

Prevalence of Diabetic Foot Syndrome and Its Determinants among Type 2 Diabetes Mellitus patients attending Integrated Diabetes & Gestational Diabetes Clinic of a Tertiary Health Care Level Hospital of Eastern India.

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Abstract: Introduction: Globally about 425 million people are suffering from diabetes mellitus and it is expected to rise to about 629 million by 2045. India is home of about 72.9 million diabetes patients which will rise to about 134 million by 2045. Diabetic foot is one of most common and devastating micro vascular complications of diabetes. Diabetic foot is defined as a group of syndromes in which neuropathy, ischemia and infection lead to tissue breakdown and possible amputation. This study was aimed to determine the prevalence of Diabetic Foot Syndrome and its determinants among Type 2 Diabetes Mellitus (T2DM) patients attending Integrated Diabetes & Gestational Diabetes Clinic (IDGDC), Durgapur (West Bengal India). **Materials & Methods:** An institution based, observational, Cross-Sectional study was conducted from July-October 2018. A pre designed, pre tested, semi structured schedule was used to collect clinic-social data. Evaluation of diabetic peripheral neuropathy was done with the help of Michigan Neuropathy Screening Instruments (MNSI). 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. The International Working Group on Diabetic Foot (IWGDF) Risk Classification System was used to classify study subjects foot problems. **Results:** Prevalence of DFS was found to be 67.1%. Increasing age, longer duration of diabetes, female gender, smoking, treatment with insulin, central obesity, obesity, hypertension, ischemic heart disease and hypothyroidism was significantly associated with DFS among study participants. **Conclusion:** There is a high prevalence of Diabetic Foot Syndrome. Most of the risk factors like obesity, smoking, hypertension are modifiable.

Key Words: Diabetic foot syndrome (DFS), Peripheral Neuropathy, Integrated Diabetes Care, Chronic Care Model, Peripheral Arterial Disease (PAD), Diabetic Foot Ulcer, Type 2 Diabetes Mellitus (T2DM)

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I. Introduction

Diabetes Mellitus is a group of metabolic disorder resulting from either insulin resistance and/or relative or absolute insulin deficiency. It is one of the global health emergencies of 21st century. Globally about 425 million people are suffering from diabetes mellitus and it is expected to rise to about 629 million by 2045¹. India is home of about 72.9 million diabetes patients which will rise to about 134 million by 2045¹. Diabetes is associated with significant mortality & morbidity, increased health care cost and reduced quality of life²⁻⁴. Globally, the burden of diabetes is on the rise and the implications of non treated and/or poorly treated diabetes will be devastating in terms of both micro & macro vascular complications. Diabetic foot is one of most common and devastating micro vascular complications of diabetes. Diabetic foot is defined as a group of syndrome in which neuropathy, ischemia and infection lead to tissue breakdown and possible amputation⁵. Results of epidemiological research shows that 15% of the diabetes patients will develop foot ulcer in their life time and it will proceed to lower limb amputation in almost 85% of cases⁶. Risk factors for foot ulcers in diabetes patients include peripheral neuropathy, limb ischemia, foot deformity, high plantar pressure and infections. Poor glycemic control, long duration of diabetes and male gender are other important risk factors for foot ulcers among diabetes patients⁷. DFS is a serious complication which is largely preventable. Simple interventions like regular foot examinations, patient education

regarding hygienic practices, appropriate footwear, early diagnosis and treatment of minor/major injuries and a multi-disciplinary team approach can decrease ulcer occurrence by 50% and lower limb amputations by up to 85%⁸⁻⁹.

Integrated Diabetes & Gestational Diabetes Clinic (IDGDC) is a joint venture of IQ City Medical College and Diabetes Awareness & You (DAY) - a nonprofit social welfare organization. IDGDC serves as a single contact point for all non emergency diabetes patients visiting IQ City Medical College. IDGDC is based on "Chronic Care Model"¹⁰ and gives team care to all diabetes patients. Team comprises of Patients, their family members, Diabetologists, Gynaecologist, dietitians and diabetes educators. IDGDC also manages referral of the patients to the different departments namely Nephrology, Surgery, Orthopedics, Physiotherapy and Cardiology. About 500 diabetes patients attend IDGDC every month. This study was aimed to determine the prevalence of Diabetic Foot Syndrome and its determinants among Type 2 Diabetes Mellitus (T2DM) patients attending IDGDC.

II. Material and Methods

This Institution based, Observational; Cross-Sectional study was conducted among T2DM patients who attended IDGDC, IQ City Medical College & Narayana Hospital, Durgapur, West Bengal (India) between July-October 2018. A total 243 study subjects participated in study.

