

# Diabetic Foot Disease—Incidence and Risk Factors: A Clinical Study

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## ABSTRACT

Diabetic foot disease is one of the most common, yet dreaded long-term complication of diabetes mellitus, especially in developing countries. It is the single-most common cause of nontraumatic lower limb amputations. Various studies worldwide have shown an incidence of diabetic foot to be 15 to 25%. Elderly males who are smokers and have habit of alcohol intake and have long duration of type 2 diabetes are at major risk for this problem. The other significant risk factors are: Poor glycemic control, neuropathy, angiopathy, nephropathy, and retinopathy. Management of diabetic foot disease involves a multidisciplinary approach. The present study was conducted with the aim to know about the prevalence of the incidence of diabetic foot disease in diabetic patients and to enumerate the different risk factors associated with it for the occurrence of diabetic foot disease in such patients at the time of presentation.

Over a period of 1 year, a prospective study involving 1,016 diabetic patients as per World Health Organization (WHO) criteria were screened for diabetic foot disease. All cases were graded as per University of Texas classification. Incidence of diabetic foot disease was calculated and the risk factors were identified through proper history taking, clinical evaluation, and specialized tests as and when required.

Some of the common risk factors identified in our study were: Elderly males from poor families having long-term type 2 diabetes and who were smokers and alcoholics. Many of these patients had other systemic complications of diabetes in the form of neuropathy, retinopathy, angiopathy, and nephropathy as well. A very important, yet easily modifiable risk factor was poor glycemic control. Our conclusion from the study is being that the diabetic foot disease is much common than anticipated in diabetes mellitus patients; it is on the rise and the resultant morbidity is very crippling to the affected individuals. Therefore it is very important to identify the risk factors and educate patients about them, especially the modifiable risk factors, so that its incidence and the morbidity can be brought down significantly.

**Keywords**: Angiopathy, Diabetes, Diabetic foot disease, Neuropathy.

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#### INTRODUCTION

Diabetes mellitus is assuming pandemic proportions worldwide and so are its associated long-term complications. In addition to the delayed complications like nephropathy, retinopathy, neuropathy, etc., diabetic foot disease is one of the most common and dreaded complication of diabetes mellitus, especially in developing countries. According to the World Health Organization (WHO) and International Working Group on the Diabetic Foot, diabetic foot is defined as the foot of diabetic patients with ulceration, infection, and/or destruction of the deep tissues, associated with neurological abnormalities and various degrees of peripheral vascular disease in the lower limb.

Diabetic foot incidence in diabetic persons increased from 0.7% in 1980 to 2.7% in 1999.<sup>1</sup> Diabetic foot is a leading cause of hospital admission among people with diabetes mellitus. It is assessed that during their life time 15% of diabetic people develop foot ulcers at the most prone site of big toe and a good number of them (14–24%) land into amputation.<sup>2</sup> Diabetic foot is the single-most common cause of nontraumatic lower limb amputation, accounting for almost 40 to 60% of nontraumatic amputations.<sup>3</sup>

Various risk factors associated with increased chances of developing diabetic foot disease are:

- Sex (more common in males)
- Older age
- Duration of diabetes for more than 10 years
- Structural foot deformities
- History of previous ulcer
- Associated systemic disorders, such as:
- Peripheral neuropathy
- Peripheral vascular disease
- Nephropathy/retinopathy
- Poor glycemic control
- Poor socioeconomic background/smoking.

Neuropathy appears to be the single-most important factor not only in developing diabetic foot but also in delaying the healing process. Patients having sensory loss appear to have seven times increased risk of developing foot ulcer. Origin of neuropathy remains unclear.<sup>4</sup> It may be due to insufficiency of intrinsic blood supply to

peripheral nerves, may be autoimmune<sup>5</sup> or microvascular ischemia caused by the accumulates of advanced glycosylated endproducts.<sup>6</sup>

Peripheral vascular disease is another important risk factor and is mainly due to widespread and often multisegmental atherosclerosis of large vessels of the leg. It is often bilateral and distal involving tibial and peroneal vessels below knee due to unknown reason.<sup>7</sup>

Though there are three main classification systems for diabetic foot, University of Texas Wound Classification<sup>8</sup> system is the most common and has been used in our study too.

Management of diabetic foot disease involves a multidisciplinary team approach involving orthopedic surgeon, diabetologist, vascular surgeon, general surgeon, pathologist, psychiatrist, occupational, and physical therapist and their approach itself can reduce the incidence of amputation by up to 85%.<sup>9</sup>

The main aim of the present study was to determine the incidence of diabetic foot disease among the diabetic patients, to find out the associated risk factors in its development, and to study the pattern of various grades of diabetic foot at the time of presentation.

