

The BDFOOT- IDGDC study: Burden of diabetic foot ulcers and its determinants among type 2 diabetes patients attending an “Integrated Diabetes and Gestational Diabetes Clinic” of Eastern India

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ABSTRACT

Background: Globally, about 425 million people are suffering from diabetes mellitus (DM) which will be about 629 million by 2045. India is popularly known as “World Diabetes Capital” and is presently home of about 72.9 million diabetes patients. Poorly managed DM will increase the burden of both microvascular and macrovascular complications. One of the most common complications among them is diabetic foot ulcer (DFU) which affects about 7%–24% of DM patients. **Aims and Objectives:** This study was planned to determine the burden of DFU and its determinants among Type 2 diabetes mellitus (T2DM) patients attending integrated diabetes and gestational diabetes clinic. **Materials and Methods:** An institution-based, observational, cross-sectional study was conducted from July to September 2018. A pre-designed, pre-tested, semi-structured schedule was used to collect clinicosocial data. Blood pressure of the study subjects was measured and classified as per Joint National Committee-8 guidelines. Peripheral vascular assessment of the feet was done by calculating “ankle-brachial index (ABI)” in both lower limbs using “Diabetik Foot Care India Pvt. Limited” vascular Doppler instrument having 8 MHz transducer. ABI ≤ 0.9 and absence of pulse in dorsalis pedis and/or posterior tibial arteries were considered as peripheral artery disease (PAD). Vibration perception threshold for peripheral sensory neuropathy was tested with the help of Diabetik Foot Care Pvt. Limited Digital Biothesiometer using 50 Hz frequency. **Results:** Data were collected from 338 study participants. The frequency of DFU was found to be 9.5%. Increasing age, longer duration of diabetes, poor educational status, overweight/obesity, poor glycemic control, treatment with insulin, PAD, diabetic peripheral neuropathy, hypertension, ischemic heart disease, and hypothyroidism were significantly associated with DFU. **Conclusion:** There is high frequency of

DFU among T2DM patients. Most of the risk factors are modifiable and if taken care of the occurrence of DFU can be prevented and/or delayed.

KEY WORDS: Diabetic Foot Ulcer; Integrated Diabetes Care; Diabetic Peripheral Neuropathy; Diabetic Foot Syndrome; Peripheral Arterial Disease

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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 suffering from DM which will be about 629 million by 2045. India is popularly known as “world diabetes capital” and is presently home of about 72.9 million diabetes patients, if corrective steps are not taken on time the number of people with diabetes will be 134 million by 2045.^[2]

DM is associated with high morbidity, mortality, and increased health-care cost to the diabetes patients than non-diabetes people.^[3-5] Poorly managed DM will increase the burden of both microvascular and macrovascular complications. One of the most common complications among them is diabetic foot ulcer (DFU) which affects about 7%–24% of DM patients.^[6,7] Epidemiological research shows that DFU is multifactorial and important risk factors include limb ischemia, foot deformity, peripheral neuropathy, high plantar pressure, infections, poor glycemic control, male gender, and long duration of diabetes.^[8] Although DFU is a common and serious complication of uncontrolled DM, it is largely preventable by simple measures such as patient education regarding hygienic practices, daily foot examinations, appropriate footwear, early diagnosis, and management of foot injuries. It has been seen that a multidisciplinary team approach can reduce the incidence of DFU by 50% and lower limb amputations by up to 85%.^[9,10]

Diabetes Awareness and You is a non-profit social welfare organization working in the field of DM. They run a “chronic care model (CCM)”^[11] based integrated diabetes and gestational diabetes clinic (IDGDC) in various parts of West Bengal, India. One such IDGDC is operational at IQ City Medical College and Multispecialty Hospital, Durgapur, West Bengal. IDGDC serves as a single contact point of all non-emergent DM patients visiting IQ City Medical College. As a mandate of CCM, IDGDC gives team care which comprises patients and their family members, dietitian, diabetes educator, diabetologist, and gynecologist. If required, IDGDC manages all the referrals of diabetes patients to the other departments, namely surgery, orthopedics, cardiology, nephrology and physiotherapy, etc. The IDGDC serves to about 300–500 DM patients every month. This study was planned to determine the burden of DFU and the factors associated with it among Type 2 diabetes mellitus (T2DM) patients attending IDGDC.