Study Design: Cross-sectional

Study Location: Integrated Diabetes & Gestational Diabetes Clinic (IDGDC), IQ City Medical College & Narayana Hospital, Durgapur, West Bengal (India)

Study Duration: July –Oct 2018.

Sample size: 243

Sample size calculation: Peripheral neuropathy is a component of DFS. In a study done by George et al the prevalence of peripheral neuropathy among diabetes patients was found to be 47%¹¹. Sample size was calculated as per World Health Organization (WHO) guidelines¹², using formula $Z\alpha^2pq/d^2$. Thus with prevalence (p) of peripheral neuropathy=47%, q=1-p, and absolute precision 15% with 95% confidence interval and 20% possible non response rate, the final sample size of 231 was obtained.

Sampling procedure: Systematic random sampling was followed throughout data collection period. Sampling interval was decided on the basis of previous patient's attendance record.

Study population: Type 2 Diabetes Patients who attended IDGDC during data collection period during data collection period.

Inclusion criteria:

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

Exclusion criteria:

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 clinic-social data. Relevant medical records were also reviewed for data collection. Data was collected from 243 study subjects. Anthropometric measurements were taken as per standard WHO protocols¹³. Blood pressure of the study subjects were measured and classified as per Joint National Committee (JNC) - 8 guidelines¹⁴. 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 8MHz transducer. Dorsalis pedis artery and posterior tibial artery in both lower limbs were palpated manually for peripheral pulses. ABI ≤ 0.9 and absence of pulse in dorsalis pedis and/or posterior tibial arteries was considered as peripheral artery disease (PAD)¹⁵.

Evaluation of diabetic peripheral neuropathy was done with the help of Michigan Neuropathy Screening Instruments (MNSI)¹⁶. MNSI has two components. First component is subjective and consists of peripheral neuropathy symptoms related 15 (yes/no type) self administered, questions. A higher score (total score 13) indicates higher neuropathic symptoms. The Second component of the MNSI is a brief physical examination involving a) inspection of the feet; b) semi-quantitative assessment of vibration sensation at the dorsum of great toe; c) grading of ankle reflexes; and d) Semmes-Weinstein monofilament testing. Patients are considered neuropathic if they are screen positive (score ≥ 2.5 on a 10 point scale) on the second component of MNSI.

The International Working Group on Diabetic Foot (IWGDF) Risk Classification System was used to classify study subjects foot problems¹⁷.

Statistical analysis:

Data were codified and analyzed using SPSS (Statistical Package for Social Sciences) version 20.0 for Windows. Frequency of clinic-social variables was calculated. Chi-square test was used to show association between categorical variables.

III. Result

The mean age of the study participants was 53.19 years (SD 10.4). 153 (63.0%) study participants were in the 41-60 years age group, followed by 60 (24.7%) and 60 (24.7%) from ≥ 61 years and 30 (12.3%) from ≤ 40 years age group. There was male preponderance in the study population, 156 (64.2%) of them were male and 87 (35.8%) were females. 178 (73.3%) were residents of urban area and rest were from rural area. 89 (36.6%) were current smoker. 122 (50.2%) of the

study population had > greater than class X education followed by 86 (35.4%), 24 (9.9) and 11 (4.5) of the study participants were educated up to class VI-X, illiterate and up to class V respectively. 101 (41.6%) of the study participants had family history of T2DM. Duration of T2DM among study participants was 0-5 years in 101 (41.6%) followed by 6-10 years and ≥ 11 years in 65 (26.7) and 77 (31.7%) of the study participants respectively. 76.1 % of study participants were treated with Oral Hypoglycemic Agents (OHA) alone and 23.9% were treated with both Insulin & OHA (Table-1).

As per WHO BMI classification for International comparison, 115 (47.3%) of study participants were normal, 90 (37.0%) were overweight, 33 (13.6) were obese and 5 (2.1%) were underweight. 172 (70.8%) of study participants had central obesity as reflected by high waist circumference. As co-morbidity, hypertension, hypercholesterolemia, ischaemic heart disease and hypothyroidism was present in 120 (49.4%), 56 (23.0%), 25 (10.3%), 42 (17.3%) of study participants respectively. Diabetic foot syndrome (DFS) was present in 163 (67.1%) of study participants (Table-1). The prevalence of DFS was found to be 67.1% (Table-1).

