Risk factors of diabetic foot in central Saudi Arabia

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ABSTRACT

الأهداف: تحديد عوامل الخطر المرتبطة بداء القدم السكرية لدى مرضى السكري.

الطريقة: أُجريت هذه الدراسة المقارنة عن طريق فحص السجلات الطبية للمرضى المصابين بالسكري والذين راجعوا مدينة الملك عبدالعزيز الطبية للحرس الوطني، الرياض، المملكة العربية السعودية خلال الفترة من يناير 2009م إلى يوليو 2010م. لقد قُسم المشاركين في الدراسة عشوائياً إلى مجموعتين وهما: مجموعة الدراسة المكونة من 50 مريضاً مصاباً بداء القدم السكرية، ومجموعة الشاهد المكونة من 50 مريضاً لا يعاني من داء القدم السكرية. وتم اختبار عوامل الخطر المرتبطة بالأوعية الدموية، والاعتلال العصبي، والتمثيل الغذائي، والرعاية الصحية، وأسلوب الحياة باستخدام تحليل الانحدار اللوجستي المتعدد من أجل تحديد النسب الأرجحية للإصابة بداء القدم السكرية.

النتائج: أشارت نتائج الدراسة إلى الارتباط الواضح بين داء القدم السكرية وكل من: الجنس، والعمر، والمستوى التعليمي، ونوع داء السكري، وفترة الإصابة بالمرض، وسرعة ترسيب كريات الدم الحمراء، وظهور الاعتلال العصبي الطرفي، واعتلال الأوعية الدموية الطرفية، وأمراض الكلى المزمنة، واحتشاء عضلة القلب، وارتفاع ضغط الدم، والإصابة السابقة بداء القدم السكرية. وبعد تعديل المعطيات وفقاً للعمر والجنس وباستخدام تحليل الانحدار اللوجستي المتعدد وُجد أن كل من: مدة الإصابة بداء السكري، وظهور الاعتلال العصبي، وسرعة ترسيب كريات الدم الحمراء هي المؤشرات المستقلة للإصابة بداء القدم السكرية. وتم تطبيق المنحنى المجمع للعمليات المميزة لإيجاد الحد الفاصل لكل من: مدة الإصابة بداء السكري (11 عاماً)، وسرعة ترسيب كريات الدم الحمراء (54 ملم/ساعة) وذلك من أجل توقع الإصابة بداء القدم السكرية.

خاتمة: يمكن أن تساعد نتائج هذه الدراسة اختصاصيي السكري في التمييز المبكر لداء القدم السكرية والتعامل مع هذه الحالة المنتشرة، وبالتالي التقليل من خطر بتر الأطراف وما يصاحبه من تبعات.

Objectives: To identify the risk factors of diabetic foot (DF) in diabetic patients.

Methods: In a case-control study, medical records of 50 patients with DF, and 50 diabetic controls without DF were selected randomly from the patients seen at King Abdulaziz Medical City (KAMC), Riyadh, Kingdom of Saudi Arabia. Selected vascular, neuropathic, metabolic, health care, and lifestyle risk factors were investigated. Multiple logistic regression was used to relate these potential risk factors to the odds of DF.

Results: Diabetic foot was significantly associated with: gender, age, education, type of diabetes, duration of disease, level of erythrocyte sedimentation rate (ESR), presence of peripheral neuropathy, peripheral vascular disease, chronic renal diseases, ischemic heart diseases, hypertension, and previous history of diabetic foot. After adjusting for the potentially confounding effects of age and gender by using the logistic regression analysis, independent predictors of DF were: the duration of diabetes, presence of neuropathy, and ESR level. In the prediction of DF, receiver operating characteristic curves (ROC) were applied to identify the most valid cut-off points of the duration of diabetes (11 years), and ESR level (54 mm/hr).

Conclusion: These findings could help diabetologists recognize early, and manage DF, and thus reduce the risk of limb amputation, and the cost that accompanies limb loss in this prevalent condition.

