Peripheral Vascular Disease in Patients with Diabetic Foot Ulcers - An Emerging Trend: A Prospective Study from North India

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Abstract

**Background:** Diabetic foot ulcer is one of the chronic complications of diabetes mellitus (DM) with 25% of patients with diabetes developing a foot ulcer during their lifetime leading to amputation. Diabetic foot is classified into 2 main types: neuropathic ulcers (NPU) and neuro-ischemic ulcer (NIU) where in addition to neuropathy peripheral vascular disease (PVD) is also present.

**Aims:** We aimed to a) assess the prevalence of Peripheral vascular disease (PVD) in patients of type 2 diabetes mellitus (T2DM) presenting with New Diabetic Foot ulcers (DFU). b) To compare the clinical profile and risk factors responsible for development of NPU and NIU in North Indian population.

**Settings and Design:** Cross sectional study conducted on first 100 T2DM patients presenting with new DFU in tertiary referral institute for one year period from August 2012 to July 2013.

**Methods and Material:** Detailed relevant clinical history including age, sex and duration of diabetes, history of smoking and hypertension (HTN) and prevalence of other complications like retinopathy, nephropathy, coronary artery disease (CAD) and stroke was obtained. Patients were examined for neuropathy, loss of pulsations, ankle brachial pressure index (ABI) and investigated for HbA1C, blood urea nitrogen (BUN) and serum creatinine. Statistical analysis used: t test, Fisher exact test and univariate analysis

**Results:** NIU was present in 30 and NPU in 70 out of 100 patients. NIU were commoner among males as compared to females (21/64 males vs 9/36 females). Strong association of smoking (20/30 patients), hypertension (24/30 patients) and longer duration of DM (14 vs 8 years) with NIU was found. Even other complications of DM like CAD (8/30 patients), stroke (4/30 patients), retinopathy (24/30 patients) and nephropathy (15/30 patients) were more prevalent in patients with NIU.

**Conclusions:** Prevalence of PVD is 30% in our study which is more than previous studies showing an increasing trend. NPU are two times more common than NIU. Hypertensive male patients with smoking habits and longer duration of T2DM are most prone to develop NIU. NIU share the similar risk factors with CAD and coexist with other complications of DM which should be looked for and treated.

Editorial Viewpoint

• With increasing incidence of diabetes in India more complications are also noted.
• Foot hygiene is always overlooked by diabetics.
• This study finds prevalence of PVD in 30% of diabetics predisposing to diabetic foot.

Introduction

India has become the diabetes capital of the world with over 40 million patients with diabetes.¹ Diabetic foot ulcer is one of the chronic complications of diabetes with around 25% of patients with diabetes developing a foot ulcer during their lifetime.² About 85% of diabetes-related amputations are preceded by foot ulcers, and it accounts for more than half of non-traumatic lower limb amputations.³ Diabetic foot is classified into 2

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Subjects and Methods

D Infection and ischemia were diagnosed in 30 patients and the rest 70 had NPU. Mean age of the patients in our study was 59.5 years with a M:F ratio of 1.78:1 (64 male and 36 female). NIU were more common among male patients as compared to female patients (21 out of 64 males vs 9 out of 36 females).

In our study average duration of diabetes was 9.8 years. The average duration of diabetes was found to be longer in patients with NIU, i.e. 14 years as compared to 8 years for those with NPU. Out of 100 patients, 32 had a history of smoking. 20 out of 30 patients (67%) having NIU were smokers as compared to only 12 out of 70 (17%) of those having NPU, indicating a strong association between smoking and NIU. Hypertension was found in 54 out of 100 patients. 80% (24/30) patients with NIU were hypertensive whereas only 43% (30/70) patients having NPU were found to have hypertension. The median HbA1c levels for NPU and NIU were 9.6% and 10.1% respectively. The association of smoking, hypertension and duration of diabetes with NIU was found to be highly significant (Table 2).

In 66 out of 100 patients other complications like CAD, stroke, nephropathy and retinopathy were coexistent. The prevalence of complications among patients having NIU was 86.6% (26 out of 30) whereas it was only 57% (40 out of 70) among those having NPU however the p value was insignificant (Table 2).

Discussion

Foot ulcer is a disabling complication of DM and incidence is increasing among people with
DM. Possible progression to amputation of digits and limbs makes it a serious problem. Out of 1244 T2DM patients visiting our out-patient department, 100 were found to have foot ulcers making the prevalence 8.02% in the north Indian population. In various studies conducted in different nations, the prevalence of DFU ranged between 1.0% and 4.1% in the United States, 4.6% in Kenya, 11.7% and 19.1% in Nigeria, 20% in Iran and 20.4% in Netherlands.5-9 So in our study incidence seems to be higher than population in Kenya and United states.

