Prevalence, Risk Factors and Associated Cardiovascular Complications of Peripheral Arterial Disease in Type 2 Diabetic Patients in Eastern Taiwan

Chen-Chung Fu, Bee-Song Chang[1], Dee Pei, Shi-Wen Kuo, Yuan-Chieh Lee[2], Jer-Chuan Li, Du-An Wu

Department of Internal Medicine, Thoracis and Cardiovascular Surgery[1], Ophthalmology[2], Buddhist Tzu Chi General Hospital, Hualien, Taiwan

ABSTRACT

Objective: The purpose of this study was to evaluate the risk factors, including albuminuria, for peripheral arterial disease (PAD), and associated complications in patients with type 2 diabetes. **Materials and Methods:** All patients with type 2 diabetes 40 years old and over, were recruited consecutively from diabetic clinics at a medical center in eastern Taiwan. Information regarding each participant's sociodemographic characteristics and medical history was gathered from the patients and their medical records. A clinical examination which included anthropometric measurements and a direct ophthalmoscope check-up was performed. After an overnight fast, serum lipids, uric acid, fasting plasma sugar, A1C and urinary albumin concentration were measured. The ankle-brachial index (ABI) was calculated by Doppler examination in both legs. PAD was diagnosed if the ABI in one of the legs was less than 0.9. **Results:** A total of 309 patients were recruited. PAD was present in 38 of the 309 diabetic subjects studied (12.3%; 12.7% of the men and 11.9% of the women). Of all subjects with PAD, 92.1% had a history of hypertension, 15.8% had stroke, 13.2% had coronary heart disease, and 47.4% had albuminuria. For those who completed the direct ophthalmoscope examination, 41.9% of patients with PAD had diabetic retinopathy. In univariate analysis, the significant associative risk factors for PAD were age, tobacco smoking, history of hypertension/stroke, duration of diabetes, insulin therapy, usage of angiotension-converting enzyme inhibitors/angiotension-receptor blockers (ACEI/ARB) and albuminuria. Multiple logistic regression analysis identified age as the most significant risk factor for PAD. The higher the age of the patient, the greater the likelihood of PAD, with a 1.11-fold increase in risk incurred for every 1-year increment. Cigarette smoking was also a significant factor with smokers incurring a 4.77-fold higher risk than non-smokers. Individuals suffering from macroalbuminuria were more likely to have PAD compared to those without albuminuria. Other significant risk factors included insulin usage. **Conclusions:** The occurrence of PAD in type 2 diabetic patients is associated with the age of the patient, smoking, insulin usage and albuminuria. Incorporation of albuminuria assessment and a smoking-cessation program are recommended in clinical practice. (***Tzu Chi Med J*** 2006; **18**:275-282)

Key words: albuminuria, peripheral arterial disease, diabetic mellitus

INTRODUCTION

Peripheral arterial disease (PAD) is a clinical manifestation of atherosclerosis and is characterized by atherosclerotic occlusive disease of the lower extremities. Compared with their unaffected counterparts, patients with PAD have a reduced life expectancy because they often have coexisting cerebrovascular and/or coronary artery disease [1-4]. PAD is also a major cause of lower-

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Address reprint requests and correspondence to: Dr. Chen-Chung Fu, Department of Internal Medicine, Buddhist Tzu Chi General Hospital, 707, Section 3, Chung Yang Road, Hualien, Taiwan

extremity amputation, especially in diabetic patients [5]. Many studies have shown that PAD is more common in diabetics than in nondiabetic subjects [5-7]. This higher prevalence of PAD in diabetics is partially attributed to co-existent cardiovascular risk factors, including hypertension [7-10], cigarette smoking [10,11], and dyslipidemia [7,10-12]. Other irreversible risk factors are age, sex and genetics [8,10-13]. Albuminuria has also been reported to be a risk factor for PAD in patients with type 2 diabetes in some studies [14-16] however, one study did not find this association [17]. Few studies have explored the risk factors of PAD in Taiwan [8,12] and none have explored the relationship between albuminuria and PAD. The aim of this study, therefore, was to evaluate the risk factors, including albuminuria, for PAD, in a sample of Chinese patients from eastern Taiwan with type 2 diabetes.