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Diabetic foot (DF) is defined as a full-thickness penetration of the dermis of the foot in a person with diabetes. Studies suggest that 2.5% of diabetic patients develop DF each year, and 15% of them develop DF during their life.[1] In Saudi Arabia, DF was prevalent in 13.5% of the diabetic patients referred to the nephrology clinic,[2] and 7.7% of the patients undergoing chronic hemodialysis.[3] Diabetic foot is the most frequent cause of hospitalization for the patients with diabetes, representing up to 25% of all diabetic hospital admissions.[4] Also, it is the most common cause of non-traumatic lower limb amputation,[5] and precedes 85% of the cases.[1] The mortality rate is higher in the patients with DF, and represents approximately twice the number of diabetic patients without DF.[5] Studies have shown that people with peripheral neuropathy (PNP), and peripheral vascular diseases (PVD) are known to be at high risk of foot complications.[1] The majority of the DF patients have retinopathy, representing 90%, while 88.1% of them have coronary arterial diseases, 85% have nephropathy, and only 70% of DF patients have neuropathy.[6] The development of DF is significantly associated with the severity of neuropathy, high levels of hemoglobin A1c (HbA1c), high levels of blood sugar, and history of amputation.[7,8] On the other hand, some studies stated that there is no significant increase of new DF development for the patients with vascular diseases, renal diseases, smoking, alcohol consumption, and low socioeconomic status.[9] Targeting patients who are at high risk of developing DF may constitute a cost-effective strategy in controlling progression to end stage complications. In the West, various reports are available on the risk factors related to the complications of diabetes in order to develop strategies for avoiding the expected deterioration in the quality of life following amputation.[10-13] However, in the Arab world generally, and in Saudi Arabia particularly, limited data are available on the risk factors of amputation following DF. The aim of this study was to identify the risk factors of diabetic foot in central Saudi Arabia.

Methods. This case-controlled study was conducted at King Abdul-Aziz Medical City (KAMC) at Riyadh, Kingdom of Saudi Arabia. The medical records of 50 diabetic patients with DF, and 50 patients without DF were reviewed. Case subjects were defined as any diabetic patient diagnosed in the diabetic foot clinic of KAMC as having a DF syndrome during the period from January 2009 to July 2010. Diabetic foot syndrome refers to foot infection, ulceration, or destruction of the deep tissues associated with neurological abnormalities, or both, and various degrees of peripheral vascular insufficiency.[14] Control subjects were defined as any diabetic patient without any evidence of DF during the same period. Of a total number of 152 diabetic patients with DF who attended the DF clinic during the study period, 50 DF cases were selected using systematic random sampling, in which every third patient was selected according to the medical record numbers. Another 50 diabetic patients with no evidence of DF were selected from the diabetic patients who attended the diabetic clinic of KAMC using simple random sampling in order to form the control group. Exclusion criteria included patients with gestational diabetes mellitus, and amputation due to trauma, or conditions other than diabetes. The age, gender, nationality, marital status, level of education, Body Mass Index (calculated from the height and weight), type of diabetes, duration of diabetes, treatment of diabetes, family history of diabetes, and degree of blood glucose control were recorded, as well as the presence of diabetic complications like: PNP, PVD, chronic renal diseases, and retinopathy. History of smoking, ischemic heart diseases (IHD), stroke, and hypertension were also recorded. Baseline laboratory investigations including HbA1c, fasting blood glucose, lipid profile, and erythrocyte sedimentation rate (ESR) were also recorded.

Peripheral neuropathy was considered to be present if there was a history of numbness in the foot, absence of the pain in the foot, or altered fine touch sensation, and proprioception.[15] Peripheral vascular disease was defined as the presence of ischemic symptoms such as, or a combination of, intermittent claudication, absence of pedial pulse, arterial occlusion, or decreased blood circulation to the foot on Doplar study.[16] A history of chronic renal diseases, retinopathy, IHD, stroke, and hypertension were considered to be present according to the doctor's diagnosis. The quality of diabetic control was classified according to the average HbA1c of the last 2 readings. An average HbA1c <6.5 was considered as good control, while an average HbA1c >6.5 was considered to be poor control.[14] The identities and addresses of all the participants were unknown to the research team. The study protocol received ethical approval from the Investigation Review Board (IRB) of King Abdullah International Medical Research Center (KAIMRC), King Saud Bin-Abdulaziz University for Health Sciences, National Guard Health Affairs, Riyadh, Kingdom of Saudi Arabia.

