite relevant to those observations reported by Samann et al. (2008) and the American Diabetes Association (2004). It was proposed that abnormal foot conditions were unlikely to occur in persons who had been diagnosed with diabetes mellitus less than 10 years. This was attributed to a slow deterioration of cell function, particularly in association with the nervous and circulatory system of the foot. It was found that most patients in the present study did not smoke and lacked a history of foot ulcers.

The practice of self-management support related to glycemic control among the diabetes mellitus patients has been established. However, the abnormality of the foot was not significantly related to self-management support behaviors in this study. It is very interesting to note that foot care behaviors are not relevant to self-management support behaviors, which suggested that patients are learning from other sources. Several possible sources have been cited, i.e., information provided indirectly during hospital visits, and other encounters with health care personnel.

The duration of diabetes mellitus is clearly influenced foot conditions, particularly peripheral vascular disease and peripheral neuropathy. The prevalence of each of the four-foot conditions is increased directly with duration of diabetes, and glycated haemoglobin is correlated directly with diabetes. In general, high glycated haemoglobin can be expected to inhibit microvascular circulation and neural activity leading to cellular deterioration (Cummings and Browne, 2001). Three groups of nerves can be affected by diabetic neuropathy, i.e., sensory, motor, and autonomic nerves. It has been postulated that how hyperglycemia contributes to

microvascular damage, and suggested several factors that may contribute to microvascular damage, i.e., increasing in polyol pathway, production of advanced glycation end-products, generation of reactive oxygen species, and activation of diacylglycerol and protein kinase C isoforms (Brownlee, 2001; Setter et al., 2003; Sheetz and King, 2002; Way et al., 2001). Previous studies showed that a high level of HbA1c is a significant independent predictor of prevalence of peripheral neuropathy and peripheral vascular disease (Selvin et al., 2006; Al-Mahroos and Al-Roomi, 2007). It was shown in the observational data describing the association between glycated hemoglobin (HbA1c) cardiovascular events and a meta-analysis of previous randomized trials of glycemic control that a 0.7 % reduction in the glycated hemoglobin value might be expected to produce a reduction in the rate of macrovascular events by approximately one sixth (Selvin et al., 2004; Stettler et al., 2006). Other risk factors of macrovascular complications are hypertension, hyperlipidemia, smoking, and obesity. The synergistic effect of these risk factors and hyperglycemia is particularly relevant to the development of arthrosclerosis in macrovascular complications (Lockman et al., 2011). The most common co-morbidities of the subjects in the present study were hypertension (64.6 %) and hyperlipidemia (40.2 %). This indicated that most subjects suffered from co-morbidity and had macrovascular complications such as peripheral vascular disease. Since intracellular glucose is converted by those enzymes to sorbitol and fructose (Setter et al., 2003), the accumulation of these products results in a decrease in the synthesis of nerve cell myoinositol, which required for normal neuron conduction. In addition, the chemical conversion of glucose results in a depletion of nicotinamide adenine dinucleotide phosphate stores, which are necessary for the detoxification of reactive oxygen species and for the synthesis of the vasodilator nitric oxide. This will lead to additional oxidative stress of the nerve cells, and vasoconstriction is led to ischemia, which will promote nerve cell injury and death (Zochodone, 2008; Clayton and Elasy, 2009). The state of persistent hyperglycemic is led to endothelial cell dysfunction and smooth cell abnormalities. Moreover, hyperglycemia in diabetes is associated with an increase in thromboxane A2, a vasoconstrictor, and platelet aggregation agonist, which leads to an increased risk of plasma hypercoagulability. There is also the potential for alterations in the vascular extracellular matrix leading to stenosis of the lumen (Paraskevas et al., 2008). In addition, smoking, hypertension, and hyperlipidemia are other factors that are common in diabetics and contribute to the development of peripheral vascular disease (Singh et al., 2005).

The present study indicated that peripheral neuropathy could predict foot ulcer, where the values of OR = 16.12, 95% CI =1.18 - 141.43. This is consistent with the earlier observation by Wheeler et al. (2007) who has stated that diabetic neuropathy is a risk factor for diabetic foot ulcer, especially the loss of protective sensation. The case-control study has demonstrated a significantly risk of foot ulcer in association with sensory lower limb neuropathy as it has been mentioned by McNeely et al. (1995) where the values of adjusted OR 18.42, 95% CI = 3.83-88.47, which both studies used a similar method of measurement. It was shown that there was a 9.9 times increased in foot ulcers among diabetic American Indians (n = 356) with impaired foot sensation measured in the same manner as the present study, during their approximately three year study (Rith-Najarian et al., 1992).

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