MATERIALS AND METHODS

The high mountain range that runs the length of central Taiwan isolates the eastern areas, effectively cutting off local residents due to the inconvenience of transportation. Tzu Chi University Hospital is the only medical center in eastern Taiwan and, before the present study there had been no previous screening for PAD in this region. All diabetic patients 40 years old and over, who visited a diabetic outpatient clinic at Tzu Chi University Hospital from July 2003 to December 2003 were recruited. Patients with a history of acute pancreatitis, gestational diabetes, and type 1 diabetes mellitus were excluded. A hospital-based study was utilized rather than a community-centered analog because the institutional environment offered both temporal and economic efficiency because of the ease of recruiting sufficient numbers of PAD patients for analysis.

Information regarding each participant's sociodemographic characteristics and medical history, including status with respect to tobacco smoking, usage of angiotension-converting enzyme inhibitors/ angiotension II receptor blockers (ACEI/ARB) and associated diabetic complications were gathered from patients and their medical records. A clinical examination which included anthropometric measurements and a direct ophthalmoscope checkup was performed. Stroke was diagnosed from the relevant history and was confirmed by the physician. Coronary heart disease was diagnosed if the patient had undergone a coronary angiography to document the lesion (>50% reduction in luminal diameter). Hypertension was considered when there was a previous diagnosis and treatment, or when blood pressure was equal to or greater than 140/90 mmHg [18]. Diabetic retinopathy was diagnosed by an ophthalmologist and was graded as follows: 1) no signs of diabetic retinopathy, 2) nonproliferative retinopathy, or 3) proliferative retinopathy.

A nurse obtained the body height and body weight of the patients. The weight was measured in light clothing while the height was obtained to the nearest 0.1 cm with the head held in the Frankfort plane. The body mass index (BMI, kg/m^2) was calculated as the weight divided by the height squared and a cutoff point of 25 for obesity was used as suggested by the WHO for the Asia-Pacific region [19].

The ankle-brachial index (ABI) was calculated automatically by a Doppler Ultrasound device (Parks Medical Electronics, Inc, Aloha, Oregan, USA) as the ankle divided by the brachial systolic pressure. A diagnosis of PAD was based on a unilateral ABI <0.9 [20]. Participants who had an abnormally high ABI (>1.5) suggestive of arterial calcification were excluded from the study.

After an overnight fast, serum total cholesterol, triglycerides, HDL-cholesterol, LDL-cholesterol, uric acid, fasting plasma sugar, HbA1C and urinary albumin concentration were measured in all study subjects. Plasma glucose was measured using a YSI 203 glucose-oxidase analyzer (Yellow Springs Instrument Co., Yellow Springs, OH, USA). Total cholesterol, triglycerides, LDL-cholesterol, HDL-cholesterol and uric acid concentration were measured using the enzymatic colorimetric method with a Hitachi 747 automated analyzer (Hitachi High-Technologies Corp., Tokyo, Japan). A first-void, mid-stream morning spot urine sample was collected from all subjects. The urinary albumin concentration was measured quantitatively by means of a near-infrared particle immunoassay (Beckman Coulter Inc, Fullerton, CA, USA). The urinary creatinine concentration was determined via an automatic biochemistry analyzer (Olympus AU640, Olympus Diagnostica, Mishima, Japan) with an Olympus system reagent. The urinary albumin-creatinine ratio (ACR) was calculated by dividing the urinary concentration of albumin (mg) by that of creatinine (g). This was repeated within 4 weeks if the ACR was ≥ 30 mg/g. A third urine sample was collected if the results of the initial two were inconsistent. Albuminuria was defined as microalbuminuria if the ACR was ≥30 and <300 mg/g, and as macroalbuminuria if the ACR was ≥300 mg/g. Urinary tract infection was treated, if present, and the urine collection then repeated. Hyperuricemia was defined as a serum uric acid level greater than 7 mg/dL and 6 mg/dL for men and women respectively, or patients used uric acidlower-

ing agents.

The investigation was approved by the Ethics Committee of Buddhist Tzu Chi General Hospital (Hualien, Taiwan). All patients were carefully instructed with respect to the study details and written informed consents were obtained.