The sample size required for the present study was estimated based on the prevalence of neuropathy as the

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most frequent risk factor of DF in previous relevant studies.[6,17] Based on a previous figure that 70% of the patients with DF had neuropathy,[6] and a 40% prevalence of no DF among diabetic patients;[17] and with the assumption of 5% type one error and 20% type 2 error, the estimated sample size was 96 patients. Thus, a total of 100 patients were allocated for the present study (50 patients with DF, and 50 patients with no DF). The Statistical Package for Social Sciences version 17 (SPSS Inc., Chicago, IL, USA) was used for the data analysis. The chi-square test was used as a test of significance to compare the categorical data. The Logistic regression analysis was performed to determine the significant risk factors of the occurrence of DF after the adjustment for age, and gender. The receiver operating characteristic curves (ROC) were constructed to determine the optimum cut-off points of the significant numerical predictors of DF. The area under the curve (AUC) was calculated with its 95% confidence interval (CI) for each of these predictors. For all the statistical analyses, a *p*-value of ≤0.05 was considered significant.

Results. **Table 1** shows that the following potential risk factors were significantly more frequent among the cases in comparison with the controls: hypertension, PNP, PVD, IHD, ESR of 60 mm/hr or more, and chronic renal disease. The other variables that were significantly more associated with DF were: male gender, age of 40 years or more, illiteracy, type 2 diabetes, and disease duration of 20 years or more. After adjustment for age and gender by applying the logistic regression analysis with the presence of DF as the dependant variable, the significant predictors of DF were: PNP, duration of diabetes, and ESR level (**Table 1**). In the prediction of DF, ROC curves were applied to identify the optimum cut-off points for: the duration of diabetes (11 years, sensitivity: 0.80, specificity: 0.72, AUC: 0.80, *p*=0.0003) and ESR level (54 mm/hr, sensitivity: 0.85, specificity: 0.70, AUC: 0.78, *p*=0.0004) (**Figure 1**).

Discussion. In the present study, the presence of DF was significantly associated with: male gender, age older than 40 years, illiteracy, type 2 diabetes, longer duration of the disease, earlier age of the onset of diabetes, higher ESR, presence of PNP, PVD, nephropathy, IHD, and hypertension. However, after the adjustment for age and gender, only the duration of diabetes, and presence of PNP, as well as higher levels of ESR were significant risk factors of DF. In a cross-sectional study in the United Arab Emirates (UAE)[4] investigating the risk factors of DF, the main risk factors for complications of DF were: male gender, poor level of education, UAE nationality, long disease duration, type 2 diabetes mellitus, presence of hypertension, and poor glycemic control. Diabetics have a high risk of atherosclerotic PVD, and in combination with PNP, and minor trauma it would be a cause of foot ulceration.[4] Of a total of 50 cases of amputations carried out in Makkah, Saudi Arabia, 86% were due to diabetes with PNP, and circulatory disorder.[18] The present study revealed that patients with DF were around 14 times more likely to have PNP, as compared with patients without DF after adjusting for age and gender, while PVD was no more associated with DF. However, PVD was not investigated using non-invasive vascular assessments such as the ankle brachial pressure index that may have permitted refining the data.[4] According to Crawford et al,[8] the length of the time that a person had diabetes was marginally predictive of DF in 2 cohort studies, although in 5 methodologically week- case-control studies, the association was not statistically significant.[8] In the present study, this association was significant, and patients with DF were more than 4 times more likely to live with diabetes for 20 years or more. Moreover, when applying the ROC curves, the duration of 11 years was the optimum cut-off point for the prediction of DF, with 80% sensitivity, and 72% specificity. It has been reported that, in DF, investigations for the presence of osteomyelitis are necessary only when the ESR, and C-reactive protein (CRP) levels are high.[19] However, studies are inadequate to support this. In the present study, raised ESR was significantly associated with DF after the adjustment for age and gender. Patients with DF were more than 5 times more likely to have an ESR of 60 mm/hr or more. Our study also showed that the value of 54 mm/hr was the optimum cut-off point for the prediction of DF, with 85% sensitivity, and 70% specificity.[20] However, in our study, neither osteomyelitis, nor infection was investigated. In a previous study,[21] all patients with an ESR >70 mm/hr had osteomyelitis, despite the lack of physical signs of inflammation. In another study,[22] ESR showed a specificity of 100%, and a sensitivity of 28% in the patients with non-inflamed DF, and the sensitivity decreased to 23% in patients with inflamed DF. However, a moderate rise in ESR may not necessarily reflect the presence of acute charcot osteoarthropathy. In the present study, male gender was a significant risk factor of DF. This was in agreement with many other studies.[4,5,8] Numerous factors may play a role in the effect of gender on lower extremity morbidity. These factors include smoking behavior, level of activity, strength of social support mechanisms, educational level, hormonal differences, degree of compliance, level of denial, as well as the prevalence, and severity of vascular disease, and neuropathy with diabetes.