MATERIALS AND METHODS

An institution-based, observational, cross-sectional study was conducted among T2DM patients who attended IDGDC at IQ City Medical College and Multispecialty Hospital from July to September 2018. A total of 338 study subjects participated in the study.

Ethical Clearance

The study was ethically approved by the Institutional Ethics Committee, IQ City Medical College and NM Hospital.

Study Design

This was a cross-sectional study.

Study Location

This study was conducted in IDGDC, IQ City Medical College and Multispecialty Hospital, Durgapur, West Bengal (India).

Study Duration

The study duration was 3 months (July–September 2018).

Sample Size

The sample size was 338.

Sampling Procedure

Non-probability, consecutive sampling technique was used.

Study Population

T2DM patients who attended IDGDC during data collection period.

Inclusion Criteria

The following criteria were included in the study:

1. Age ≥ 18 years
2. Duration of T2DM ≥ 6 months.

Exclusion Criteria

The following criteria were excluded from the study:

1. Stress-induced diabetes
2. Steroid-induced diabetes
3. Known case of neurological disorder
4. Refusal to give consent
5. Critically ill.

Study technique

Written informed consent was taken from all study subjects. A pre-designed, pre-tested, semi-structured schedule was used to collect clinicosocial data. Relevant medical records were also reviewed for data collection. A total of 636 T2DM patients attended IDGDC during data collection period, of which 338 patients consented to participate in our study. Hence, data were collected from 338 study subjects. Anthropometric measurements were taken as per standard

WHO protocols.^[12] Blood pressure of the study subjects was measured and classified as per Joint National Committee-8 guidelines.^[13] Peripheral vascular assessment of the feet was done by calculating “ankle-brachial index (ABI)” in both lower limbs using “Diabetik Foot Care India Pvt. Limited” vascular Doppler instrument having 8 MHz transducer. ABI ≤ 0.9 and absence of pulse in dorsalis pedis and/or posterior tibial arteries were considered as peripheral artery disease (PAD).^[14] Vibration perception threshold (VPT) for peripheral sensory neuropathy was tested with the help of Diabetik Foot Care Pvt. Limited Digital Biothesiometer using 50 Hz frequency.

Statistical Analysis

Data were codified and analyzed using the SPSS (Statistical Package for the Social Sciences) version 20.0 for Windows.

Table 1: Clinicosocial characteristics of the study subjects ($n=338$)

Clinicosocial characteristics	<i>n</i> (%)
Age group	
≤ 40 years	42 (12.4)
41–60 years	210 (62.1)
≥ 61 years	86 (25.5)
Sex	
Male	214 (63.3)
Female	124 (36.7)
Residence	
Urban	251 (74.3)
Rural	87 (25.7)
Current smoker	
Yes	212 (62.7)
No	126 (37.3)
Educational status	
Illiterate	41 (12.1)
Up to Class V	25 (7.4)
Class VI–X	117 (34.6)
$>$ Class X	155 (45.9)
Family history of Type 2 diabetes mellitus	
Yes	168 (49.7)
No	170 (50.3)
Duration of diabetes	
0–5 years	144 (42.6)
6–10 years	92 (27.2)
>10 years	102 (30.2)
Treatment regimen	
Insulin+oral antidiabetic medicines	77 (22.8)
Oral antidiabetic medicines	261 (77.2)

(Contd...)

Frequency of clinicosocial variables was calculated. Chi-square test was used to show association between categorical variables. Unpaired *t*-test was performed to show mean difference for continuous variables.