Statistical analysis

Data were analyzed using the SPSS PC software package. Student's t test was used to compare continuous variables. The chi-square test or Fisher exact test was used for categorical variables. Differences in the prevalence of PAD across strata of study subjects' age were tested by χ^2 for linear trend. Multivariate logistic regression analysis was used to investigate the risk factors associated with PAD, with variables included on the basis of univariate analysis and other previous studies. Age was entered as a continuous variable, whereas gender (male/female), tobacco smoking history (never, ex/current), diabetes duration (<5, 5-9 or ≥10 years), insulin therapy (yes/no), hypertension (yes/no), stroke (yes/no), albuminuria (normo/micro/macro-) and usage of ACEI/ARB (user/non-user) were entered as categorical variables.

RESULTS

A total of 309 patients participated in this study (158 men and 151 women); their mean age was 63.3 ± 11.4 years (range: 40-86). Among them, 257 patients (83.2%) completed the direct ophthalmoscope examination. Clinical characteristics of the studied subjects are presented in Table 1. Overall, 42.4% of the patients were aged ≥65 years, 71.5% had hypertension, and 33.7% were current or former smokers. Of all subjects with hypertension, 75.6% were receiving ACEI/ARB. PAD was present in 38 of the 309 subjects studied (12.3%; 12.7% of the men and 11.9% of the women) (Table 2). Of all subjects with PAD, 92.1% had a history of hypertension, 15.8% had stroke, 13.2% had coronary heart disease, and 47.4% had albuminuria. For those who completed the direct ophthalmoscope examination, 13 (41.9%) patients with PAD and 74(32.7%) patients without PAD had diabetic retinopathy (p=0.21).

In Tables 2 and 3, selected variables are compared for diabetic subjects with and without PAD. The prevalence of PAD significantly increased with longer durations of diabetes. The PAD prevalence was significantly higher in ex/current smokers than in non-smokers. The

Table 1. Clinical Characteristics of Study Subjects

Variable	N=309
Number (%)	
Gender (M, %)	51.1
Aboriginals (%)	12.0
Hypertension (%)	71.5
Stroke (%)	7.1
Confirmed coronary heart disease (%)	10.0
Insulin user (%)	27.2
Smoking status (%)	
Never	66.3
Ex/current	33.7
Means ± standard deviation	
Age (yr)	63.3 ± 11.4
Diabetic duration (yr)	8.3 ± 7.7
Body mass index (kg/m^2)	25.9 ± 3.8

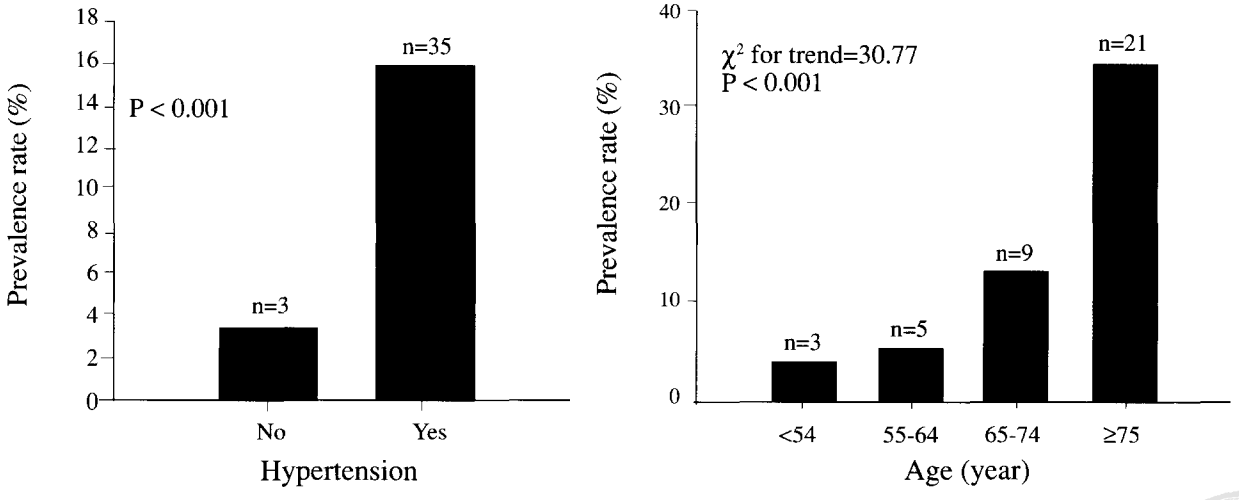

Fig. 1. Prevalence of PAD in relation to hypertension and age.

percentages of patients who received insulin and ACEI/ARB therapy were significantly higher in the patients with PAD than in those without PAD. No significant differences existed in baseline characteristics including gender, general obesity (BMI >25 kg/m^2), hyperuricemia, mean serum cholesterol, triglyceride, HDL-cholesterol, LDL-cholesterol, uric acid, systolic and diastolic blood pressure, and HbA1C levels.

