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Original Article

Surgery Section

# Clinical Grading of Diabetic Foot Ulcer Infection and its Predictors among Type 2 Diabetes Mellitus Patients: A Cross-sectional Study

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## ABSTRACT

**Introduction:** Globally, about 425 million people are living with diabetes mellitus. Diabetic Foot Ulcers (DFU) are one of the severe complications of poorly controlled diabetes and over the time, about 50% of DFUs become infected which may require hospitalisation.

**Aim:** To find out the DFU infection severity pattern and its predictors among Type 2 Diabetes Mellitus (T2DM) patients.

**Materials and Methods:** This cross-sectional study was conducted at Integrated Diabetes and Gestational Diabetes Clinic (IDGDC), IQ City Medical College and Multispeciality Hospital, Durgapur, West Bengal, India, among T2DM patients from June 2018 to November 2018. Total 1534 T2DM patients attended IDGDC during data collection period of four months and 132 of them had diabetic foot ulcer. After taking written informed consent, detailed data were collected from 132 of study participants using predesigned, semi structured and pretested schedule developed with the help of Infectious Disease Society of America (IDSA) and International Working Group on the Diabetic Foot (IWGDF/IDSA) classification system. Socio-demographic characteristic like age, sex, education, residence were recorded along with clinical data like glycated haemoglobin (HbA1c), duration of diabetes, treatment modalities. Anthropometric measurements were taken as per World Health Organisation (WHO) guidelines. T2DM was defined and classified as per American Diabetes Association (ADA) Guidelines. DFU infection severity was classified into uninfected, mild infection, moderate infection and severe infection as per IWGDF/IDSA guidelines. Chi-square test was used to show association between categorical variable. One-way Analysis of Variance (ANOVA) with Tukey's post-hoc test was used to show association between mean HbA1c level and DFU infection severity. The p-value ≤0.5 was considered significant.

**Results:** Proportion of DFU was found to be 8.6%. As per the IWGDF/IDSA classification of DFU infection severity was found to be moderate in 59 (44.7%) of the study participants and mild in 32 (24.2%) of the study participants. 22 (16.7%) of study subjects had severe infection and required hospitalisation for optimal care. Only 14.4% of study subjects did not have DFU infection. Increasing age (p-value=0.023), rural residence (p-value=0.015), poor education (p-value=0.001), obesity (p-value=0.001), central obesity (p-value=0.001), longer duration of diabetes (p-value=0.028), and poor glycaemic control (p-value=0.001) was found to be significant risk factors for severe infection in DFU.

**Conclusion:** Routine clinical assessment of DFU infection may help in making clinical decision of treatment modalities and help in saving lower limb as well as life of people with T2DM.

**Keywords:** Diabetic foot infection, Foot amputation, Foot infection

## INTRODUCTION

Diabetes Mellitus (DM) is a chronic metabolic disorder resulting from either insulin resistance and/or relative or absolute insulin deficiency [1]. Globally, About 425 million people are living with diabetes mellitus. India is home of about 72.9 million diabetes mellitus patients and popularly known as "world diabetes capital" [2]. DM itself is associated with high mortality and morbidity, the poorly controlled DM further increases the chronic complications of diabetes [3-5]. Diabetic Foot Ulcer (DFU) is one such common and important complication of poorly controlled diabetes mellitus which affects about 7-24% of People with Diabetes (PwD) [6,7]. Diabetic foot ulcers are one of the severe complications of poorly controlled diabetes and are now one of the frequent causes for diabetes related hospitalisation [8-10]. Causes of DFU are multifactorial and important risk factors include foot deformity, peripheral neuropathy, peripheral arterial disease, high planter pressure, poor glycaemic control, male gender, infection and long duration of diabetes [11].

Over the time, about 50% of DFUs become infected which may require hospitalisation [12]. The severity of DFUs infection ranges from mild to limb threatening and sometimes even life threatening. Most of the lower limb amputations even in developed countries are due to diabetes related complications and infection plays as precipitating factor in about 90% of these amputations [12-14]. Although, DFU is a serious complication, a multidisciplinary team approach can reduce incidence of DFU by 50% and lower limb amputations by 85% [15,16]. Optimal treatment of DFU infection requires thorough evaluation of ulcer, appropriate antimicrobial therapy.