Table 1 - Patient characteristics, disease characteristics, co-morbidities, and complications in patients with diabetic foot and controls.

Risk category	Patients with DF (n=50)	Patients without DF (n=50)	Chi-Square	cOR (95% CI)	aOR (95% CI)
	n (%)				
Patient characteristics:					
Gender					
Male	31 (62.0)	21 (42.0)	4.01	2.25 (1.01-5.02)	-
Female	19 (38.0)	29 (58.0)		*p*=0.045	
Age group (years)					
40 or more	48 (96.0)	22 (44.0)	32.19‡	30.55 (6.19-204.09)	-
Less than 40	2 (4.0)	28 (56.0)		*p*=0.00000001	
Level of education					
Illiterate	13 (59.0)	3 (15.0)	6.87†	8.19 (1.6-49.1)	3.18 (0.56-17.98)
Non-illiterate	9 (41.0)	17 (85.0)		*p*=0.009	*p*=0.19
Smoking					
Yes	5 (10.0)	2 (6.0)	FET	2.3 (0.4-18.5)	-
No	40 (90.0)	37 (94.0)		*p*=0.44	
Disease characteristics:					
Type of diabetes					
Type 1	3 (6.0)	26 (52.0)	25.69‡	16.97 (4.3-78.8)	0.54 (0.09-3.38)
Type 2	47 (94.0)	24 (48.0)		*p*=0.000004	*p*=0.51
Duration of diabetes (years)					
20 years or more	22 (50.0)	9 (18.0)	10.84‡	4.56 (1.64-12.95)	1.09 (1.02-1.16)
Less than 20	22 (50.0)	41 (82.0)		*p*=0.001	*p*=0.0.013
Age at onset of diabetes (years)					
40 years or more	27 (61.4)	14 (28.0)	10.59‡	4.08 (1.58-10.71)	1.07 (1.03-1.10)
Less than 40 years	17 (38.6)	36 (72.0)		*p*=0.001	*p*=0.0065
Treatment of diabetes*					
Oral hypoglycemic agent	8 (16.0)	5 (10.0)	2.77	0.44 (0.15-1.29)	-
Insulin	35 (70.0)	42 (84.0)		*p*=0.096	
OHA + Insulin	7 (14.0)	3 (6.0)			
Glucose control					
Controlled	3 (6.0)	2 (4.0)	0.23	0.64 (0.07-5.01)	-
Uncontrolled	45 (94.0)	47 (96.0)		*p*=0.63	
Comorbidities or complications:					
Peripheral neuropathy					
Present	34 (68.0)	3 (6.0)	41.23‡	33.29 (8.15-158.42)	13.86 (3.43-56.03)
Absent	16 (32.0)	47 (94.0)		*p*=0.00000001	*p*=0.0002
Peripheral vascular diseases					
Present	26 (52.0)	6 (12.0)	18.38‡	7.94 (2.63-25.19)	2.18 (0.67-7.11)
Absent	24 (48.0)	44 (88.0)		*p*=0.0000181	*p*=0.20
Chronic renal diseases					
Present	19 (38.0)	9 (18.0)	4.96†	2.79 (1.02-7.78)	1.45 (0.48-4.39)
Absent	31 (62.0)	41 (82.0)		*p*=0.026	*p*=0.51
Retinopathy					
Present	19 (38.0)	12 (24.0)	2.29	1.94 (0.75-5.05)	-
Absent	31 (62.0)	38 (76.0)		*p*=0.13	
Ischemic heart diseases					
Present	22 (44.0)	7 (14.0)	10.93‡	4.83 (1.67-14.45)	1.04 (0.31-3.45)
Absent	28 (56.0)	43 (86.0)		*p*=0.00095	*p*=0.95
Stroke					
Present	7 (14.0)	7 (14.0)	0.00	1.00 (0.28-3.53)	-
Absent	43 (86.0)	43 (86.0)		*p*=1.0	
Hypertension					
Present	41 (82.0)	19 (38.0)	20.17‡	7.43 (2.72-20.88)	1.03 (0.27-3.94)
Absent	9 (18.0)	31 (62.0)		*p*=0.0000071	*p*=0.97
Overweight/obesity					
Obese (BMI: 25 or more)	34 (69.4)	26 (57.8)	1.37	1.66 (0.65-4.23)	-
Non-obese (BMI: <25)	15 (30.6)	19 (42.2)		*p*=0.24	
Average ESR (mm/hour)					
60 or more	24 (70.6)	8 (30.8)	9.39‡	5.40 (1.56-19.42)	1.03 (1.01-1.05)
Less than 60	10 (29.4)	18 (69.2)		*p*=0.002	*p*=0.005
Previous DF or amputation					
Yes	0 (0.0)	18 (36.0)	21.95‡	28.13 (3.64-592.72)	1.0004 (0.0-1.5)
No	50 (100.0)	32 (64.0)		*p*=0.000012	*p*=0.998

