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Association between Renal Function and Diabetic Foot Ulcer in Type 2 Diabetic Patients

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Abstract

Background

Diabetic nephropathy and diabetic foot syndrome (DFS) are two major diabetes complications . The aim of study to evaluate renal function in diabetic foot ulcers patients.

Methods

75 adulttype2 DM patients were enrolled, divided into 2 groups , group 1 ,50 patients with active diabetic foot ulcer (DFU) and group 2 , 25 patients without , excluding diabetics with ESRD or undergoing hemodialysis. The number of DFU episodes and highest stages were recorded according to internationally accepted classifications of Wagner and Armstrong. Serum creatinine, urea, HbA1C, lipid profiles, urinalysis, urinary albumin/creatinine ratio. eGFR was estimated using (MDRD).

Results

DFU patients were older, exhibited higher HbA1c, longer diabetes duration, higher mean systolic blood pressure, higher serum creatinine and lower eGFR. Patients with DFU had higher incidence of complications. There was increased prevalence of foot ulcers by increasing degree of renal impairment. There was increased prevalence of foot ulcers with increasing degree of albuminuria. In group 1, there was significant correlation between Wagner stages of DFU and eGFR and Armstrong stages of DFU and eGFR.

Conclusion

There was strong association between degree of renal impairment and DFU. CKD diabetic patients should regularly be screened for DFS.

Keywords: Diabetic foot ulcer, Diabetic foot syndrome, CKD, e GFR

Introduction

Diabetes is the most common cause of ESRD in the western world, responsible for about 20% to 45% of incident renal replacement therapy **(1).** ESRD invariably increases the risk of diabetic foot ulceration and amputation. Therefore, the progression of diabetic nephropathy to more advanced renal failure and ultimately to dialysis treatment may be associated with an ominous rise in the burden of foot ulceration, and amputation with associated morbidity and mortality **(2).** In fact, foot complications are encountered at a more than twofold frequency in diabetic patients with end-stage renal disease, and the rate of amputations is 6.5-10 times higher in comparison to the general diabetic population **(3).**There has been a renewed interest in understanding the association between diabetic foot complications and advanced renal

impairment or ESRD, as illustrated by recent studies**(4,5,6).** The majority of earlier studies have investigated only dialysis patients **(7,8,9,3)** In addition, most of these studies point to an association between CKD and peripheral arterial disease rather than with diabetic foot syndrome (DFS) **(6**). The aim of the study is to evaluate possible association between degree of renal function in form of eGFR with diabetic foot ulcers in patients with type 2 DM.

Patients and Methods

This cross sectional study included 75 adult patients aged >35 years old, with history of diabetes mellitus type 2, excluding end-stage renal disease patients or those undergoing regular hemodialysis. Patients were collected from surgical and medical units of Ain Shams University Hospitals. They were divided into 2 groups; Group 1: included 50 patients with active diabetic foot ulcer (25 male & 25 female) and Group 2: included 30 patients without active or past history of diabetic foot ulcer (12 male & 13 female).Diabetic foot diagnosis was established on the basis of clinical criteria; referring to all ulcers and limb-threatening lesions which occur on or below the malleoli **(4).** The number of episodes of foot ulceration and their highest stages were recorded according to the internationally accepted classifications of Wagner and Armstrong. The Wagner classification determines the depth of foot ulcers using stage 0 (feet at risk), stage 1 (superficial lesion) to stage 5 (total necrosis of foot),Armstrong classification is a more comprehensive scale which includes risk stratification and expresses tissue breakdown, infection and gangrene separately [stages 0–3] **(10,11).** Full history was taken with emphasis on the time since diagnosis of diabetes , it's treatment, smoking status, current foot ulcer, past history of non-traumatic lower extremity amputation and history of co-morbid conditions. Diagnosis of comorbid conditions [hypertension, ischemic heart disease and Cerebrovascular accident (CVA)] was based on meticulous histort taking. Full clinical examination with detailed lower limb examinations including: body mass index, systolic and diastolic blood pressure, lower-limb pulses, neuropathy , and evidence of peripheral arterial disease (PAD) defined as a history of peripheral artery revascularization or angiography confirming PAD, the absence of two or more foot pulses on palpation **(12)** or an ankle-brachial index (ABI) < 0.9 according to method described by **(9).**Urine examination for albuminuria and its quantification by urine albumin creatinine ratio (ACR)was done. Laboratory analysis for serum creatinine, glycated hemoglobin (HbA1c) and lipild profile was measured. Estimated glomerular filtration rate (eGFR) was calculated according to the Modification of Diet in Renal Disease equation (MDRD) equation **(13);** eGFR was used to determine the stage of CKD corresponding to the Kidney Disease Outcomes Quality Initiative staging **(14).**