Table 2. Differences in the Distributions of Risk Factors in the Patients with and without PAD

Variables	With PAD (n=38)		Without PAD (n=271)	
	Number	(%)	Number	(%)
Age (year)				
<65	8	21.1	170	62.7
65-74	9	23.7	61	22.5
>75	21	55.3	40	14.8**
Smoking status				
Non-smoker	20	52.6	185	68.3
Ex/current smoker	18	47.4	86	31.7*
Hypertension				
No	3	7.9	85	31.4
Yes	35	92.1	186	68.6**
Diabetes duration (year)				
< 5	10	26.3	124	92.5
5-9	10	26.3	70	87.5
≥ 10	18	47.4	77	81.1*
Insulin treatment				
No	20	52.6	205	75.6
Yes	18	47.4	66	24.4**
ACEI/ARB				
Non- user	10	26.3	114	41.9
User	28	73.7	157	58.1*
Stroke				
No	32	84.2	255	94.1
Yes	6	15.8	16	5.9*
Albuminuria				
Normal	20	52.6	202	74.5
Microalbuminuria	9	23.7	52	19.2
Macroalbuminuria	9	23.7	17	6.3**

ACEI/ARB: angiotension-converting enzyme inhibitors/ angiotension II receptor blockers; Non-significant variables that did not display included gender, diabetic retinopathy, coronary heart disease, hyperuricemia, and obesity (BMI≥ 25 kg/m^2); *: P <0.05; **: P <0.005 at chi-square test or Fisher's Exact test

Table 3. Difference in the Mean Values of Risk Factors in the Subjects with and without PAD

Variables	With PAD (n=38)	Without PAD (n=271)	P value
Age (yr)	72.6 ± 10.6	61.7 ± 10.4	0.001
Diabetes duration (yr)	12.1 ± 10.3	7.79 ± 7.2	0.017
Serum total cholesterol (mg/dL)	179 ± 44	176 ± 40	0.721
Serum triglyceride (mg/dL)	184 ± 154	157 ± 112	0.183
Serum HDL-C (mg/dL)	43 ± 12	45 ± 12	0.196
Serum LDL-C (mg/dL)	106 ± 32	111 ± 34	0.410
Systolic BP (mmHg)	139 ± 21	135 ± 18	0.184
Diastolic BP (mmHg)	78 ± 12	74 ± 12	0.186
Uric acid (mg/dL)	6.4 ± 1.8	6.0 ± 1.6	0.159
Fasting plasma sugar (mg/dL)	177 ± 72	166 ± 60	0.284
A1C (%)	8.0 ± 1.7	8.0 ± 2.0	0.956

Data expressed as means ± standard deviation

Table 4. Logistic Regression Analysis to Assess the Effect of Each Risk Factor on the Presence of PAD

Determinants	Odds Ratio	95% C.I.	P value
Age (1-yr increments)	1.11	1.06-1.15	0.000
Gender (F vs M)	1.67	0.85-8.56	0.084
Insulin user (yes vs no)	2.87	1.23-6.73	0.015
Hypertension (yes vs no)	3.25	0.88-12.04	0.109
Stroke (yes vs no)	1.00	0.30-3.36	0.998
Diabetic duration (yr)			
< 5	1.00		
5-9	1.21	0.40-3.62	0.702
≥ 10	1.19	0.43-3.23	0.735
Smoking status			
Ex/current smoker vs non-smoker	4.77	1.46-15.56	0.009
ACEI/ARB (user vs non-user)	0.92	0.35-2.40	0.976
Albuminuria			
Normoalbuminuria			
Microalbuminuria	1.96	0.75-5.13	0.161
Macroalbuminuria	4.30	1.41-13.11	0.013