Sometimes, DFU infection may require surgical intervention in Outpatient Department and even hospitalisation in case of severe infection. Identifying the severity of infection is one of the important decision making factor for clinicians, it helps them in deciding the mode and urgency of treatment required [17]. Various guidelines are in place for the classification of DFU [18-24] and few guidelines are also there for the assessment of severity of DFU infection [25,26]. Despite having different guidelines to assess the severity of DFU infection only two classification systems helps in clinical decision making [27]. One such DFU infection severity classification system based on the clinical signs and symptoms were published by the Infectious Disease Society of America (IDSA) [17] and International Working Group on the Diabetic Foot (IWGDF) [28]. IWGDF/IDSA classification system was originally developed as part of the PEDIS

(perfusion, extent, depth, infection and sensation) and it consists of four grades of severity of DFU infections [28].

Although there are numerous studies on the microbiological growth pattern of DFUs [29-31], the study on the severity of DFU is very few in India [32]. Keeping in mind the importance of the grading of wound infection severity in the management of DFU, this study was conducted with an aim to find out the DFU infection severity pattern and its predictors at a chronic care model based diabetes clinic at a tertiary healthcare facility of Eastern India.

## MATERIALS AND METHODS

This cross-sectional study was conducted among Type 2 Diabetes Mellitus (T2DM) patients at Integrated Diabetes and Gestational Diabetes Clinic (IDGDC), IQ City Medical College and Multispeciality Hospital, Durgapur, West Bengal, India, from June 2018 to November 2018. The ethical clearance was obtained from Institutional Ethics Committee (IEC) of IQ City Medical College and Multispeciality Hospital {Ref. No.IQMC/IEC/LTR/18/04/23 (11)}.

Non probability, consecutive sampling technique was used. All T2DM patients who attended Integrated Diabetes and Gestational Diabetes Clinic (IDGDC), IQ City Medical College and Multispeciality Hospital, during data collection period of 4 months (June 2018 to September 2018) were screened for any diabetic foot ulcer and recruited as study participants if they had foot ulcer and consented to participate in study. Out of 1534 attendees of IDGDC only 132 attendees had diabetic foot ulcer and they were recruited as study participants.

**Inclusion criteria:** Age ≥18 years and duration of diabetes ≥6 months were included in the study.

**Exclusion criteria:** Known case of neurological disorders, stress induced hyperglycaemia, hyperglycemia in pregnancy, patients on steroids and critically ill patients were excluded from the study.

### Procedure

Total 1534 T2DM patients attended IDGDC during data collection period of four months. Out of 1534 T2DM patients 132 had diabetic foot ulcer. After taking written informed consent, detailed data were collected from 132 of study participants using predesigned, semi-structured and pretested schedule developed with the help of IWGDF/IDSA classification system [28]. Data on socio-demographic characteristic like age, sex, education, residence were recorded along using schedule and relevant medical records were also reviewed to get clinical data like glycated haemoglobin (HbA1c), duration of diabetes, treatment modalities. Anthropometric measurements were taken as per World Health Organisation (WHO) guidelines [33] and Body Mass Index (BMI) was classified as per WHO guidelines [34]. T2DM was defined and classified as per American Diabetes Association (ADA) Guidelines [35,36]. DFU infection severity was classified into uninfected, mild infection, moderate infection and severe infection as per IWGDF/IDSA guidelines [Table/Fig-1] [28].

## STATISTICAL ANALYSIS

Data were codified and analysed using Statistical Package for Social Sciences (SPSS) version 20.0 for windows. Frequency of clinic-social variables were calculated and presented as frequency distribution tables. Chi-square test was used to show association between categorical variable. One-way Analysis of Variance (ANOVA) with Tukey's post-hoc test was used to show association between mean HbA1c level and DFU infection severity. The p-value ≤0.5 was considered significant.