Statistical Analysis

Data were analyzed using PASW (predictive analysis software) version 22 (IBM© Corp., Armonk, NY, USA). Normality of data was tested using D'Agostino-Pearson test. Numerical data were compared using unpaired t test, qualitative data were compared using chi-square t test, or Fisher exact test. Correlations among numerical variables were tested using the Pearson product-moment correlation. Multivariate logistic regression analysis was performed for predictors of development of FU. A two-sided P-value (probability of chance) <0.05 was considered statistically significant.

Results

The study involved 75 adult patients with Type 2 DM who were divided into 2 groups. Group 1 included 50 patients with active diabetic foot ulcers and group 2 included 25 patients without foot ulcers. The distribution of foot ulcers in group 1 according to Wagner classification which determines the depth of foot ulcers on 5 grades. Most of patients in group 1 were in grade 3 (21/50; 42%) followed by grade 1(13/50 patients; 26%) as shown in (Figure 1).The distribution of foot ulcers in group 1 according to Armstrong classification which refers to the presence or absence of infection and ischemia on 3 grades. Most of group 1 patients were on grade 3A (11/50 patients; 22%) as shown in (Table 1). Group 1 included 50 patients with active foot ulcers whose ages ranged between 40-70 years with mean age of 58.14±8.10 years that was significantly higher than mean age of group 2 patients (45.92±7.01years).Both groups were similar regarding gender, body mass index, smoking status, treatment with oral hypoglycemics, biguanides and glitazones with no statistically significant difference between both groups as seen in (Table 2). On the other hand, group 1 patients had significantly higher duration of diabetes since first diagnosis compared to group 2 (18.0±10.74 years vs 4.327±2.497 years (Table 2, Figure 2).

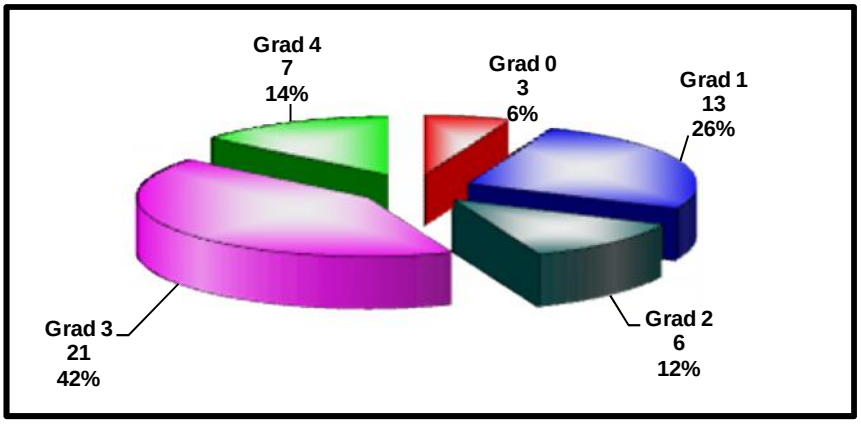

Figure 1: Grades of foot ulcers according to Wagner Grading.

Table 1: Analysis of foot ulcers in group 1 by Armstrong grading.