### MATERIALS AND METHODS

This is a prospective study conducted at a tertiary care centre during a period of 1 year between 2011 and 2012. All 1,016 diabetic patients (WHO criteria) were included in the study after taking consent and incidence of diabetic foot was calculated as per formula.

|             | Number of new cases of specific disease |        |
|-------------|---|--------|
| Incidence = | during the given period of time         | × 1000 |
|             | Population at risk during that period   | × 1000 |

All cases of diabetic foot were graded as per University of Texas Wound Classification (Table 1).<sup>8</sup>

Once the patient was selected for study, he/she was assessed in relation to age, sex, socioeconomic status, duration and type of diabetes, history of smoking, family history of diabetic mellitus, earlier foot ulcers, and the treatment taken.

Clinical evaluation of the patient was done by general physical examination. Neurological assessment was performed, using the Semmes–Weinstein 5.07 monofilament for touch, vibration sense by tuning fork, and the motor reflexes using rubber hammer. Vascular examination was done to show the presence/absence of peripheral pulses and ophthalmological examination was done to rule out retinopathy. Assessment of glycemic control was done by measuring mean HbA1c, fasting, and mean random blood glucose. Fasting plasma glucose up to 120 mg/dL was taken as good, between 120 and 150 mg/dL

| Table 1: University of Texas Wound Classification           for diabetic foot ulcers |   |                                     |  |  |
|--|---|-------------------------------------|--|--|
| Grade 0:   | Pre- or postulcerative lesion completely epithelialized |                                     |  |  |
|  | Stage A   | Without infection or ischemia       |  |  |
|  | Stage B   | With infection                      |  |  |
|  | Stage C   | With ischemia                       |  |  |
|  | Stage D   | With infection and ischemia         |  |  |
| Grade 1:   | Superficial wound bone                                  | d not involving tendon, capsule, or |  |  |
|  | Stage A   | Without infection or ischemia       |  |  |
|  | Stage B   | With infection                      |  |  |
|  | Stage C   | With ischemia                       |  |  |
|  | Stage D   | With infection and ischemia         |  |  |
| Grade 2:   | Wound penetration                                       | ng to tendon or capsule             |  |  |
|  | Stage A   | Without infection or ischemia       |  |  |
|  | Stage B   | With infection                      |  |  |
|  | Stage C   | With ischemia                       |  |  |
|  | Stage D   | With infection and ischemia         |  |  |
| Grade 3:   | Wound penetrating to bone or joint                      |                                     |  |  |
|  | Stage A   | Without infection or ischemia       |  |  |
|  | Stage B   | With infection                      |  |  |
|  | Stage C   | With ischemia                       |  |  |
|  | Stage D   | With infection and ischemia         |  |  |

 Stage B
 With infection

 Stage C
 With ischemia

 Stage D
 With infection and ischemia

 as fair, and above 150 mg/dL as poor. Specialized investigations, such as Color Doppler, were done if it was presumed to be of importance to quantitatively assess the blood flow or to spot out the occluded area.

#### **OBSERVATIONS**

Following the observations, various risk factors for the development of diabetic foot ulcers were made among all the surveyed (1,016) diabetic patients (Table 2). Different grades of the diabetic foot ulcers were observed as per the classification used in this study (Table 3 and Figs 1A to D).

Interesting facts were revealed when we compared alcohol drinkers *vs* nondrinkers. Of the 613 nondrinkers only 80 (13.05%) had diabetic foot disease and the number increased significantly in drinkers, where of the 403 such patients, 113 (28.04%) had diabetic foot disease.

We inferred from the observations that risk factors, such as male gender, longer duration of disease, type-2 diabetes, smoking, alcohol intake, poor glycemic control, neuropathy, nephropathy, retinopathy, peripheral vascular disease, and treatment protocol with Insulin, seem to be statistically highly significant in the development of diabetic foot disease. The most important, yet modifiable risk factor being the poor glycemic control. Smoking and alcohol intake are other modifiable risk factors. Among the treatment options, Insulin was found to be highly significant in the development of foot ulcers as compared to the oral hypoglycemic agents. These observations can