C.I.: 95% confidence interval

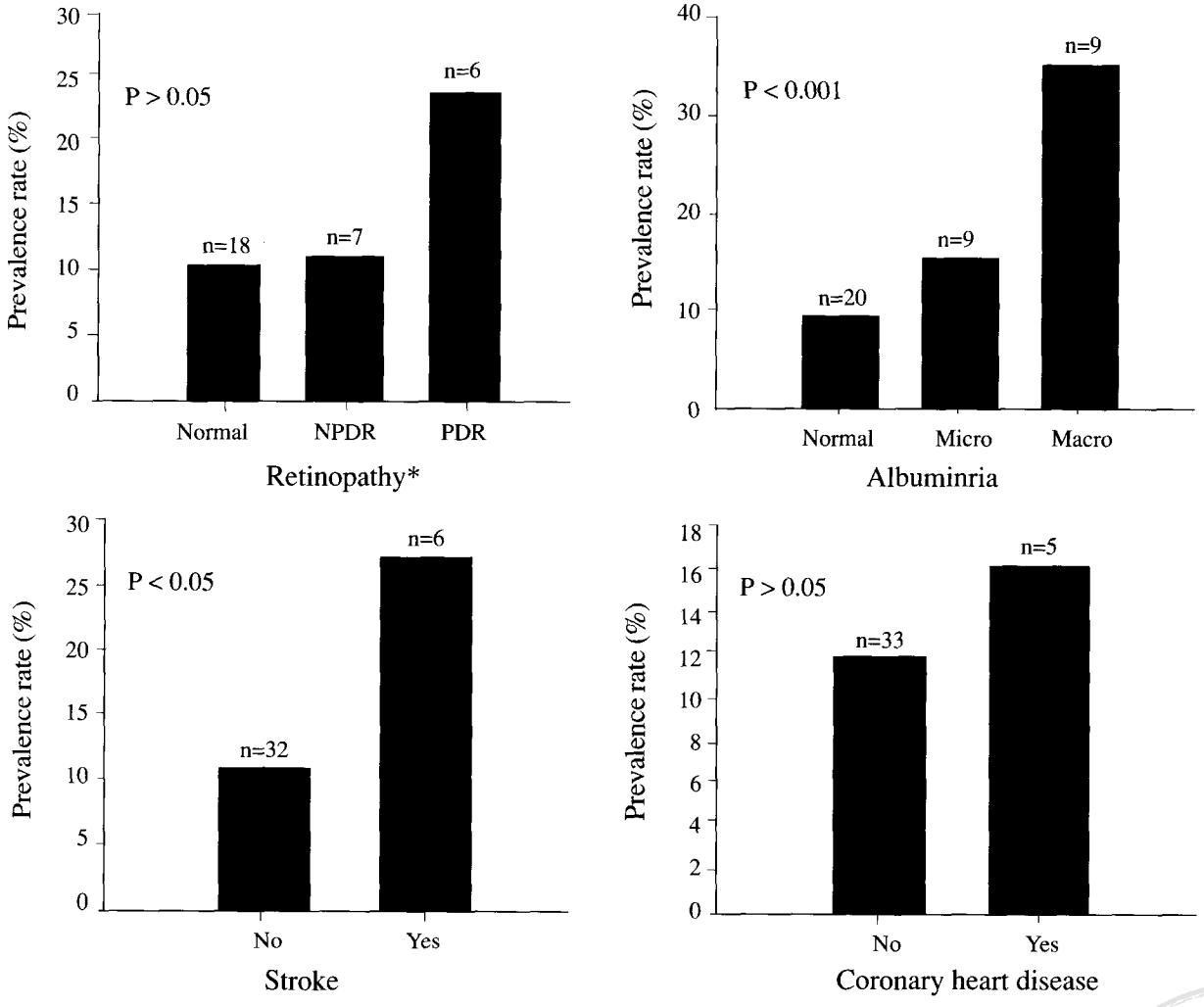

Fig. 2. Prevalence of PAD in relation to associated complications (*n=257).

Fig. 1 and 2 depict the relationships between the PAD prevalence and age, hypertension, and related diabetic complications. Notably, the prevalence of PAD increased almost tenfold across patient age groups, from 3.7% to 34.4% for those <54 years old and >75 years old, respectively (χ^2_{trend} =30.77, P <0.001). In addition, the PAD prevalence was significantly higher in patients with stroke and hypertension. Further, there was a dramatic increase in the PAD prevalence from 9.0% to 34. 6% in the normoalbuminuria and macroalbuminuria groups, respectively. No significant difference in PAD prevalence was demonstrated in different diabetic retinopathy groups, or for those with coronary heart disease.