Armstrong grading of current ulcer		
	N	**%**
No	3	6.00
1A	7	14.00
2A	5	10.00
3A	11	22.00
1B	2	4.00
3B	5	10.00
1C	2	4.00
2C	1	2.00
3C	5	10.00
1D	2	4.00
3D	7	14.00
Total	50	100.00

Table 2: Baseline characteristics of the study population.

Variable	**Group 1 (foot ulcers)**	**Group 2 (no foot ulcers)**	***P*-value**
Number	50	25	
Males (N,%)	25(50%)	37(49.33)	0.87
Age (*years*) **Range** **Mean±SD**	 40-70 58.14±8.10	 33-56 45.92±7.01	**<0.001***
Body Mass Index	25.23±3.534	25.52±3.45	0.73
Smoking	32(64%)	17(68%)	0.73
Time since diagnosis of diabetes (years) **Range** **Mean±SD**	 3.0- 40 18.0±10.74	 0.5-10 4.327±2.497	**<0.001***
Diabetic Treatment **Oral hypoglycemic intake**	 19 (38 %)	 33(44%)	 0.139
Biguanides	29(58%)	44(58.67%)	0.868
Glitazones	4(8%)	7(9.33%)	0.581

* Statistical significant

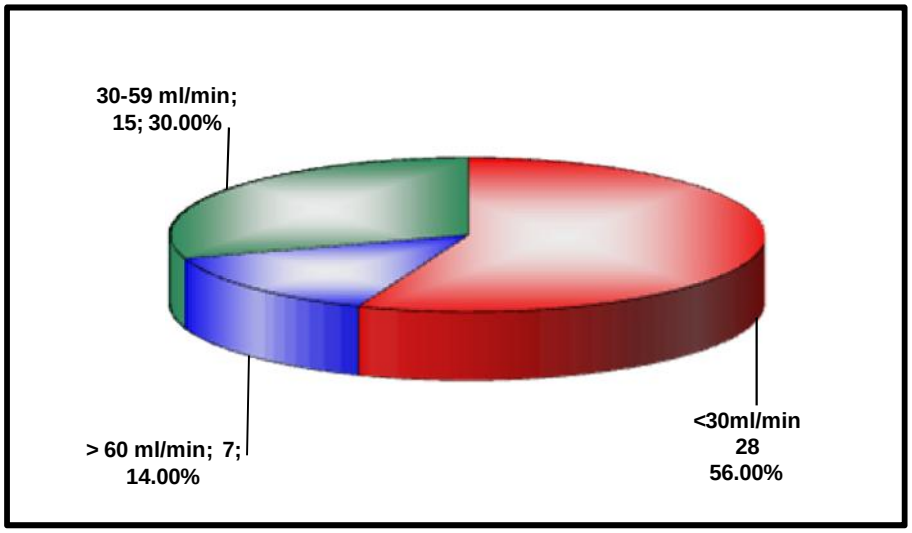

Figure 2: Prevalence of foot ulcers according to stage of CKD by eGFR.(CKD stage 2 : > 60 ml/min, CKD stage 3:30-59ml/min and CKD stage 4:< 30ml/min)

