

## ORIGINAL RESEARCH

### **The associated risk factors and the prevalence of diabetic foot ulcer - A cross sectional study**

**<sup>1</sup>Dr.UroojNajami, <sup>2</sup>Dr. Faisal Mumtaz, <sup>3</sup>Dr.PrabodhBansal, <sup>4</sup>Dr Gopal**

<sup>1,2</sup>Assistant Professor, <sup>3</sup>Professor, <sup>4</sup>Associate Professor Department of General Surgery, National Capital Region Institute of Medical Sciences, Meerut, Uttar Pradesh, India

#### **Correspondence:**

Dr Gopal

Associate Professor, Department of General Surgery, National Capital Region Institute of Medical Sciences, Meerut, Uttar Pradesh, India

**Email:**[gopalsinghmtc@gmail.com](mailto:gopalsinghmtc@gmail.com)

#### **ABSTRACT**

**Background:** Diabetes Mellitus is a worldwide epidemic, affecting over 346 million people globally, with India ranking second with 65.1 million diabetic patients. Foot ulceration is the most common consequence of diabetes mellitus. It affects about 15% of diabetic individuals over the course of their lives and is quite frequent. To a considerable extent, it is preventable if the risk factors are identified early. The aim of present study is to evaluate the association of risk factors with diabetic foot ulcer and to estimate prevalence of diabetic foot ulcer (DFU).

**Material and Methods:** A systematic random sample of 500 diabetic patients was selected from patients attending the outpatient department of General Surgery, National Capital Region Institute of Medical Sciences, Meerut. A standardized form was used to record data obtained from reviewing the medical records, interviewing, and examining the patients.

**Results:** The sample had a male-to-female ratio of 48 percent. The average age of the participants was 55 years, and they had diabetes for an average of 8.9 years. The prevalence of diabetic foot ulcers was 4.8%, sensory neuropathy was 15.3%, lower limb ischemia was 8.2%, and amputation was 2%. Ulceration was linked to male gender, neuropathy, and having diabetes for a longer period of time.

**Conclusion:** Future efforts should focus on educating both healthcare professionals and patients about proper foot care. To ascertain the true prevalence of diabetic foot problems, community-based research is also required.

**Keywords:** Diabetic foot ulcer, diabetes, neuropathy.

#### **INTRODUCTION**

Diabetes Mellitus is a worldwide epidemic, with the number of diabetics increasing from 108 million in 1980 to 422 million in 2014. Its prevalence among persons over the age of 18 years has increased from 4.7 percent in 1980 to 8.5 percent in 2014.<sup>1</sup> With 65.1 million diabetes patients, India is ranked second in the world in prevalence of the disease.<sup>2</sup>

A full-thickness wound below the ankle in a diabetic patient, regardless of duration, is referred to as a Diabetic Foot Ulcer (DFU). Skin necrosis and gangrene are among the symptoms. Because of morbidity, loss of mobility, loss of employment, loss of money, and limitation of social activities, foot ulcers have a significant negative impact on one's quality of life. The global prevalence of diabetic foot ulcers ranges from 1.4 percent to 11.9

percent.<sup>3</sup> A prospective study by Jayaprakash et al found that 9 percent of participants had a foot ulcer.<sup>4</sup>

In India, the clinical profile of diabetic foot differs and is impacted by variables such as walking barefoot or in improper footwear, illiteracy, faith in alternative medicine, and lack of expertise in the treatment by primary care physicians.<sup>5</sup> Foot ulceration is preventable, and relatively simple interventions can bring down amputation rates by up to 80 percent. Though there is an obvious increase in diabetic foot care awareness, there are tremendous gaps in routine foot evaluations. To prevent the development of foot ulcer, early detection of the foot at risk should be afforded a high clinical priority.<sup>6</sup> Not many studies are done in India and due to the socio-cultural reasons risk factors are also different here. The aim of present study was to evaluate the association of risk factors with diabetic foot ulcer and to estimate prevalence of diabetic foot ulcer (DFU).

## **MATERIAL AND METHODS**

A random sample of 500 diabetic patients was selected from patients attending the outpatient department of General Surgery, National Capital Region Institute of Medical Sciences, Meerut for the first time were evaluated in a hospital-based cross sectional study. Study was carried out for a period of ten months from July 2021-February 2022.

A standardized form was used to record data obtained from reviewing the medical records, interviewing, and examining the patients. Information recorded was age, gender, weight, height, type and duration of diabetes, three recent HbA1C values, treatment modality, smoking status, and presence of hypertension in patient. Vascular, neurological, musculoskeletal, dermatological status, nail and foot wear conditions, and ulcer risk category were also assessed.