RESULTS

The minimum and maximum age of the study population was 26 years and 78 years, respectively, with a mean age of 52.9 ± 10.6 years. Clinicosocial characteristics of the study participants are tabulated in Table 1. About 62.1% of the study population were in the 41–60 years age group followed by 25.5% and 12.4% in the age group of ≥ 61 years and ≤ 40 years, respectively. More than 3/5th, i.e., 63.3% of the study population were male and 36.7% were female. Two hundred and fifty-one (74.3%) of the study population had urban residence and rest 25.7% had rural residence. Two

Table 1: (Continued)

Clinicosocial characteristics	<i>n</i> (%)
Waist circumference (cm)	
Normal (male <90 , female <80)	96 (28.4)
High (male ≥ 90 ; female ≥ 80)	242 (71.6)
BMI (Kg/m^2)	
Normal (18.5–24.99)	177 (52.4)
Overweigh/obese (≥ 25.00)	161 (47.6)
Hypertension (mmHg)	
Normal	169 (50.0)
High ($\geq 140/90$)	169 (50.0)
Hypercholesterolemia	
Present	83 (24.6)
Absent	255 (75.4)
Ischemic heart disease	
Present	37 (10.9)
Absent	301 (89.1)
Hypothyroidism	
Present	62 (18.3)
Absent	276 (81.7)
Ankle-brachial index (ABI)	
<0.9	41 (12.1)
≥ 0.9 to ≤ 1.3	297 (87.9)
Vibration perception threshold	
Normal	198 (58.6)
Increased	140 (41.4)
Diabetic foot ulcer	
Present	32 (9.5)
Absent	306 (90.5)

Table 2: Association between clinicosocial determinants and diabetic foot ulcer (*n*=338)

C-S factors	Diabetic foot ulcer		Total <i>n</i> (%)	χ^2 (df)	<i>P</i> value
	Yes (%)	No (%)			
Age group					
≤40 years	2 (4.8)	40 (95.2)	42 (100.0)	8.8 (2)	0.012
41–60 years	15 (7.1)	50 (92.9)	210 (100.0)		
≥61 Years	15 (17.4)	71 (82.6)	86 (100.0)		
Sex					
Male	15 (7.0)	199 (93.0)	214 (100.0)	4.1 (1)	0.053
Female	17 (13.7)	107 (86.3)	124 (100.0)		
Residence					
Urban	22 (8.8)	229 (91.2)	251 (100.0)	0.56 (1)	0.289
Rural	10 (11.5)	77 (88.5)	87 (100.0)		
Educational status					
Illiterate	10 (24.4)	31 (75.6)	41 (100.0)	21.3 (3)	0.000
Up to Class V	4 (14.0)	21 (84.4)	25 (100.0)		
Class VI–X	14 (12.0)	103 (88.0)	117 (100.0)		
>Class X	4 (2.6)	151 (97.4)	122 (100.0)		
Addiction (current smoker)					
Yes	17 (8.0)	195 (92.0)	212 (100.0)	1.4 (1)	0.161
No	15 (11.9)	111 (88.1)	126 (100.0)		
Family history of Type 2 diabetes mellitus					
Yes	16 (9.5)	152 (90.5)	168 (100.0)	0.001 (1)	0.560
No	16 (9.4)	154 (90.6)	170 (100.0)		
Duration of diabetes					
0–5 years	6 (4.2)	138 (95.8)	144 (100.0)	15.1 (2)	0.001
6–10 years	7 (7.6)	85 (92.4)	92 (100.0)		
≥11 years	19 (18.6)	83 (81.4)	102 (100.0)		
Treatment regimen					
Insulin+OHA	15 (19.5)	62 (80.5)	77 (100.0)	11.7 (1)	0.002
OHA only	17 (6.5)	244 (93.5)	261 (100.0)		
Waist circumference					
Normal	5 (5.2)	91 (94.8)	96 (100.0)	2.8 (1)	0.103
High (male >90; female >80)	27 (11.2)	215 (88.8)	242 (100.0)		
BMI (Kg/m ²)					
Normal (18.5–24.99)	10 (5.6)	167 (94.4)	177 (100.0)	6.3 (1)	0.015
Overweight/obese (≥25.00)	22 (13.7)	139 (86.3)	161 (100.0)		

hundred and twelve (62.7%) of the study population were current smoker. One hundred and fifty-five (45.9%) had >Class X level education, followed by 34.5%, 12.1%, and 7.4% study participants had education up to Class VI–X, illiterate and up to Class V, respectively. About half of the study participants had positive family history of T2DM among the first-degree relatives. Duration of T2DM was 0–5 years in 144 (42.6%), >10 years in 102 (30.2%), and 6–10 years in 92 (27.2%) of the study participants. More than 3/4th, i.e., 77.2% of the study participants were treated with oral antidiabetic (OAD) medicines only and 77 (22.8%) were treated with both insulin and OADs. Two hundred and forty-two (71.6%) of them had central obesity and