We found that 30% of patients with diabetes with new ulcers were having NIU whereas 70% were having NPU. NIU are on a rise as other authors in recent studies have also found NIU ranging from 23.3% to 30.5%.5,10 However Chalya et al found NIU to be only 4.4%.11 Thus NPU are more prevalent than NIU but the prevalence of NIU is continuously increasing.

Mean age of patients was 59.5 years in our study. Our findings are in agreement with studies by Chalya et al, Viswanathan V from south India, Al Mahroos from Saudi Arabia with mean ages of patients being 54.32, 60.5 and 57.3 years respectively.11-13 Morbach et al found similar mean ages in Tanzanian (51.4 years) and Indian (56.4 years) patients in one of his studies on comparison of the two populations with DFU.14 The comparable mean ages in these different populations getting different type of diabetic care can be attributed to the time dependent risk factors in the evolution of diabetic foot ulcers which are independent of geographic and environmental constraints.11 Increasing age increases the propensity of skin to damage with decreased angiogenesis and increased sepsis. Older cells do not proliferate as fast and may not have an adequate response to stress in terms of gene up regulation of stress-related proteins.15

In our study, male patients were affected more than female patients (64 vs 36) with a male to female ratio of 1.77:1 which is in agreement with studies by Chalya et al, Norazifah Haji Zaine et al and Doumi A.11,16,17 Male predominance may be attributed to their smoking habits.

In our study the mean duration of diabetes in patients with NPU and NIU was 8 and 14 years respectively. The mean duration of diabetes reported by other researcher’s ranged from 9-12 years.18,13 Thus increased duration of T2DM significantly increases the risk of neuropathy as well as NIU.

While evaluating the risk factors of foot ulcers in patients with diabetes, we found that risk factors responsible for higher prevalence of NIU were male gender, poor glycemic control (median HbA1c of 10.1%), hypertension, smoking and patients with longer duration of diabetes. Our findings are in concordance with Nyamu et al who also found similar risk factors along with other factors such as dyslipidemia, infection and poor self-care.5 AK Agarwal et al and Khurana A et al also found HbA1c >7% as significant predictors of PVD.19,20 Smoking is a contributory factor as a result of vascular wall thickening, reduction in blood circulation and ischemic changes in the affected neurons.21 The resultant effect is also loss of sensation and increased predisposition to injuries. Thus the major risk factors of NIU are similar to those of CAD. These risk factors are all modifiable to achieve prevention, delay in formation or improved healing of foot ulcers in patients with diabetes.

It was also found that the persons having NIU were having higher prevalence of other complications of Diabetes such as Retinopathy, Nephropathy and Coronary Artery Disease than the patients having NPU.

Thus our study has recorded higher prevalence of NIU in India as previous data available mainly from South India had reported a prevalence of only 5%.12 This is probably due to increasing age of the diabetic population and the consequent increase in the duration of diabetes from the time of diagnosis. Increase in incidence of smoking and prevalence of uncontrolled hypertension has also contributed the higher prevalence reported in our study.

So this calls for early detection and differentiation of diabetic foot ulcers into ischemic and non-ischemic. Aggressive treatment of NIU is required to reduce the number of amputations. We recommend that, Peripheral pulses should be palpated in all patients with DM and ABI
should be measured in addition to clinical evaluation in patients presenting with DFU. If ABI is less than 0.9, patients should be advised evaluation of leg vessels by peripheral Doppler study and/or peripheral angiography. They should be advised to stop smoking and educated about diabetic foot care.

The need to look for other complications like CAD, retinopathy and nephropathy is also required in all patients with DM especially those with evidence of PVD. Ischemic foot ulcers have a poor healing; hence a multidisciplinary approach involving a podiatrist, diabetologist, orthopaedic surgeon, general surgeon, vascular surgeon, cardiologist, rehabilitation physician and orthopaedic shoe maker should be used to treat such patients.

Conclusions

NPU are two times more common than NIU. Major risk factors for NIU are similar to those of CAD. Hypertensive male patients with smoking habits and longer duration of type 2 diabetes are most prone to develop NIU. There is a need to look for other complications of Diabetes in all the patients especially those with evidence of PVD.

This study adds to the limited data available from India on this neglected but devastating complication of diabetes. Further studies are required to assess the independent effect of the major risk factors contributing to the development of foot ulcers in patients with diabetes.

References