## **DEFINITIONS**

A monofilament test for neuropathy was performed on four plantar locations on the forefoot, the great toe, the base of the hallux, and the third and fifth metatarsals with a 10-g Semmes-Weinstein monofilament.<sup>7</sup> Lower extremities vascular disease was defined as the absence of a tibialis posterior pulse with or without other signs or symptoms, or the absence of a dorsalis pedis pulse with at least one lower extremity vascular sign or symptom.<sup>8</sup> Claudication, oedema, and pale, mottled skin were all signs and symptoms of vascular disease in the lower extremities. A foot ulcer was characterised as a full thickness skin break of at least Wagner's stage 1. Any of the following structural anomalies were defined as deformities: hammer toes, claw toes, hallux valgus, prominent metatarsal heads, status after neuroosteoarthropathy, amputations, or other foot operations. Stiffness or restricted range of motion of a joint in one or both feet were classified as limited joint mobility.

The range of motion was assessed by moving the ankle, subtalar joint, metatarsal joints, and phalangeal joints through their usual ranges of motion and assessing whether there was any pain, restriction, or crepitus.<sup>9</sup>

Skin was assessed by evaluating for quality (normal, dry, thin, shiny, and atrophy of the plantar fat pad), color (normal, red, pale and mottled, or blue and cyanotic), and temperature (normal, cold, warm, and hot). Other skin abnormalities that were recorded were blisters, cellulitis, dilated veins, fissures, swelling, calluses, corns, dermatopathy, macerations, oedema, verruca, and tinea pedis.

Ill-fitting foot wear was defined as the presence of one or more of the following: too tight, or too wide, high heel, poor quality or hard leather, or soft insole for patients with neuropathy.

Risk categories were defined as: grade 0= No neuropathy present; grade 1= Neuropathy without deformity or history of ulceration; grade 2= Neuropathy with deformity or peripheral vascular disease; and grade 3= History of ulcer or amputation.<sup>10</sup>

Wagner ulcer classification system was defined as: grade 0= No ulcer, but high-risk feet (bony prominences, callus, claw toes, etc.); grade 1= Superficial full-thickness ulcer; grade 2= Deep ulcer, may involve tendons but no bone involvement; grade 3= Deep ulcer with bone involvement, osteomyelitis; grade 4= Localized gangrene; grade 5= Gangrene of whole foot.<sup>11</sup>

### STATISTICAL ANALYSIS

Data were entered and analysed using the Statistical Package for Social Sciences software (SPSS), version 24. Data was described using means and standard deviation for continuous variables and frequencies and percentages for categorical variables. Percentages were compared using a chi-square test. Multivariate analysis was conducted using binary logistic regression analysis to determine the factors associated with diabetic foot ulcers. A p-value of less than 0.05 was considered statistically significant.

### RESULTS

**Table 1: Demographic and clinical characteristics of the study population**

Characteristic	No. patients ( N=500)	Percent (%)
Male -no. (%)	240	48%
Female - no. (%)	260	52%
Age -yr(Mean $\pm$ SD)	55 $\pm$ 15	
Weight - Kg (Mean $\pm$ SD)	79.8 $\pm$ 17.5	
Height - cm (Mean $\pm$ SD)	162 $\pm$ 11.1	
BMI- kg/m2(Mean $\pm$ SD)	35.8 $\pm$ 7.8	
Duration of diabetes-yr(Mean $\pm$ SD)	8.9 $\pm$ 6.5	
DM Type 1 - no. (%)	55	11%
DM Type 2 - no. (%)	445	89%
Mean Range HbA1C-%(Mean $\pm$ SD)	7.9 $\pm$ 2.1	
Treatment - no. (%)		
Diet alone	12	2.4%
Oral agents	230	46%
Insulin alone	112	22.4%
Oral agent + Insulin	146	29.2%
Hypertension - no. (%)	278	55.6%
Smoking -no. (%)		
Non-smoker	309	61.8%
Current smoker	102	20.4%
Ex-smoker	89	17.8%

The study included a total of 500 diabetic patients (240 males and 260 females). Diabetes type 1 and type 2 were present in 11% and 89% of patients, respectively. The mean of the patients' ages was 55 years (SD  $\pm$  15). The mean duration of diabetes was 8.9 years (SD  $\pm$  6.5). The mean body mass index was 35.8 kg/m<sup>2</sup> (SD $\pm$ 7.8), and the mean HBA1C level was 7.9% (SD $\pm$  2.1). Table 1 represent the demographic and clinical characteristics of the study population.