In the logistic regression model as shown in Table 4, the most significant factor associated with PAD was patient age, with a 1.11-fold increase in risk incurred for every 1-year increment. Insulin treatment was the second most-important factor for PAD (odds ratio = 2.87, 95% CI = 1.23-6.73). Other significant risk factors included tobacco smoking and albuminuria. Patients who were ex/current smokers had a 4.77-fold higher chance of PAD than subjects who had never smoked. Individuals suffering from macroalbuminuria were more likely to have PAD than their counterparts without albuminuria. No statistically significant differences were demonstrated for PAD risk when comparing gender, diabetic duration, history of hypertension, usage of ACEI/ARB and stroke.

DISCUSSION

Our findings are quite consistent with those of other researchers who have reported that patient age is a very important associative factor for PAD [10,21]. In this study, the rates of PAD were only 3.7% and 5.2% for patients aged <55 and 55-64 years, respectively. However, the PAD prevalence increased to 12.9% in those 65-74 old and then markedly to 34.4% in those over 75 years. It is recommended, therefore, that physicians take greater care to screen for PAD in elderly diabetics to facilitate early diagnosis in this high-risk group.

Although smoking was not associated with PAD in one study done in Taiwan [8], we found that tobacco smoking was a PAD risk factor in diabetic patients, as in our previous study and others [10-11,22]. Smoking has also been considered an important risk factor for coronary heart disease. Thus, it is strongly advised that a smoking-cessation program be incorporated in diabetic care.

Many studies, including this one, have found no association between the BMI and PAD [3,23]; however, others have demonstrated a positive relationship in all study subjects [24] or an inverse association [8,10]. One reason for this inconsistent result is that obesity may not be a risk factor for PAD. One study published recently revealed that height is an independent predictor of lower-extremity amputation among patients with type 1 and type 2 diabetes mellitus [25]. Besides, BMI may be a poor indicator of obesity in elder people as abdominal girth increases and lean muscle mass decreases.

In accordance with other investigations [10,13-16], we found a clear relationship between increasing levels of albuminuria and the presence of PAD, with the rate of the latter increasing from 9.0% to 14.8% and 34.6% in patients with normoalbuminuria, microalbuminuria and macroalbuminuria, respectively (p<0.001). In addition, compared with the normoalbuminuria group, patients with macroalbuminuria incurred a 4.30-fold higher risk of PAD in stepwise logistic regression analysis. One might argue that patients' age could be an influencing factor related to albuminuria; however, sub-analysis revealed that there was no significant age difference among these three groups. Therefore, incorporation of albuminuria assessment is recommended as part of the PAD-prevention strategy for diabetic patients.

Of all subjects with PAD, 47.4% had albuminuria and 41.9% of those with PAD who completed the direct ophthalmoscope examination had diabetic retinopathy. Albuminuria is reportedly an independent cardiovascular risk factor and is associated with increased risks of cardiovascular disease mortality and morbidity and renal function deterioration in patients with diabetes [26, 27]. Therefore it is necessary to remind medical personnel to do renal and ophthalmologic evaluations in diabetic patients.

In univariate analysis, the percentage of patients who received ACEI/ARB therapy was significantly higher in patients with PAD than in patients without PAD. This could be because 47.4% of diabetic patients with PAD had albuminuria and physicians usually prescribe ACEI/ARB for this group. After adjusting for this factor, usage of ACEI/ARB was no longer a significant factor for PAD.

We found that the percentage of patients who received insulin therapy was significantly higher in patients with PAD than in those without PAD. However, sub-analysis revealed that patients who received insulin therapy did not have a significant difference in the blood lipid levels from those who did not. Although it had been suggested that hyperinsulinemia may increase the risk of ischemic heart disease mainly through related dyslipidemia and alterations in metabolic processes [28], the mechanisms responsible for the association between

PAD and insulin therapy remain speculative. As such, more work is needed to explore this.

Although the duration of diabetes was associated with PAD in the analysis, the relationship was not significant after adjustment for age and sex. It appears reasonable to assume that there is a correlation between patient age and diabetes duration (Pearson correlation coefficient=0.34, $p<0.001$).