161 (47.6%) had body mass index (BMI) ≥25.00. Among comorbidities, hypertension was present in 50.0% of the study participants, hypercholesterolemia, ischemic heart disease, and hypothyroidism were present in 83 (24.6%), 37 (10.9%), and 62 (18.3%) of the study participants, respectively. PAD as defined by the “ABI” <0.9 was present in 41 (12.1%) of them. Peripheral sensory neuropathy as indicated by increased “VPT” was present in 140 (41.4%) of the study participants. DFU was present in 32 (9.5%) of the study participants [Table 1 and Figure 1]. Table 2 and Table 3 show the risk factors which influenced occurrence of DFU. Increasing age, poor educational status, longer duration of diabetes, treatment with insulin, and BMI ≥ 25.00

significantly favored the occurrence of DFU [Table 2]. Comorbidities such as hypertension, ischemic heart disease, hypothyroidism, PAD, and peripheral sensory neuropathy were also significantly associated with DFU [Table 3] in our study population. Mean HbA1c was significantly higher among the study participants who had DFU [Table 4].

DISCUSSION

The frequency of DFU in this study was found to be 9.5%. Chandrashekar and Muralidhar reported a DFU prevalence of 12%.^[15] Vibha *et al.* reported that 9.8% of diabetes patients had a history of DFU while 1.5% had active DFU.^[16] About 6.6% prevalence of DFU was reported by Thakur *et al.*^[1] Few

other international studies reported DFU prevalence between 13.6% and 14.8%.^[17,18] PAD is one of the important risk factors for DFU; in this study, the frequency of PAD was found to be 12.1%. A PAD prevalence of 14.8% was reported by Thakur *et al.*^[1] and 36.0% prevalence of PAD in among diabetes patients was reported by Shukla *et al.*^[19] Few other studies reported a lower prevalence 3.5%^[20] and a higher prevalence 42.6%^[21] of PAD using ABI. Another important risk factor for DFU is diabetic peripheral neuropathy (DPN), whose frequency is found to be 41.4% in this study. A DPN prevalence of 51.8% and 51.4% was reported by Vibha *et al.*^[16] and Thakur *et al.*,^[1] respectively. Few other studies reported a DPN prevalence of 26%–29.2%.^[22,23] Higher DPN prevalence in our study may be due to the selective referral of high-risk patients to the specialty clinic IDGDC.

In this study, increasing age was found to be significantly associated with high prevalence of DFU. Various studies also reported similar association of increasing age and diabetic foot syndrome.^[1,16,24] A non-significant female preponderance of DFU was found in this study, but a significant female preponderance was reported by few other studies.^[1,25-27] Although a non-significant higher prevalence of DFU was found among rural resident people in this study, a significant association between rural residence and DFU was observed by many international studies.^[17,28,29] A significant higher proportion of 24.4% DFU was found among illiterate study subjects as compared to 14.0%, 12.0%, and 2.6% proportion of DFU among the study subjects who were educated up to Class V, Class VI–X, and >Class X, respectively. Longer duration of diabetes was identified as one of the significant

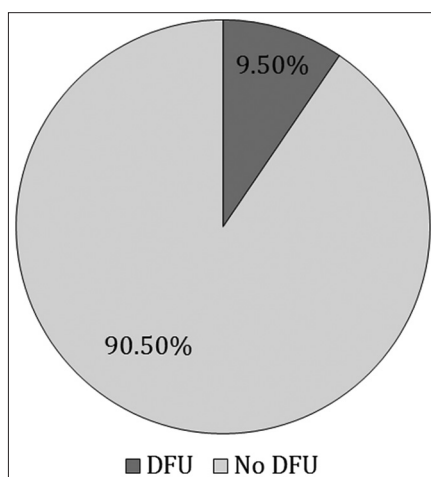


Figure 1: Frequency of diabetic foot ulcer ($n = 338$)