|    |   | Table 2: Observations |                   |         |
|----|---|-----------------------|-------------------|---------|
|    |   | Patient scre          | eened: 1,016      |         |
|    | Parameter/Risk factor                       | DFU cases             | Non-DFU cases     | p-value |
| 1  | Incidence                                   | 193 (18.99%)          | 823               |         |
| 2  | Mean age (years)                            | 59.09±10.30           | $55.41 \pm 20.93$ | 0.018   |
| 3  | Sex:  |                       |                   |         |
|    | Male  | 139                   | 473               | < 0.001 |
|    | Female                                      | 54                    | 350               |         |
| 4  | Mean duration of diabetic mellitus in years | 13.36                 | 10.97             | < 0.001 |
| 5  | Fasting blood sugar:                        |                       |                   |         |
|    | 121–150 mg %                                | 10                    | 233               | < 0.001 |
|    | >150 mg %                                   | 183                   | 590               |         |
| 6  | Mean random blood sugar                     | 297.22                | 237.29            | < 0.001 |
| 7  | Peripheral neuropathy                       |                       |                   |         |
|    | Not present                                 | 8                     | 334               | < 0.001 |
|    | Present                                     | 185                   | 489               |         |
| 8  | Peripheral vascular disease                 |                       |                   |         |
|    | Nonpalpable peripheral pulse                | 159                   | 794               | < 0.001 |
|    | Palpable                                    | 34                    | 29                |         |
| 9  | Nephropathy                                 |                       |                   |         |
|    | Present                                     | 136                   | 703               | < 0.001 |
|    | Not present                                 | 57                    | 120               |         |
| 10 | Retinopathy                                 |                       |                   |         |
|    | Present                                     | 146                   | 468               | < 0.001 |
|    | Not present                                 | 47                    | 355               |         |
| 11 | Any h/o previous ulcer                      |                       |                   |         |
|    | Present                                     | 120                   | 117               | < 0.001 |
|    | Not present                                 | 73                    | 706               |         |
| 12 | Smoking                                     |                       |                   |         |
|    | Present                                     | 107                   | 177               | < 0.001 |
|    | Not present                                 | 86                    | 646               | 01001   |
| 13 | Socioeconomic status                        |                       |                   |         |
| 10 | Upper class                                 | 0                     | 1                 | < 0.027 |
|    | Middle class                                | 93                    | 482               | 0.021   |
|    | Lower class                                 | 100                   | 340               |         |
| 14 | Diabetic treatment undertaken               | 100                   | 0.10              |         |
|    | No drug                                     | 36                    | 71                | < 0.001 |
|    | Insulin                                     | 75                    | 273               | 0.001   |
|    | Oral hypoglycemic                           | 82                    | 479               |         |
| 15 | Type of diabetes                            | 02                    | 110               |         |
| 10 | Type 1                                      | 8                     | 14                | < 0.036 |
|    | Type 2                                      | 185                   | 809               | ~0.000  |
| 16 | Previous foot deformity                     | 100                   | 009               |         |
| 10 |   | 149                   | 240               | < 0.001 |
|    | Present                                     |                       |                   | < 0.001 |
|    | Absent                                      | 44                    | 583               |         |

Table O. Observations

Diabetic Foot Disease—Incidence and Risk Factors: A Clinical Study

| <b>Table 3:</b> Different grades of diabetic foot ulcers as per |  |
|---|--|
| University of Texas classification                              |  |

| Grade | No. of cases                | Percentage |
|-------|-----------------------------|------------|
| 0     | 41 (A-12, B-14, C-2, D-13)  | 21.24      |
| 1     | 50 (A-7, B-29, C-8, D-6)    | 25.90      |
| 2     | 45 (A-5, B-19, C-5, D-16)   | 23.32      |
| 3     | 57 (A-13, B-13, C-15, D-16) | 29.54      |

help us to educate the diabetic people to control and minimize the modifiable risk factors so as to reduce the risk of diabetic foot disease and the resultant morbidity.

#### DISCUSSION

Diabetic foot disease is one of the most feared complications of diabetes mellitus. Ultimately, as an end point, it can lead to complete loss of vascularity and dead and necrotic tissues and thus amputation, which is always a traumatic experience and associated with significant morbidity and mortality, along with immense social, psychological, and financial consequences. So herein has the importance of identifying risk factors in the development of diabetic foot so that these amputations can be minimized.



**Figs 1A to D:** Different grades of diabetic foot ulcers: (A) Grade 0, stage B: Commonest presentation among grade 0 (7.25% of total DFUs); (B) grade 1, stage B: Commonest presentation among grade 1, (15.03% of DFUs); (C) grade 2, stage B: Commonest grade 2 presentation (9.84% of DFUs); and (D) grade 3, stage D: Commonest grade 3 presentation (8.29% of DFUs)

The incidence of diabetic foot in our study is 19%, which is comparable to other literatures which show an incidence of 15 to 25%, especially in a prospective study of 248 patients from three large diabetic foot centres.<sup>10</sup>

As per the classification system, the maximum incidence of diabetic foot was grade 3 (30.05%) and as per substaging was stage B (38.86%), i.e., infection but no loss of blood supply. In a study of 193 diabetic foot patients, 46.91% patients were stage A, while 29.29% belonged to stage B of grade 3.<sup>11</sup> Probably, a large number of patients in our study were grade 3, stage B due to illiteracy, walking bare foot, religious and economic compulsion, self-treatment, and reporting late to tertiary care centre.

