

**A Retrospective Study of Risk Factors for Diabetic Foot Ulcers****Milind Gautam<sup>1</sup>, Varun Kulshreshtha<sup>2</sup>**<sup>1,2</sup>Assistant Professor, Department of General Surgery, Saraswathi Institute of Medical Sciences Hapur UP, India

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Conflict of interest: Nil

**Abstract:****Background and Objectives:** Foot ulcers are one of the main complications in diabetes mellitus, with a 15% lifetime risk in all diabetic patients. The rate of lower extremity amputation among diabetic patients is 20–40 times higher than in non-diabetics. This study aimed to link the Diabetic foot ulcer with different risk factors.**Methods:** This descriptive cross-sectional retrospective study was conducted in institute. Data of all patients presenting between Sept 2023 to August 2024 were analyzed for risk factors. Analysis was done on SPSS version 25.**Results:** Total of 1000 patient were seen during this period, out of which 620 patient data was picked up as it was complete in respect to the information needed. Middle age, Male gender, Type 2 diabetes, and Hypertension, were insignificantly co-related. High waist circumference, Comorbidity like Neuropathy, Dyslipidemia, Greater body mass index, Poor compliance with Medication and type of medication used (combination of oral and injectable) were found statistically significant predictor for DFU. However retinopathy was not found to be a risk factor of DFU. This result was statistically significant.**Conclusion:** Factors like obesity, waist circumference, combination of oral along with injectable therapies, neuropathy, dyslipidemia, retinopathy and poor compliance with medication were statistically significant and can be strongly linked with diabetic foot ulcer. Middle age, Male gender, Type 2 diabetes, and Hypertension were insignificantly co-related. However, Awareness of physicians about foot problems in diabetic patients, clinical examination and preclinical assessment, regular foot examination, patient education, simple hygienic practices and provision of appropriate footwear combined with prompt treatment of minor injuries can decrease ulcer occurrence by 50%.**Keywords:** Diabetic Foot Ulceration, Link, Neuropathy, Retinopathy, Medication.This is an Open Access article that uses a funding model which does not charge readers or their institutions for access and distributed under the terms of the Creative Commons Attribution License (<http://creativecommons.org/licenses/by/4.0>) and the Budapest Open Access Initiative (<http://www.budapestopenaccessinitiative.org/read>), which permit unrestricted use, distribution, and reproduction in any medium, provided original work is properly credited.**Introduction**

The increasing incidence of foot ulcer in patient with diabetes mellitus has placed a huge burden on health care system. [1] In 1985, diabetic patients numbered 30 million, which increased to 285 million in 2010, and the latest global estimate from the International Diabetes Federation in 2020 reports 489 million people with diabetes mellitus and that, in 2045, the patients will be 700 million. [2,3] Diabetes is the leading cause of end-stage renal disease, adult-onset blindness and non-traumatic lower extremity amputations. [4] Diabetic complications can be disabling or even life-threatening. [5] Patients with DM are exposed to developing multiple complications, among which diabetic foot ulcers (DFUs) are very common among the diabetic population. [6] According to the International Working Group on the Diabetic Foot (IWGDF), a diabetic foot ulcer is a full-thickness wound penetrating through the dermis (the deep vascular and collagenous inner layer of the skin) located below the ankle in a

diabetic patient. [7] The prevalence of DFU in hospitalized patients ranges from 4 to 10% and the risk of patients with diabetes developing a foot ulcer in their lifetime could be as high as 25%. [8] A systematic review study reports that the prevalence of DFU is 6%. [9] DFU occurs because of a lack of Hb1AC control, foot traumas, mechanical pressures, obesity and overweight, tobacco, increased diabetes duration and age. [10-12] Also, diabetic neuropathy, vasculopathy, ischemia and neuropathy are known as causative factors. [13,14] We know the factors that affect the incidence of diabetic foot ulcer, but it is more important to know the factors that influence the severity of foot ulcers. Diabetic foot ulcer is a marker for increased mortality rate in diabetes patients. [15] Every year, 5% of patients with diabetes develop foot ulcers, and 1% require amputation. [16] Hence, they contributed to societal cost of diabetes as foot problems in diabetic patients were the commonest cause of