*Chi-square and odds ratios were calculated based on dichotomous variables (insulin versus other treatments), cOR - crude odds ratio, aOR - adjusted odds ratio, †statistical significance at $p<0.05$, ‡statistical significance at $p<0.01$, FET - Fisher exact test,
OHA - Oral hypoglycemic agent, ESR - erythrocyte sedimentation rate, BMI - body mass index.
Given data are only for subjects whose data were available.

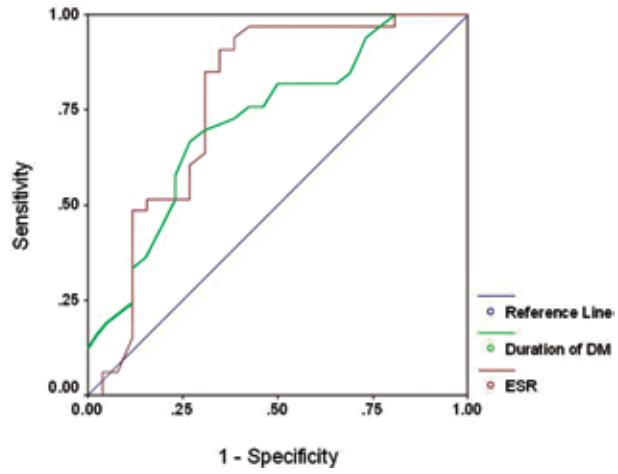

Figure 1 - Receiver operating characteristic curves of the durations of diabetes and ESR levels in relation to the presence of diabetic foot. ESR - erythrocyte sedimentation rate

This study has some limitations. It was difficult to correlate the clinical findings with the electrophysiological, and morphologic findings of the neuropathy, such as nerve conduction studies, especially that discordance between symptoms and electrophysiological testing was reported in diagnosing diabetic neuropathy among Saudi diabetics.[23] Moreover, PVD was not investigated using non-invasive vascular assessments such as the ankle brachial pressure index, may validate the data.[4] Another limitation was that the patients were selected based on attending a specialized center, where the prevalence of the risk factors such as PVD may be higher than that those among patients in the primary health care setting.[24] However, despite the limitations mentioned and the limited resources, this study was able to disclose important information on the problem of DF in Saudi Arabia.

In conclusion, this study could be considered as a preliminary study of the risk factors of DF in Saudi patients, and to be followed in the future by a large scale prospective study, including all the possible risk factors derived from the current study and other studies. It emphasizes the importance of early detection of PN among Saudi diabetic patients. The introduction of such a strategy is essential in any program aiming to reduce the burden of DF complications. Regular screening for foot complications is recommended in all patients in view of the high rates of PN reported in the population. Treating physicians should be encouraged to exert more attention and care to foot examination, especially for the patients who have lived with diabetes for more than 10 years, as well as those with a high ESR of more than 54 mm/hr.

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Related topics

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