**Table 2: Distribution of risk factors among the study population and in patients with ulcers**

Risk factor	No. of patients	Ulcers n (% of ulcers among
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		patients in the specific group)
Age		
≤40	31	0
41-50	66	4 (6.06)
51-60	269	19 (7.06)
61-70	89	5 (5.6)
>70	45	2 (4.4)
p value		0.57
Gender		
Male	240	16(6.66)
Female	260	7(2.69)
p value		<b>0.038</b>
Type of DM		
Type 1	55	1(1.81)
Type 2	445	28(6.29)
p value		<b>0.024</b>
Duration of DM		
<5	167	1 (0.59)
5-10	152	1 (0.65)
>10	181	28 (15.46)
p value		<b>0.019</b>
Mean of the most recent three HbA1C values		
HbA1C<7	165	2 (1.21)
HbA1C>7	335	21 (6.26)
p value		<b>0.026</b>
Treatment		
Diet	12	0
Oral agent	230	4 (1.73)
Insulin	112	6 (5.35)
Insulin + oral agent	146	15 (10.27)
p value		0.09
Total	500	24
Prevalence %		4.8%

Table 2 represents the distribution of risk factors for diabetic foot ulcers among the study participants and in patients with foot ulcers. Of those examined, 4.8% had foot ulcers. Table 3 shows the prevalence of local foot complications. Two percent had amputations with 30% of the amputations were either above or below the knee. Of the ulcers, 33.33% were advanced and belonged either to Wagner grade 2 (16.66%) or grade 3 (16.66%). Poor foot wear condition was present in 77.6%, calluses in 44.6%, fissures in 25%, tinea pedis in 25.6% and 8.2% subjects had lower limb ischemia. Incidence of peripheral sensory neuropathy was 15.3% in study patients while 70% in patients with foot ulcers. In the multivariate analysis, factors that were associated with a foot ulcer were gender, duration of diabetes, and sensory neuropathy. Males were almost twice more likely to have a foot ulcer compared to women (OR=2.24). An increased duration of diabetes was significantly associated with the increased odds of having a foot ulcer. Peripheral sensory neuropathy to 10 gm monofilament was significantly associated with increased odds of having a foot ulcer (OR=10.56).

**Table 3: Prevalence of local foot complications, amputation, risk category, and Wagner classification among the study population**

Local foot complications	N	Percent (%)
Fissures	125	25
Deformity	160	32
Limited joint mobility	60	12
Calluses	223	44.6
Cellulitis	12	2.4
Tineapedis	128	25.6
Blisters	6	1.2
Ingrown toe nails	15	3
Poor foot wear condition	388	77.6
Amputation		
Toes	5	1
Foot	2	0.4
Belowknee	1	0.2
Above knee	2	0.4
Oedema	10	2
Risk category		
Low	290	58
Moderate	127	25.4
High	45	9
Previous ulcer	29	5.8
Wagner classification		
Grade 0	37	7.4
Grade 1	16	3.2
Grade 2	4	0.8
Grade 3	4	0.8

## DISCUSSION

The prevalence of diabetic foot ulcers was found to be 4.8 percent in this cross-sectional, hospital-based investigation. Although precise comparisons are difficult to make because populations and definitions of foot diseases differ among research. This finding is consistent with other studies from Canada, Greece, and Iran.<sup>12</sup> It also resembles a research conducted in Jordan in 2001.<sup>13</sup> The previous study, in contrast to this one, did not delve at the risk factors for diabetic foot ulcers. In this study ulcers were found to be associated with male gender, duration of diabetes, and presence of sensory neuropathy. These findings are consistent with previous research.<sup>14</sup>

Lower limb ischemia was found in a low rate of 8.2%; this low rate could be due to the use of a sensitivity-deficient criteria. Because many patients can be asymptomatic, current diabetes guidelines propose using the ankle brachial index to screen for peripheral PVD.<sup>15,16</sup> Nevertheless, developing countries have similar low rates of PVD; a study of diabetic patients with foot lesions in Germany, India, and Tanzania found that while 80 percent of patients in each centre had peripheral neuropathy, only 12 percent and 13 percent of patients in Tanzania and India, respectively, had PVD, compared to 48 percent in Germany.<sup>17,18</sup>

Peripheral sensory neuropathy, as measured by the 10-g Semmes-Weinstein monofilament, was seen in 15.3% of study participants and 70% of those with foot ulcers. This is similar to previous research, which found prevalence rates of 70-100 percent among ulcer patients.<sup>14</sup> Nevertheless, the prevalence of peripheral neuropathy would have been overestimated, as

despite its widespread usage, the 10-g monofilament may not be the most sensitive test for detecting diabetic neuropathy.<sup>19,20</sup>

We also discovered a significant prevalence of avoidable local foot issues, such as ill-fitting shoes (77.6%), calluses (44.6%), tinea pedis (25.6%), and fissures (25%). These numbers point to the need to improve our patients' local foot care. Our patients had poor glycemic control, with roughly 67 percent of them having a mean HBA1C of more than 7% in the last three months. In 11% of the individuals, type 1 diabetes was observed. These traits point to a group with a high risk of underlying issues, which could lead to an overestimation of a foot complication.