Both hyperuricemia and mean serum uric acid level were not significantly associated with PAD in this study although another study revealed an association [29]. It would appear that the small sample recruited in this cross-section study could not provide an indicative analysis; a larger prospective study might solve this issue.

It is also important to realize that coronary heart disease was diagnosed only if patients had undergone a coronary angiography to prove the existence of coronary stenosis. Therefore, the true prevalence of coronary artery disease was underestimated in this study.

In conclusion, the occurrence of PAD in our sample of Chinese type 2 diabetic patients from eastern Taiwan is associated with albuminuria and a number of the traditional risk factors noted in other populations, including patient age, insulin treatment and tobacco smoking.

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東台灣第2型糖尿病患罹患周邊血管疾病的盛行率、危險因子與相關血管併發症

傅振宗　張比嵩[1]　裴　駒　郭熙文　李原傑[2]　李哲全　吳篤安

佛教慈濟綜合醫院內科　心臟胸腔外科[1]　眼科[2]

摘要

目的：探討第2型糖尿病患罹患周邊血管疾病的危險因子與相關的血管併發症。**材料與方法**：我們在東台灣某醫學中心的糖尿病門診選取40歲以上的第2型糖尿病患，除了收集病患的基本資料外，並安排眼底、生化及周邊血管超音波檢查，其中，生化檢查包括空腹血糖、血脂肪、尿酸、糖化血色素和微蛋白尿，周邊血管疾病的診斷是病患下肢的ABI值＜0.9。**結果**：總共有309位病患參加，其中的38位罹患周邊血管疾病(盛行率：12.3%，男性：12.7%，女性：11.9%)。合併周邊血管疾病的病患中92.1%有高血壓，15.8%有中風，13.2%有冠心症，47.4%有微蛋白尿，41.9%有視網膜病變(257位接受眼底檢查)。單變項分析顯示和周邊血管病變有關的因素包括年齡、抽菸、高血壓、腦中風、糖尿病罹患時間長短、使用胰島素治療與微蛋白尿。多變項分析顯示年齡是罹患周邊血管疾病的最重要因素，病人每增加一歲，危險性就增加1.11倍；其次是抽菸，有抽菸的病患危險性是沒抽菸的4.77倍；有蛋白尿的病患危險性較高；此外，是否有接受胰島素治療也是相關因素。**結論**：第2型糖尿病患罹患周邊血管的相關因素包括病患年齡、抽菸、使用胰島素治療與是否有微蛋白尿，建議在臨床診療中應包括微蛋白尿評估與戒菸課程。(**慈濟醫學** 2006; **18**:275-282)

關鍵語：微蛋白尿，周邊血管疾病，糖尿病

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蘭嶼達悟族之中老年族群的眼部翼狀贅片流行病學分析

林淑芳[1]　蔡榮坤[1,2]　童逸禎[1]　許明木[1,2]

佛教慈濟綜合醫院眼科[1]　慈濟大學眼科[2]

摘要

目的：分析臺灣之蘭嶼島上達悟族中老年族群之翼狀贅片流行率。**材料與方法**：四十歲以上居民以隨機方式採樣，並以裂隙燈等檢查。**結果**：共有兩百四十九人接受檢查，共計一百零一名男性，一百四十八名女性。自四十歲至八十七歲，平均年齡58.54歲(standard deviation, SD±12.95)。男性平均60.09歲，女性平均57.49歲。翼狀贅片之整體發生率為53.01%(95%CI: 39.18%-66.84%)，平均每人有1.03片翼狀贅片。中年族群平均發生率為42.5%(95%CI: 28.79%-56.20%)，平均每名患者0.79片。老年族群發生率為71.91%(95%CI: 59.45%-84.37%)，平均每名患者1.47片。翼狀贅片發生率於中或老年族群中並無性別之發生差異，發生型態以鼻側為好發位置。達悟族各年齡層男女之翼狀贅片發生比並無男女差異。**結論**：整體而言，達悟族的翼狀贅片發生率與其他原住民族相近，且均較臺灣本島人民為高，且發生率均隨年齡增加而攀升，可能與緯度及紫外線曝曬及戶外生活型態有關。(**慈濟醫學** 2006; **18**:283-286)

關鍵語：原住民族，蘭嶼，流行率，翼狀贅片

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抽印本索取及聯絡地址：花蓮市中央路3段707號　佛教慈濟綜合醫院眼科　許明木醫師