| Clinical manifestation | Infection severity | PEDIS grade |
|---|---|---|
| Wound lacking purulence or any manifestations of inflammation. | Uninfected | 1 |
| Presence of ≥2 manifestations of inflammation (purulence, or erythema, tenderness, warmth, or induration), but any cellulitis/erythema extends ≤2 cm around the ulcer, and infection is limited to the skin or superficial subcutaneous tissues; no other local complications or systemic illness. | Mild | 2 |
| Infection (as above) in a patient who is systemically well and metabolically stable but which has ≥1 of the following characteristics: cellulitis extending >2 cm, lymphangitic streaking, spread beneath the superficial fascia, deeptissue abscess, gangrene, and involvement of muscle, tendon, joint or bone. | Moderate | 3 |
| Infection in a patient with systemic toxicity or metabolic instability (e.g. fever, chills, tachycardia, hypotension, confusion, vomiting, leukocytosis, acidosis, severe hyperglycemia, or azotemia). | Severe | 4 |

**[Table/Fig-1]:** Operational definition of wound infection severity as per IWGDF/IDSA Guidelines [28].

## RESULTS

The minimum and maximum age of study population was 35 years and 72 years respectively and the mean age was 54.66±9.79 years. It was observed that 68.9% of study population was female and 31.1% were male [Table/Fig-2].

| Clinico-social characteristics | n, % |
|---|---|
| **Age group** | |
| 20-40 years | 10 (7.6 %) |
| 41-60 years | 53 (40.2%) |
| ≥61 years | 69 (52.2%) |
| **Gender** | |
| Male | 41 (31.1%) |
| Female | 91 (68.9%) |
| **Residence** | |
| Urban | 44 (33.3%) |
| Rural | 88 (66.7%) |
| **Educational status** | |
| Illiterate | 56 (42.4%) |
| Upto class V | 31 (23.5%) |
| Class VI-IX | 28 (21.2%) |
| ≥Class X | 17(12.9%) |
| **Duration of diabetes** | |
| 1-5 years | 26 (19.7%) |
| 6-10 years | 24 (18.2%) |
| ≥11 years | 82 (62.1%) |
| **Body mass index (Kg/m$^2$)** | |
| Normal (18.5-24.99) | 40 (30.3%) |
| Overweight/Obese (≥25.00) | 92 (69.7%) |
| **Waist Circumference (WC)** | |
| Male <90 cm, Female <80 cm | 28 (21.2%) |
| Male ≥90 cm, Female ≥80 cm | 104 (78.8) |
| **Treatment** | |
| Insulin±Oral hypoglycaemic medicines | 86 (65.2%) |
| Oral hypoglycaemic medicines | 46 (34.8%) |
| **HbA1c** | |
| ≤7% | 16 (12.1%) |
| >7% | 116 (87.9%) |

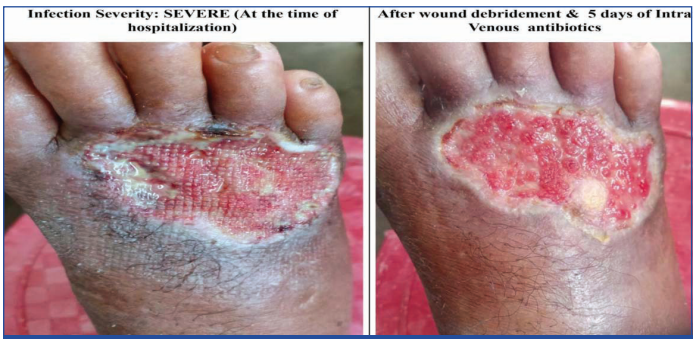
**[Table/Fig-2]:** Clinico-social characteristics of study population, n=132.

Proportion of Diabetic Foot Ulcer (DFU) was found to be 8.6% (total DFU=132/total screened population=1534×100). As per the IWGDF/IDSA classification of DFU infection severity was found to be moderate in 59 (44.7%) of the study participants and mild in 32 (24.2%) of the study participants [Table/Fig-3,4]. Patients with mild and moderate DFU infections were treated in Outpatient Department setting with wound debridement and oral antibiotics for 10 days and follow-up was done after 10 days or earlier if they feel worsening of infection. Total 22 (16.7%) of study subjects had severe infection and required hospitalisation for optimal care [Table/Fig-3,5].

| Number (%) | IWGDF/IDSA grading | PEDIS classification |
|---|---|---|
| 19 (14.4) | No infection | 1 |
| 32 (24.2) | Mild infection | 2 |
| 59 (44.7) | Moderate infection | 3 |
| 22 (16.7) | Severe infection | 4 |

**[Table/Fig-3]:** Grading of diabetic foot ulcer Infection as per IWGDF/IDSA grading system, N=132.


**[Table/Fig-4]:** Image showing IWGDF/IDSA DFU infection severity (No infection, mild Infection and moderate Infection).