admission to hospital with risk of amputation estimated to increase 15–20 times. In fact, some 50% of all lower limb amputations were done in diabetic patients. [14] In addition to increased cost of treating foot ulcer patient especially those requiring inpatient care, limb amputation was a major impact on the individual. It not only distorted body image, but also caused increased dependency and loss of productivity with patients reporting stigma, social isolation, loss of social role, and unemployment. [15] In order to prevent this morbidity, many studies were conducted globally by investigators to find out the risk factors contributing to occurrence and recurrence of foot ulcers in diabetic patients. [16] However, there was lack of sufficient research data available which could specifically highlight the incidence of diabetic foot ulcers in relation to different risk factors, including medication being used by the patient. It was part of a study done in Iraq which showed that patients using a combination of insulin and oral antidiabetic agents were more prone to develop diabetic foot ulcer. [16] The same finding was observed in an Pakistan study which showed that usage of a combination of insulin plus oral hypoglycemic agents to be the most important risk factor. [17] It was observed that combination therapy was commonly given to diabetic patients probably because it was a progressive disease that became less responsive to treatment with time. [18] Moreover, use of many medications decreased patient compliance to therapy, [19] which further meant loss of glycemic control [14] and increasing DFU risk to the patient. [16]

This study aimed to link diabetic foot ulcer with different risk factors in our population. In addition to this we also saw the effect of these factors contributing in DFU formation. In this way we hoped to contribute in prevention of disastrous consequence of diabetic foot ulcer.

## Methods

The present cross-sectional study was carried out in an outpatient setting of institute. It included all diabetes mellitus patients who attended the clinic between Sept 2023 to August 2024. The study was approved by the Ethical Review Committee of institute.

The study included patients of either sex diagnosed with diabetes mellitus of any duration, established as per American Diabetes Association (ADA) guidelines (random blood sugar >200 mg/dL or fasting blood sugar >126 mg/dL).

They were further classified into diabetes mellitus type 1 (previous history of diabetic ketoacidosis) and type 2 (those with no history of ketoacidosis). Information was collected by participant regarding demographics (age, sex), lifestyle characteristics (diet, exercise, smoking, alcohol consumption).

Documentation from latest laboratory investigation reports documented in clinical records was used to derive biochemical parameters. At the time of recruitment anthropometric measurements including weight, height, body mass index (BMI; kg/m<sup>2</sup>) and waist circumference were carried out. Blood pressure of the participants was measured in the sitting position in the right arm to the nearest 2 mmHg with a mercury sphygmomanometer.

The patients were categorized into three age groups (<45years, 45-65years and >65years). The patients were either on oral medications, on insulin or on both. Compliance of the patients was assessed using blood sugar level in fasting or random and HbA1c according to American Diabetic Association criteria, and patient self-description regarding his diet, lifestyle and adherence to prescribed medication dose. On the basis of BMI, the patients were either under-weight (<18.5kg/m<sup>2</sup>), normal (18.5-24.9kg/m<sup>2</sup>), over-weight (25-30kg/m<sup>2</sup>) or obese (>30kg/m<sup>2</sup>).

The patients were assessed for the presence or absence of any other comorbid condition like neuropathy, nephropathy, retinopathy and dyslipidemia. Neuropathy was assessed using pinprick sensations, ankle reflexes and vibration perception threshold using Neurothesiometer. Inability to perceive the sensation at any one site was considered abnormal. In addition, ankle reflexes were also assessed with a percussion hammer. The diagnosis of diabetic retinopathy was made by an ophthalmologic examination that included funduscopy or retinal photography and measurement of visual acuity. The diagnosis of nephropathy was confirmed from laboratory parameters including micro-albuminuria from clinical records.

Statistical software (SPSS v. 25) was used for data input and analysis. Cross tables were made between presence and absence of foot ulcer and compared with the involvement of a particular risk factor in it. Chi-square test for independence was used to test the significance of association between discrete variables. The dependent variable includes the presence or absence of diabetic foot ulcer. Findings with a P value less than 0.05 were considered significant.