There were no statistically significant differences between both groups regarding presence of hypertension, mean diastolic blood pressure, presence of retinopathy, ,presence of ischemic heart disease, mean ankle brachial Index, presence of dorsalispedis pulsations, presence of posterior tibia pulsations, performance of revascularization, or performance of angiography as seen in (Table 3).On the other hand, patients with foot ulcers had statistically significant differences regarding mean systolic blood pressure (135.40±19.91 vs 126.00±15.81 mmgH ; P=0.043, and had higher incidence of peripheral neuropathy (62% Vs 28%; P=0.005), cerebrovascular accidents (10 % Vs 6.67 %; P=0.040) and history of lower limb amputations (24 % Vs 0.0 %; P=0.001) compared to patients with no foot ulcers .There were no statistically significant differences between both groups regarding lipid profile in form of mean levels of serum total cholesterol, mean levels of s.LDL, s. HDL,s. triglycerides . On the other hand, there were statistically significant differences between both groups regarding degree of diabetic control. Group 1 patients showed statistically significant differences regarding mean fasting blood glucose (247.28±70.75 VS 180.28±48.86; P<0.001), mean 2 hours post prandial glucose (293.94±82.25 VS 225.32±56.34; P<0.001) and mean HbA1c % (8.42±1.02 VS 7.58±0.57; P<0.001) as shown in (Table 4). As regards the comparison between both groups regarding renal functions and degree of albuminuria group 1 patients showed significantly higher mean s. creatinine (2.46±1.005 Vs 1.68±0.516; p <0.001) and significantly lower mean estimated GFR (41.196±25.542 vs 61.856±24.641; p= 0.001) in comparison to group 2, and there were no statistically significant differences between both groups regarding mean urine albumin /creatinine ratio (241.622±294.84 vs 113.57±114.08;p=0.267) as shown in (Table 5). There was graded increase in the prevalence of foot ulcers in group 1 by increasing degree of renal impairment (14% with CKD stage 2, 30% with CKD stage 3 and 56% with CKD stage 4) as clear in (Figure 2) and also increase in the prevalence of foot ulcers in group1 with increasing degree of albuminuria (12% with Normo-albuminuria,26% with microalbuminuria and 62% with Macro-albuminuria) as seen in (Figure 3). The prevalence of foot ulcers according to combined presence or absence of albuminuria and preserved or impaired eGFR is shown in (Table 6) revealing that the combined presence of albuminuria and impaired eGFR scored the highest prevalence of foot ulcers (62%) followed by impaired eGFR without albuminuria (18%) then albuminuria with preserved GFR (12%).There is a statistically significant correlation between eGFR and grades of foot ulcers whether by Wagner or Armsterong grading system as shown in (Table7). In a trial to know the best and independent predictors of foot ulcers, a multivariate binary logistic regression analysis model was done that including the significant parameters in univariate analysis. As shown in (Table 8), the most independent predictors of foot ulcers was duration of diabetes then the presence of peripheral neuropathy.

Table 3: Comparison between study groups regarding associated diabetic complications.

Variable	Group 1 (foot ulcers)	Group 2 (no foot ulcers)	*P*-value
Number	50	25	
Hypertension	27(54%)	36(48%)	0.141
Systolic blood pressure	135.40±19.91	126.00±15.81	0.043*
Diastolic blood pressure	83.40±9.39	80.00±9.57	0.146
Retinopathy	16(32%)	21(28%)	0.275
Peripheral Neuropathy	31(62%)	7(28%)	**0.005***
IHD	16(32%)	21(28%)	0.275
CVA	5(10%)	5(6.67%)	**0.040***
Ankle Brachial Index	1.024±0.239	1.084±0239	0.309
History of LL amputation	12(24%)	0.0(0%)	**0.001***
Dorsalispedis pulsation	24(48%)	13(52%)	0.744
Post. Tibial pulsation	38(76%)	21(84%)	0.425
Revascularization performance	7(14%)	1(4%)	0.154
Angiography performance	9(18%)	6(24%)	0.540

* Statistical significant

Table 4: Comparison between study groups regarding laboratory investigations.

Variable	Group 1	Group 2	*P*-value
Number	50	25	
Fasting blood glucose (mg/dl)	247.28±70.75	180.28±48.86	**<0.001***
2h PP glucose(mg/dl)	293.94±82.25	225.32±56.34	**<0.001***
HbA1c(%)	8.42±1.02	7.58±0.57	**<0.001***
S. cholesterol (mg/dl)	233.62±50.11	219.04±68.74	0.299
S.LDL(mg/dl)	156.16±29.76	141.84±31.753	0.059
S.HDL(mg/dl)	42.58±12.64	46.04±14.20	0.287
S. triglycerides(mg/dl)	218.80±53.85	200.76±64.04	0.204

* Statistical significant

Table 5: Comparison between study groups regarding renal function and urine Albumin/Creatinine ratio.