**[Table/Fig-5]:** Image showing IWGDF/IDSA DFU infection severity (Severe infection at the time of hospitalisation and after five days of intravenous antibiotics).

Increasing age (p-value=0.023), rural residence (p-value=0.015), poor education (p-value=0.001), obesity (p-value=0.001), central obesity (p-value=0.001) was found to be significant risk factors for severe infection in DFU. Longer duration of diabetes was associated with significant (p-value=0.028) higher risk of severe DFU infection. Poor glycaemic (HbA1c>7%) was found to be a significant (p-value=0.001) risk factor for severe diabetic foot ulcer infection [Table/Fig-6].

There was a significant mean HbA1c difference between grades as determined by one-way ANOVA statistics [F(132,3)=5.577, p-value <0.001] [Table/Fig-7]. It was found that mean HbA1c as dependent variables in the standard ANOVA model are significantly predictive of the independent variables grading of diabetic foot ulcer infection category (No Infection, Mild Infection, Moderate Infection, Severe Infection). Mean plot of HbA1c against infection severity shows significant increase in DFU infection severity with increase in mean HbA1c [Table/Fig-8]. To see the between group difference, one-way ANOVA was further extended with "Tukeys post-hoc test" to do multiple comparison. After post-hoc analysis, it was noted that there was significant difference in mean HbA1c level between no infection vs moderate infection (10.30±2.27, p-value=0.023) and no infection vs severe infection (11.29±1.67, p-value=0.001).

## DISCUSSION

In the present study, prevalence of DFU was found to be 8.6%. Slightly lower 6.6% and slightly higher 9.5% prevalence of DFU was reported by Thakur JK et al., [1] and Gupta SK et al., [37] respectively. Few other studies reported a 9.8-12% prevalence of DFU [38,39]. Using the IWGDF/IDSA classification [28], proportion of DFU infection in present study was found to be 85.2%. It was observed that 44.7% of the study population had moderate infection followed by about 24.2% and 16.7% of the study population who had mild infection and severe infection requiring hospitalisation for treatment respectively.

A similar study using IWGDF/IDSA classification system done by Lavery LA et al., [17] reported 47.0% proportion of mild infection followed by 34.0% and 17.9% proportion of moderate and severe DFU infection respectively. Although the proportion of severe infection in present study (16.7%) and study done by Lavery LA et al., [17] (17.9%) are comparable the overall proportion of DFU infection in present study is slightly higher which can be attributed to the setting of the present study which is a dedicated diabetes clinic of a tertiary healthcare facility which is bound to get more