## Results

Demographics of the patients are shown in Table-I. Out of 620 patients, 280 were male and 340 were females. Total 88 were above 45 years of age. There were 136 patients with diabetic foot ulcer. Patients with normal blood pressure were 95 in number while 279 were hypertensive. Another 159 patients were overweight and 23 were in obese category. Patients having poor compliance with the medications, diet and lifestyle modifications were 469 in number. Total 1996 patients were with co-

morbid conditions, 535 patients developed dyslipidemia. neuropathy, 20 nephropathies, and 457 had

**Table 1: Comparison of Demographics of study population.**

Parameters		Patients with DFU (n=136)	Patients without DFU (n=484)	Total (n=620)	P value
Gender	Male	56(41.3%)	188(38.9%)	244(39.3%)	0.219
	Female	80(58.7%)	296(61.1%)	376(60.7%)	
Age	<45	48(35.2%)	190(39.3%)	238(38.3%)	0.598
	45 – 65	79(58%)	256(52.8%)	335(54.0%)	
	>65	9(6.6%)	38(7.8%)	47(7.5%)	
Medication	Oral	40(29.4%)	317(65.4%)	357(57.5%)	0.002
	Insulin	2(1.4%)	8(1.6%)	10(1.6%)	
	Combination	96(70.5%)	159(32.8%)	255(41.2%)	
Type of Diabetes Mellitus	DM1	43(31.6%)	170(35.1%)	213(34.3%)	0.209
	DM2	93(68.3%)	314(64.8%)	407(65.6%)	
Compliance	Good	42(30.8%)	109(22.5%)	151(24.3%)	0.032
	Poor	94(69.1%)	375(77.4%)	469(75.6%)	
Waist	>80 for Females & >90 for Males	104(76.4%)	92(19%)	196 (31.6%)	0.000
	<80 for Females & <90 for Males	32(23.5%)	392(80.9%)	424(68.3%)	
BMI	Underweight	1(0.7%)	7(1.4%)	8(1.29%)	0.004
	Normal	87(63.9%)	343(70.8%)	430(69.3%)	
	Overweight	38(27.9%)	121 (25%)	159(25.6%)	
	Obese	10(7.3%)	13(2.6%)	23(3.7%)	
Blood Pressure	Low	2(0.6%)	1(0.06%)	3(0.1%)	0.118
	Normal	18(13.2%)	77(15.9%)	95(15.3%)	
	Pre-Hypertension	53(39%)	198(39.8%)	251(40.4%)	
	Hypertension	65(47.7%)	214(44.2%)	279(45%)	
Comorbidity	Yes	132(97%)	463(95.6%)	595(95.9%)	0.001
	No	4(2.9%)	21(7.6%)	25(4.0%)	
Neuropathy	Yes	129(94.8%)	406(83.8%)	535(86.2%)	0.000
	No	7(5.1%)	78(16.1%)	85(13.7%)	
Nephropathy	Yes	6(4.4%)	14(2.8%)	20(3.2%)	0.001
	No	130(95.6%)	470(97.1%)	600(96.7%)	
Dyslipidemia	Yes	85(62.5%)	372(76.8%)	457(73.7%)	0.001
	No	51(37.5%)	112(23.1%)	163(26.2%)	

The correlation of diabetic foot ulcer with different conditions are shown in Table 1. Development of diabetic foot ulcer was significantly associated with use of combination therapy, poor compliance, higher waist, obesity and co-morbid conditions like, neuropathy and dyslipidemia.<sup>0</sup>

### Discussion

In literature, the risk factors of foot ulceration varied in studies, and some of them were similar. We found that patients taking a combination of insulin and oral medication were more likely to develop foot ulcer than were patients whose diabetes was managed with either oral glycemic agent or insulin alone.

This result was statistically significant (p value 0.00). Reason may be because of the fact that with time, diabetes progressed and became less responsive to treatment.<sup>8</sup> Moreover, use of many

medications may decrease patient compliance to therapy, [9] which led to loss of glycemic control and resultant increase in DFU risk. [15,16] An additional explanation could be that when patients started insulin, they may already had diabetes for a longer duration, with greater associated complications already present. It could also be because insulin had played the role of confounder. The reasons might be the unequal number of patients in the two groups. This finding was compatible with other studies like Yazdanpanah et al. [17] A prospective cohort study done in Iran and Mohammed et al. [10] a cross sectional study done in Iraqi patients. Sample size was low in both these studies as compared to our study. In a systematic review, seven studies out of 16 reported an association between DFU and insulin treatment. [13] Further studies should be carried out to find the association between DFU and their risk factors.