Variable	Group 1	Group 2	*P*-value
Number	50	25	
S. Creatinine (mg/dl)	2.46±1.005	1.68±0.516	**<0.001***
eGFR (ml/min/1.73 m^2)	41.196±25.542	61.856±24.641	**0.001***
Urine albumin/creat ratio	241.622±294.84	113.57±114.08	0.267

* Statistical significant

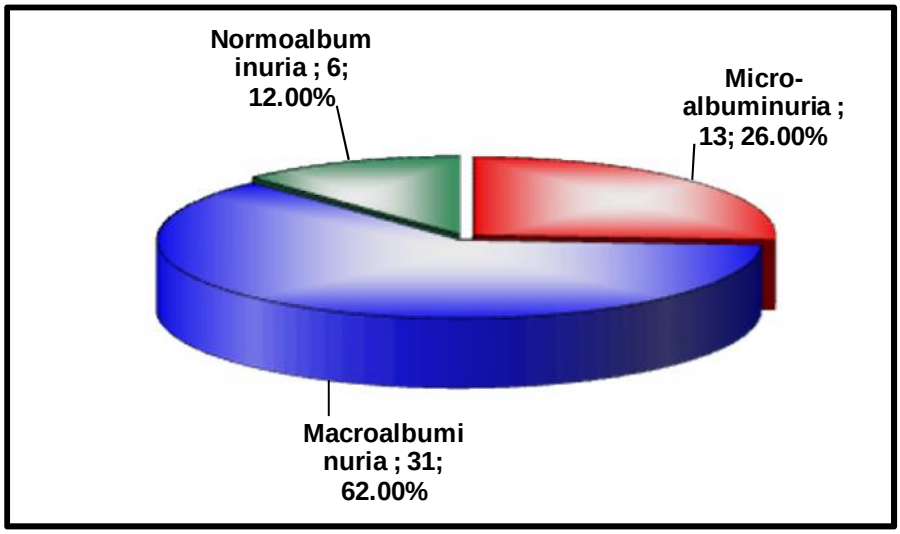

Figure 3: Prevalence of foot ulcers in group 1 according to degree of albuminuria.

Table 6: Prevalence of foot ulcers according to combined CKD stage (eGFR) and degree of albuminuria.

Variable	Patient with foot ulcers (n=50)
Normo-albuminuria &eGFR> 60	4(8%)
Albuminuria &eGFR> 60	6(12%)
Normoalbuminuria&eGFR<60	9(18%)
Albuminuria &eGFR< 60	31(62%)

Table 7: Correlation between Wagner & Armstrong grades of foot ulcers and grades of eGFR**.**

Current foot ulcer		eGFR				X^2	P-value
		<30 ml/min	30-60 ml/min	>60 ml/min	Total		
Wagner grading	**Grade 0**	**0(0%)**	**0(0%)**	**3(20%)**	**3(20%)**	57.158	**<0.001***
	Grad 1	**0(0%)**	**2(28.57%)**	**11(73%)**	**13(26%)**		
	Grad 2	**2(7.14%)**	**4(57.14%)**	**0(0%)**	**6(12%)**		
	Grad 3	**19(67.86%)**	**1(14.29%)**	**1(6.67%)**	**21(42%)**		
	Grad 4	**7(25%)**	**0(0%)**	**0(0%)**	**7(14%)**		
Armstrong grading	**No**	**0(0%)**	**0(0%)**	**3(20%)**	**3(6%)**	63.830	**<0.001***
	1A	**0(0%)**	**1(14.29%)**	**6(40%)**	**7(14%)**		
	2A	**2(7.14%)**	**3(42.86%)**	**0(0%)**	**5(10%)**		
	3A	**11(39.29%)**	**0(0%)**	**0(0%)**	**11(22%)**		
	1B	**0(0%)**	**1(14.29%)**	**1(6.67%)**	**2(4%)**		
	3B	**4(14.29%)**	**1(14.29%)**	**0(0%)**	**5(10%)**		
	1C	**0(0%)**	**0(0%)**	**2(13.33%)**	**2(4%)**		
	2C	**0(0%)**	**1(14.29%)**	**0(0%)**	**1(2%)**		
	3C	**4(14.29%)**	**0(0%)**	**1(6.67%)**	**5(10%)**		
	1D	**0(0%)**	**0(0%)**	**2(13.33%)**	**2(4%)**		
	3D	**7(25%)**	**0(0%)**	**0(0%)**	**7(14%)**		