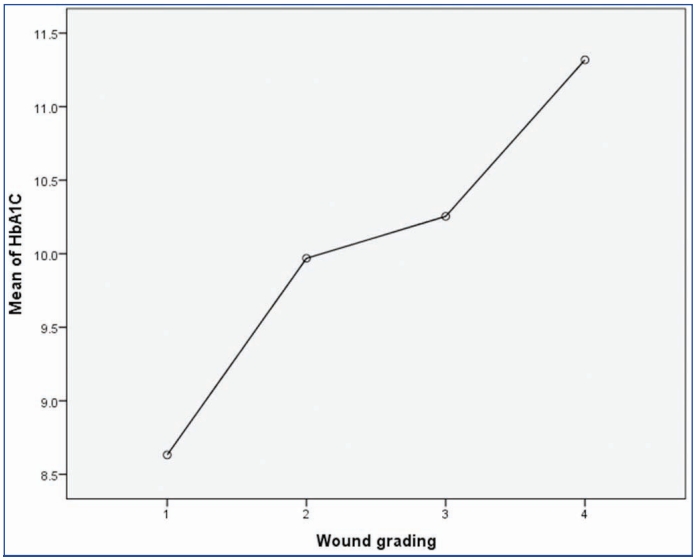
| Clinico-social factors | Wound grading | | | | Total (n, %) | $\chi^2$ (df) | p-value |
|---|---|---|---|---|---|---|---|
| | No infection (n, %) | Mild (n, %) | Moderate (n, %) | Severe (n, %) | | | |
| **Age group** | | | | | | | |
| 20-40 years | 5 (50%) | 1 (10%) | 3 (30%) | 1 (10%) | 10 (100%) | 14.69 (6) | 0.023 |
| 41-60 years | 7 (13.2%) | 12 (22.7%) | 28 (52.8%) | 6 (11.3%) | 53 (100%) | | |
| ≥61 Years | 7 (10.1%) | 19 (27.5%) | 28 (40.7%) | 15 (21.7%) | 69 (100%) | | |
| **Gender** | | | | | | | |
| Male | 8 (19.5%) | 13 (31.7%) | 15 (30.6%) | 5 (12.2%) | 41 (100%) | 4.03 (3) | 0.257 |
| Female | 11 (12.1%) | 19 (20.8%) | 44 (48.4%) | 17 (18.7%) | 91 (100%) | | |
| **Residence** | | | | | | | |
| Urban | 12 (27.3%) | 11 (25%) | 17 (38.6%) | 4 (9.1%) | 44 (100%) | | |
| Rural | 7 (8%) | 21 (23.8%) | 42 (47.7%) | 18 (20.5%) | 88 (100%) | 10.43 (3) | 0.015 |
| **Education** | | | | | | | |
| Illiterate | 3 (5.4%) | 7 (12.5%) | 34 (60.7%) | 12 (21.4%) | 56 (100%) | 30.73 (9) | 0.001 |
| Upto class V | 5 (16.1) | 6 (19.4%) | 15 (48.4%) | 5 (16.1%) | 31 (100%) | | |
| Class VI-IX | 5 (17.9) | 14 (50%) | 5 (17.9) | 4 (14.2%) | 28 (100%) | | |
| ≥Class X | 6 (35.3%) | 5 (29.4%) | 5 (29.4%) | 1 (5.9%) | 17 (100%) | | |

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| **Body mass index (Kg/m²)** | | | | | | | |
| 18.5-24.99 | 13 (32.5%) | 11 (27.5%) | 11 (27.5%) | 5 (12.5%) | 40 (100%) | 17.71 (3) | 0.001 |
| ≥25.00 | 6 (6.5%) | 21 (22.8%) | 48 (52.2%) | 17 (18.5%) | 92 (100%) | | |
| **Waist circumference** | | | | | | | |
| Male <90 cm/Female <80 cm | 12 (42.9%) | 5 (17.9%) | 9 (32.1%) | 2 (7.1%) | 28 (100%) | 23.78 (3) | 0.001 |
| Male ≥90 cm/Female ≥80 cm | 7 (6.7) | 27 (26.0) | 50 (48.1) | 20 (19.2) | 104 (100%) | | |
| **Duration of diabetes** | | | | | | | |
| 1-5 years | 9 (34.6%) | 5 (19.3%) | 9 (34.6%) | 3 (11.5%) | 26 (100%) | 14.19 (6) | 0.028 |
| 6-10 years | 3 (12.5%) | 9 (37.5%) | 8 (33.3) | 4 (16.7%) | 24 (100%) | | |
| ≥11 years | 7 (8.5%) | 18 (22%) | 42 (51.2%) | 15 (18.3%) | 82 (100%) | | |
| **Treatment** | | | | | | | |
| Insulin | 7 (8.1%) | 23 (26.8%) | 39 (45.3%) | 17 (19.8%) | 86 (100%) | 8.79 (3) | 0.032 |
| Oral anti diabetic | 12 (26.1%) | 9 (19.5%) | 20 (43.5%) | 5 (10.9%) | 46 (100%) | | |
| **Glycated hemoglobin (HbA1c)** | | | | | | | |
| ≤7% | 9 (53.3%) | 4 (25%) | 2 (12.5%) | 1 (6.2) | 16 (100%) | 27.57 (3) | 0.001 |
| >7% | 10 (8.6) | 28 (24.2%) | 57 (49.1%) | 21 (18.1%) | 116 (100%) | | |