Despite the fact that this was a significant study, it had two major flaws. First and foremost, this was a single-centre study. As a result, the prevalence of ulcers and risk factors may have been overstated, and the findings cannot be generalised. Second, because of the limited sensitivity of the definition used, lower limb ischemia may have been underestimated.

## CONCLUSION

Diabetic foot ulcers were found in 4.8 % of patients in the study. Ulceration was linked to the male gender, neuropathy, and having diabetes for a longer period of time. Future efforts should focus on educating both healthcare professionals and patients about proper foot care. To ascertain the true prevalence of diabetic foot problems, community-based research is also required.

## REFERENCES

1. World Health Organization website: Facts and figures about Diabetes. Available at :<http://www.who.int/mediacentre/factsheets/>(last accessed November10,2015).
2. Abraham S, Jyothylekshmy V, Menon A. Epidemiology of diabetic foot complications in a podiatry clinic of a tertiary hospital in South India. *Indian Journal of Health Sciences*,2015; 8(1), p.48.
3. Boulton, AJ. The diabetic foot: a global view. *Diabetes/Metabolism Research and Reviews*,2000; 16 Suppl 1, pp.S2–5.
4. Jayaprakash, P. Magnitude of foot problems in diabetes in the developing world: a study of 1044 patients. *Diabetic Medicine: A Journal of the British Diabetic Association*,2009; 26(9), pp.939–942.
5. Pendsey, S. Clinical profile of diabetic foot in India. *The International Journal of Lower Extremity Wounds*, 2010;9(4), pp.180–184.
6. Shankhdhar K, Shankhdhar U & Shankhdhar S. Diabetic foot problems in India. An overview and potential simple approaches in a developing country. *Current Diabetes Reports*2008;8: 452-457.
7. Smieja M. Clinical examination for the detection of protective sensation in the feet of diabetic patients. *International Cooperative Group for Clinical Examination Research. Journal of General Internal Medicine*. 1999, 14: 418-424.
8. Ndip EA, Tchakonte B, Mbanya JC. A study of the prevalence and risk factors of foot problems in a population of diabetic patients in Cameroon. *The International Journal of Lower Extremity Wounds*. 2006, 5: 83-88.
9. Frykberg RG. Diabetic foot disorders. A clinical practice guideline (2006 revision). *Journal of Foot and Ankle Surgery*. 2006, 45: S1-S66.
10. Peters EJ, Lavery LA. Effectiveness of the diabetic foot risk classification system of the International Working Group on the Diabetic Foot. *Diabetes Care*. 2001, 24: 1442-1447.
11. Wagner FW. The dysvascular foot: a system for diagnosis and treatment. *Foot and Ankle*. 1981, 2: 64-122.
12. Boulton AJ. The global burden of diabetic footdisease. *Lancet*. 2005, 366: 1719-1724

13. Jbour AS. Prevalence and predictors of diabetic foot syndrome in type 2 diabetes mellitus in Jordan. *Saudi Medical Journal*. 2003, 24: 761-764.
14. Singh N, Armstrong DG, Lipsky BA. Preventing foot ulcers in patients with diabetes. *JAMA*. 2005, 293: 217-228.
15. American Diabetes Association. Standards of medical care in diabetes ± 2009. *Diabetes Care*. 2009, 32 (Suppl 1): S13-S61.
16. Marso SP, Hiatt WR. Peripheral arterial disease in patients with diabetes. *Journal of American College of Cardiology*. 2006, 47: 921-929.
17. Morbach S. Regional differences in risk factors and clinical presentation of diabetic foot lesions. *Diabetes Medicine*. 2004, 21: 91-95.
18. Unwin N. The diabetic foot in the developing world. *Diabetes/Metabolism Research and Reviews*. 2008, 24 (Suppl 1): S31-S33.
19. Kamei N. Effectiveness of Semmes-Weinstein monofilament examination for diabetic peripheral neuropathy screening. *Journal of Diabetes and its Complications*. 2005, 19: 47-53.
20. Miranda-Palma B. A comparison of the monofilament with other testing modalities for foot ulcer susceptibility. *Diabetes Research and Clinical Practice*. 2005, 70: 8-12.