* Statistical significant

Table 8: Multivariate logistic regression analysis of predictors of foot ulcers.

	Unstandardized Coefficients		P-value
	B	Std. Error	
Age (years)	0.017	0.012	0.184
Time since diagnosis of diabetes(years)	-0.028	0.011	**0.025***
SBP (mmHg)	-0.006	0.006	0.318
Peripheral neuropathy	-1.232	0.620	**0.047***
CV accident	-0.006	0.236	0.982
History of non traumatic lower limb amputation	-0.397	0.143	-0.309
Fasting blood glucose (mg/dl)	0.001	0.003	0.606
2h post prandial blood sugar (mg/dl)	-0.003	0.003	0.276
HbA1c(%)	-0.078	0.085	0.369
Urine albumin creat ratio	0.000	0.001	0.639
s. creatinine (mg/dl)	0.112	0.167	0.511
eGFR(ml/min)	0.003	0.006	0.640

* Statistical significant

Discussion

There are surprisingly very little data regarding the relationship between diabetic foot complications and earlier stages of CKD in patients with diabetes. The present study is a cross sectional observational study of 75 adult patients with type 2 DM who were recruited from surgical and medical units of Ain Shams University Hospitals. Our study showed that patients with foot ulcers had a highly statistically significant difference regarding history of lower limb amputations (24 % Vs 0.0 %). However, there was comparable results between both groups regarding other evidence of peripheral vascular disease in form of mean Ankle Brachial Index, absence of dorsalispedis pulsations, absence of posterior tibia pulsations, performance of revascularization or performance of angiography, as well as statistically significant differences between both groups regarding degree of diabetic control. Group 1 patients showed poor glycemic control in form of a higher HbA1c values, a higher mean fasting blood glucose and mean 2 hours post -prandial blood glucose .In agreement with our results, Margolis, and colleges reported association between DFU and hyperglycemia, PAD, peripheral neuropathy, hypertension, history of myocardial infarction, age, and previous history of (lower extremity amputation)LEA**(5).** Similarly, Wolf and colleagues reported that type 2 DM with diabetic foot syndrome (DFS) were significantly older, exhibited a higher HbA1c, had a longer duration of diabetes compared with type 2 patients without DFS**(6).**Ankle brachial pressure index (ABPI) measurement was suggested to identify subclinical PAD. However, use of ankle brachial index can be easily challenged, particularly in the ESRD population in whom vascular calcification is highly prevalent; the coexistence of ESRD and diabetes, especially in those with neuropathy, further complicates the interpretation of ABPIs as vascular calcification had been reported to occur in more than one third of these individuals. Aboyans and colleagues **(15)** also Ndip and colleagues **(16)** have recommended using a combination of criteria to identify PAD among people with diabetes, including those who are on dialysis. Such criteria should include, among others, an assessment of peripheral pulses, Doppler waveforms, ABPIs, and where possible toe blood pressures as simple noninvasive methods.