**[Table/Fig-6]:** Chi-square test showing association between Clinico-social determinants and severity of DFU infection (N=132).

| Groups | Mean±SD | F-test (p-value) |
|---|---|---|
| No infection | 8.63±0.77 | 5.577 (0.001) |
| Mild infection | 9.98±2.57 | |
| Moderate infection | 10.30±2.27 | |
| Severe infection | 11.28±1.67 | |

**[Table/Fig-7]:** One-way ANOVA between HbA1c as dependent variable and Grading of diabetic foot ulcer infection as independent variable (N=132).




**[Table/Fig-8]:** Mean plot of HbA1c against severity of Diabetic foot ulcer infection (n=132).
F test: 5.577, p-value: 0.001. 1=No infection, 2=Mild infection, 3=Moderate infection, 4=Severe infection

complicated cases. Although, there are limited studies ascertaining the clinical severity of DFU infection, there are numerous studies on the incidence of DFU infection which shows an incidence of 26% to 61% of infection in DFU [14, 26, 40-44].

In the present study, increasing age was found to be significant risk factor for severe DFU infection. More severe infection with increasing age may be because of the increase in risk factors for DFU like peripheral neuropathy, peripheral artery disease and reduced immunity. Study by Jia L et al., [45] reported younger age as a risk factor for severe DFU infection and Leibovitch M et al., [46] reported a similar trend in DFU infection with increasing age which is consistent with our study findings. In the present study a non significant female preponderance of severe DFU infection was found but Lavery LA et al., [17] and Jia L et al., [45] reported a significant male preponderance of DFU infections. While rural residence was found to be significant risk factor for DFU infection in the present study there are studies which reported non significant rural area preponderance of DFU [1,37] and non significant association of residence with DFU infection [45].

Significant high proportion of severe infection among study participants from rural area may be due to the less access of quality diabetes care among rural area residents. Poor educational status was found to be significant risk factors for developing severe DFU infection. Poor educational status may have resulted in poor understanding of the disease process, its treatment and progression leading to poor compliance and consequent complications of poorly controlled T2DM. Severe DFU infections were found to be significantly higher among overweight, obese and study participants having central obesity.

Various studies reported significant high prevalence of DFU among overweight and obese people with T2DM [1,37,47-49]. More duration of T2DM was found to be significant risk factors for having severe DFU infections. While studies done by Thakur JK et al., [1] and Gupta SK et al., [37] reported significant risk of DFU with increasing duration of T2DM, Jia L et al., [45] reported non significant role of T2DM duration on the severity of DFU infection. Treatment with insulin based regimen was significantly high among severe DFU infections. This may be due to the fact that most guidelines recommend insulin based treatment of diabetes mellitus during acute illness or hospitalisation [50].

Significantly high proportion of severe DFU infection was found among study participants having poor glycaemic control (HbA1c ≥7%). In present study, the mean HbA1c was found to be significantly high among those who had severe and moderate DFU infections than those who had no infection. Poor glycaemic control is a known risk factor for reduced immunity, increased risk for DFU and non healing of DFU [1, 37]. The present study is probably the first of its kind at least in Eastern India which is reporting the importance of clinical grading of DFU infection severity and its predictors.

## Limitation(s)

Failure to include few important risk factors for DFU like smoking, tobacco, alcohol addiction in the present study. Few other confounding factors for DFU like CKD, burgers disease and history of previous revascularisation surgery were also not included in present study. Results of the present study cannot be generalised

because this study was done at an advanced diabetes care clinic which is bound to get complicated and referred cases.

## CONCLUSION(S)

Increasing age, rural residence, poor education, obesity, central obesity, longer duration of diabetes, and poor glycaemic control was found to be significant risk factors for severe infection in DFU. Routine clinical assessment of DFU infection may help in making clinical decision of treatment modalities and help in saving lower limb as well as life of people with T2DM.

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