Table 3: Association between clinicosocial determinants and diabetic foot ulcer ($n=338$)

C-S factors	Diabetic foot ulcer		Total n (%)	χ^2 (df)	P value
	Yes (%)	No (%)			
Hypertension					
Yes	23 (13.6)	146 (86.4)	169 (100.0)	6.8 (1)	0.007
No	9 (5.3)	160 (94.7)	169 (100.0)		
Hypercholesterolemia					
Yes	9 (10.8)	74 (89.2)	83 (100.0)	0.243 (1)	0.667
No	23 (9.0)	232 (91.0)	255 (100.0)		
Ischemic heart disease					
Yes	10 (27.0)	27 (73.0)	37 (100.0)	14.9 (1)	0.001
No	22 (7.3)	279 (92.7)	301 (100.0)		
Hypothyroidism					
Yes	22 (35.5)	40 (64.5)	62 (100.0)	59.9 (1)	0.000
No	10 (3.6)	266 (96.4)	276 (100.0)		
Ankle-brachial index					
<0.9	19 (46.3)	22 (53.7)	41 (100.0)	74.0 (1)	0.000
≥ 0.9 – ≤ 1.3	13 (4.4)	284 (95.6)	297 (100.0)		
Vibration perception threshold					
Increased	25 (17.9)	115 (82.1)	140 (100.0)	19.6 (1)	0.000
Normal	7 (3.5)	191 (96.5)	198 (100.0)		

Table 4: Mean HbA1c among the study population having foot ulcer and not having foot ulcer ($n=338$)

Foot ulcer	Number	Mean±SD	t-test (df)	P value
HbA1c				
Yes	32	10.78±2.17	7.86 (336)	0.000
No	306	7.86±1.98		

risk factors of DFU among the study subjects. Similar significant link between longer duration of diabetes and DFS was reported by various other studies.^[23,31,32] Although smoking is an established risk factor for DFU and the same was reported by many other studies,^[1,16] a non-significant relationship between smoking and DFU was found in this study.

DFU was significantly more common among the study subjects who were treated with insulin and OAD medication as compared to those were treated with OADs alone. This may be due to the long-standing, more complicated, poorly controlled T2DM study subjects who required insulin for their glycemic control. High prevalence of DFU among insulin-treated patients was also reported by few other studies.^[1,16] In this study, overweight/obesity was significantly associated with more frequency of DFU. It may be due to the fact that obesity itself is a contributory factor for poor glycemic control which, in turn, leads to the development of various diabetes-related complications including DFU. Few other epidemiological researches had also reported the significant association between overweight/obesity and high prevalence of DFU;^[1,28,31-33] however, there are few studies who did not find any significant association between BMI and DFU.^[23,33] Hypertension and ischemic heart disease were significantly associated with higher frequency of DFU, which is in agreement with the various other studies.^[16,23,25,30] Although there are very few studies who studied the association between hypothyroidism and DFU, we found that hypothyroidism significantly favored the occurrence of DFU. Similar finding was reported by Thakur *et al.*^[1] DPN is a risk factor for DFU; a study from China reported a positive association between hypothyroidism and DPN.^[34] PAD and DPN are proven risk factors for DFU,^[35] we also found a significant higher proportion of DFU among the study subjects who had PAD and DPN, which are in agreement with other studies.^[1,16] Poor glycemic control as indicated by high HbA1c is a known risk factor for DFU.^[8] In this study, mean HbA1c was significantly higher among the study subjects who had DFU.

The findings of the study cannot be generalized as the study setting is a specialty clinic at a tertiary health-care facility which is bound to get more complicated cases.

CONCLUSION

The frequency of the DFU is 9.5%. Increasing age and longer duration of diabetes are two most important non-modifiable

risk factors for DFFU. High BMI, poor glycemic control, and poor educational status are important modifiable risk factors for DFU. Adequate management of associated comorbidities such as hypertension, hypothyroidism, ischemic heart disease, peripheral arterial disease, and peripheral neuropathy may prevent or delay the occurrence of DFU.

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