The most important finding in the present study is the significant association between renal function and diabetic foot ulcers. Patients with foot ulcers showed significantly higher s. creatinine (2.46±1.005 Vs 1.68±0.516) and significantly lower mean estimated GFR (41.196±25.542 Vs 61.856±24.641) compared to patients without ulcers. Moreover, foot ulcers showed a graded increase in the prevalence by increasing degree of renal impairment (14% with CKD stage 2, 30% with CKD stage 3 and 56% with CKD stage 4). There was also a statistically significant correlation between eGFR and grades of foot ulcers by internationally accepted classifications of Wagner and Armsterong **(10,11).** Another important finding in the current study is the increase in the prevalence of foot ulcers with increasing degree of albuminuria (12% with normoalbuminuria, 26% with microalbuminuria and 62% with macroalbuminuria). Moreover, the present study assessed the prevalence of foot ulcers according to combined presence or absence of albuminuria and preserved or impaired eGFR. The combined presence of albuminuria and low eGFR showed the highest prevalence of foot ulcers (62%) followed by impaired eGFR with normoalbuminuria (18%) then albuminuria with preserved GFR (12%).

In line with the present study, an earlier study by Lavery and colleagues **(17)** reported that diabetic foot ulcers occur significantly more often in patients with nephropathy, macroalbuminuria, end-stage renal disease, but not in those with microalbuminuria. However, no calculations of eGFR were done in this older study and no classification of DFS was performed. Game and colleagues **(4)** also demonstrated a close association of FU and amputations in diabetic patients started to undergo dialysis. In agreement with our data, recently Margolis and colleagues **(5)** retrospectively analysed data from over 900 000 individuals with diabetes who were treated by medical practitioners in the UK who participated in The Health Information Network (THIN). The findings of this large study showed a strong association between the stage of CKD (in patients who did not receive renal replacement therapy) and diabetic foot ulcers or LEA, as well as demonstrating that this relationship is also seen in those with less severe CKD stages (eGFR<60 ml/min per 1.73m2). These associations were independent of peripheral arterial disease **(5).** However, a major difference from our study, Margolis and colleagues **(5)** did not incorporate albuminuria in prevalence of foot ulcers or tested eGFR with albuminuria. Based on their finding, Margolis and colleagues **(5)** stated that it is likely that CKD and DFU or LEA among those with diabetes are associated more tightly then was recognized previously. Wolf and colleagues **(6)** reported that each 10 mL/min decrease in eGFR was associated with a 30% increased risk of DFS in type 1 diabetes patients and a 13% increased risk in type 2 diabetes patients .Although the pathophysiologic mechanisms between PAD and both albuminuria and low eGFR are not fully elucidated, it is believed that the presence of both abnormalities are markers of the generalized burden of atherosclerotic disease **(4,5,6,16).**Based on these reports, it is logical to contend that the spectrum of diabetic nephropathy from microalbuminuria through ESRD/dialysis represents a continuum of risk for diabetic foot disease, the greatest risk occurring in patients with ESRD and on dialysis **(18).**People with diabetes and those with advanced CKD or ESRD share three pivotal risk factors whose interaction undoubtedly increases their risk for developing foot ulceration and amputation: neuropathy, peripheral arterial disease (PAD), and increased susceptibility to infection with impaired wound healing. The deleterious impact on foot complications conferred by the coexistence of these three factors in people with diabetes and ESRD justifies the coinage of “trilogy of risk factors.” **(2,16).**Also, impairment of wound healing is a major feature of DFS, and advanced glycated end products(AGEs) have also been implicated in this process. The blocking of AGEs improves diabetic nephropathy as well as restoring effective wound healing in diabetic mice, indicating a common pathophysiological pathway between these two diabetic complications **(5,6).**In our study, type 2 diabetes patients with DFU exhibited higher HbA1c levels; additionally underscoring that suboptimal glycemic control may mediate CKD and DFUs in diabetes. Other factors such as PAD and polyneuropathy that clearly contribute to are also found more commonly in patients with CKD **(9).**In a trial to know the best and independent predictors of foot ulcers, a multivariate binary logistic regression analysis model was done that including the significant parameters in univariate analysis. The most independent predictors of foot ulcers were duration of diabetes then the presence of peripheral neuropathy.

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