Another well-known risk factor identified was distal neuropathy (94.8% people with DFU had peripheral neuropathy). This was congruous with many studies including Yazdanpanah L et al. [16] and Says et al. [18] It was indeed worrying as patients with distal neuropathy could endure minor trauma without being aware of the injury until it worsens. It had been suggested that this condition can be prevented with an improved health education program offering advice on protection in the home and at work, good hygiene and physical examination.

Comorbidities results in increased number of medication which can cause poor compliance. It resulted in poor glycemic control and hence increased risk of DFU. On the other hand, Mohammed et al. [16] contradicted with this findings. He emphasized that an increase in demand for glycemic control, increased patient's compliance with medical advice. [14] This improved glycemic control and fewer complications from hyperglycemic attacks. [16,17]

Greater BMI and increased waist circumference were a risk factor for DFU. [20] Both these results were found statistically significant. In literature, the results were statistically insignificant, which was contradicting. The possible reason could be due to the presence of higher foot pressure in those with higher body mass index (BMI) might decrease intensively the normal blood circulation pattern at the lower extremities leading to DFU.

Poor compliance and dyslipidemia were found statistically significant risk factors for DFU. However, some studies did not found them associated with diabetic foot ulcer. [16] Another finding of this study was predominance of male patients developing DFU. However, from p value this difference was insignificant. Moreover, this result was in accordance with Yazdanpanah L et al. [14] which reported similar finding probably because of more foot exposure to risk factors due to outdoor activity and plantar pressure in males. But again, their finding was significant in univariate analysis and not in multivariate analysis.

A statistically insignificant finding of the present study pointed out that nephropathy was not an independent risk factor for DFU. This is inconsistent with Says et al [17] and American Diabetes Association consensus group. It was not possible to explain this variation and may be a feature only present in our patients. More work may be required with higher number of patients to confirm our findings.

In our study females were more commonly presenting with foot ulcer but there is no significant correlation found. Yazdanpanah L et al in their study having association with neuropathy, peripheral arterial disease, female sex, increasing age,

duration of diabetes and high HbA1c had some similarities and some dissimilarities with our study. Khan A et al. [19] also documented similar findings in the local population, with female dominance. The occurrence of DFUs mostly in middle aged subjects had been reported by several researchers. In the present study, we found that people with age between 45 and 65 years had highest percentage of DFUs and thus support the findings of previous workers like Mohamed et al. [16] and Says et al. [17] and other studies. [20] However, the result was not found statistically significant.

Hypertension and type 2 DM [20,21] were also independent risk factors for development of diabetic foot ulcer, but results were statistically insignificant. Hypertension was usually associated with type 2 diabetes, which resulted in higher risk of cardiovascular diseases and mortality. Such association leads to the development of nephropathy, retinopathy, and diabetic cardiomyopathy. Since systemic arterial hypertension increased the risk of micro and macro-vascular injuries, the risk of Peripheral Arterial Disease also increased. [25] Type 2 DM had associated complications for foot ulcer. It included mechanical changes in the conformation of the bony architecture of the foot, peripheral neuropathy, and atherosclerotic peripheral arterial disease. As a result, the patient may have less tissue epithelization, consumption of oxygen, nutrient transportation, and cell detoxification resulting in ulceration in the extremities.

## Conclusion

Factors like combination of oral and injectable medication in management, higher waist circumference, greater BMI, neuropathy, dyslipidemia, and poor compliance were strongly linked. However, middle age, male gender, Type 2 diabetes and Hypertension were insignificantly correlated. These finding provided support for a multifactorial etiology of DFU. We need further studies in larger population to support these findings. Many of these factors related to lifestyle and self-care, so health care programmes may be effective in preventing severe foot ulcer.

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