The mean age of diabetic foot in our study was  $55.09 \pm 10.30$  years, which correlates with a study that found mean age to be  $57.04 \pm 11.63$  years.<sup>12</sup> Males were much more commonly involved (78.64%), which have been clearly shown in various studies in the literature as well.<sup>11,13,14</sup> In Indian conditions, males being mostly the primary earners in families, their outdoor activity is higher compared to that of females, and added to that the condition of decreased sensation due to neuropathy,

they have a higher tendency to be more prone to injury, therefore making them more susceptible to diabetic foot disease.

In this study of diabetic foot patients, 61.81% were from poor strata and low-income group, which is also found to be a well-known risk factor in some other studies as well.<sup>1,15</sup> Smoking was another important risk factor (44.56%) in our study which correlates well with a study showing 41.4%.<sup>16</sup> Most of the patients in our study were type 2 diabetes mellitus as shown by various studies.<sup>11,12,14,17</sup>

Mean duration of disease in our study was  $13.36 \pm 6.93$  years, which correlates closely with a study showing mean duration of  $14.2 \pm 7.4$  years.<sup>18</sup> Thus, as the duration of disease increases, the chances of developing diabetic foot disease also increase. Poor diabetic control is a highly significant and modifiable risk factor in our study that has been authenticated in various other studies as well.<sup>19,20</sup> Poor glycemic control lead to glycosylated immune proteins which leave patients more prone to infection.<sup>21</sup> Thus glycemic control is the most effective therapy for reducing incidence of diabetic foot disease. Peripheral



neuropathy was seen in 95.85% of diabetic foot patients in our study, which was seen in many other studies in literature as well.<sup>14,22-27</sup> Autonomic neuropathy results in the loss of sweating and as such the dryness of the skin can lead to the formation of cracks in the skin and tissues. This coupled with motor neuropathy led to atrophic changes in foot musculature, leading to foot deformity and areas of increased plantar foot pressure. Decreased sense of touch makes an individual unaware of minor traumas which can lead to ulceration.<sup>28</sup>

In our study, 17.62% patients had signs of peripheral vascular disease, which is much higher than another Indian study showing 13% of such cases.<sup>14</sup> Peripheral vascular disease is probably less in Indian studies, probably due to shorter duration of diabetes, less number of smokers, and ethnicity-related reasons than in developed countries (36.42%).<sup>12</sup>

Nephropathy was seen in 29.55% of cases as seen in various studies.<sup>1,26,29,30</sup> Similarly, retinopathy was present in 75.65% cases as seen in another study.<sup>16</sup> It was unclear whether the renal and ocular conditions were simply associations or risk factors. Presence of having ulcers previously (37.82%) and foot deformity (77.20%) were found to be strong risk factors in our study as seen in most of the studies.<sup>1,28-34</sup> Foot deformity leads to formation of abnormal pressure point, mostly at 1st or 5th metatarsal head leading to skin breakdown and ulceration. If we correlate the diabetic foot disease to the treatment history for the diabetes, the dreaded problem of diabetic foot was highest in patients who have not had any treatment (33.64%), followed by insulin users (21.99%), and then followed by oral hypoglycemic agents (14.43%). Surprisingly, another study has shown insulin to be a known risk factor for diabetic foot disease.<sup>33</sup> Perhaps untreated patients were left out in this study.

## CONCLUSION

From the present study we conclude that diabetic foot is common, yet potentially disastrous complication of diabetes mellitus if not managed effectively. Diabetic foot disease is more common in patients with longstanding diabetes, retinopathy, nephropathy, low socioeconomic status, smokers, and untreated diabetic patients. Chances of getting diabetic foot increase many folds if the patients develop neuropathy, PVD, poor glycemic control, and previous history of ulcers. Management of diabetic foot, therefore, is a multidisciplinary approach that requires not only medical and surgical management but also patient's education at all levels. The only way going forward for minimizing the morbid condition of diabetic foot disease is to educate the patients regarding its modifiable risk factors and the effective prevention so as to reduce the chances of development of primary ulcers.

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