Numbness of feet, burning sensation in feet, too sensitive to touch and prickling sensation in feet was reported by 56.8%, 50.2%, 40.3% and 37.0% of study participants respectively. About 21.0% of study participants were unable to differentiate between hot & cold sensation and about 35.4% of study participants reported worsening of symptoms at night. About 9% and 6% of study participants had history of peripheral neuropathy and lower limb amputation respectively (Table-2). On physical examination, about 64% study participants had abnormal appearance of their feet. Dry Skin/Callus, infection, deformity, ingrown nails and fissure were present in the feet of 46.5%, 20.2%, 13.1%, 9.9% and 4.9% of study participants respectively. Foot ulcers were present in 6.6% of study participants. A reduced/absent ankle jerk was present in 20.2% of study participants. 51.4% of study participants had reduced/absent vibration perception with 128Hz tuning fork and 37.9% had loss of protective sensation on 10g SW Monofilament testing (Table-3). 36 (14.8%) of the study participants had peripheral vascular disease (PAD) as reflected by reduced Ankle-Brachial Index (<0.9).

The overall prevalence of DFS in our study participants was 67.1% (Table-1). According to “the International Working Group on Diabetic Foot (IWGDF) Risk Classification System”, 32.9% were category 0 (normal) and remaining 67.1% had foot risk. 42.4% of study participants foot were in risk category 1, 15.2% were in the risk category 2 and 9.5% were in the risk category 3 (Table-4). Increasing age, longer duration of diabetes, female gender, smoking, treatment with insulin, central obesity, obesity, hypertension, ischemic heart disease and hypothyroidism was significantly associated with DFS among study participants. There was no statistically significant association between study participant’s residential area, educational status, positive family history of T2DM, hypercholesterolemia and DFS (Table-5).

Table 1: Shows clinico-social characteristics of study subjects (n=243)

Clinico-Social characteristics	n(%)	Clinico-Social characteristics	n(%)
Age group		BMI (Kg/m²)	
≤40yrs	30(12.3)	Underweight (<18.5)	5 (2.1)
41-60yrs	153 (63.0)	Normal (18.5-24.9)	115 (47.3)
≥61 yrs	60 (24.7)	Overweight (25.0-29.9)	90 (37.0)
Sex		Obese (≥30.0)	33 (13.6)
Male	156 (64.2)	Waist Circumference (Cm)	
Female	87 (35.8)	Normal	71 (29.2)
Residence		High(Male>90;Female>80)	172 (70.8)
Urban	178 (73.3)	Hypertension (mmHg)	
Rural	65 (26.7)	Normal	123 (50.6)
Current smoker		High(≥140/90)	120 (49.4)
Yes	89 (36.6)	Hypercholesterolemia	
No	154 (63.4)	Present	56 (23.0)
Educational status		Absent	187 (77.0)
Illiterate	24 (9.9)	Ischemic Heart Disease	
Up to class V	11 (4.5)	Present	25 (10.3)
Class VI-X	86 (35.4)	Absent	218 (89.7%)
>Class X	122 (50.2)	Hypothyroidism	
Family History of T2DM		Present	42 (17.3)
Yes	112 (46.1)	Absent	201 (82.7)
No	131 (53.9)	Diabetic Foot Syndrome	
Duration of Diabetes		Present	163 (67.1)
0-5years	101 (41.6)	Absent	80 (32.9)
6-10 years	65 (26.7)		
>10years	77 (31.7)		
Treatment Regimen			
Insulin + Oral Hypoglycemic Medicines	58 (23.9)		
Oral Hypoglycemic medicines	185 (76.1)		

Table-2: Shows response of study participants to the first component of Michigan Neuropathy Screening Instruments (MNSI) questionnaire* (n=243)

Questions	Response	
	Yes (%)	No (%)
Q1-Are your legs and/or feet numb?	138 (56.8)	105 (43.2)
Q2- Do you ever have any burning pain in your legs and/or feet?	122 (50.2)	121 (49.8)
Q3- Are your feet too sensitive to touch?	98 (40.3)	145 (59.7)
Q5- Do you ever have any pricking feelings in your legs or feet?	90 (37.0)	153 (63.0)
Q6- Does it hurt when the bed cover touches your skin?	43 (17.7)	200 (82.3)
Q7- When you get into the tub or shower, are you able to tell the hot water from the cold water?	193 (79.5)	50 (20.5)
Q8- Have you ever had an open sore on your foot?	40 (16.5)	203 (83.5)

Q9- Has your doctor ever told you that you have diabetic neuropathy?	22 (9.1)	121 (90.9)
Q11- Are your symptoms worse at night?	86 (35.4)	157 (64.6)
Q12- Do your legs hurt when you walk?	33 (13.5)	210 (86.5)
Q13- Are you able to sense your feet when you walk?	210 (86.4)	33 (13.6)
Q14- Is the skin on your feet so dry that it cracks open?	52 (21.4)	191 (78.6)
Q15- Have you ever had an amputation?	14 (5.7)	129 (94.3)

*Question number 4 & 10 excluded because they are not part of score calculation.

Table-3: Shows 2nd component of the Michigan Neuropathy Screening Instruments (MNSI) assessment findings of the study participants (n=243)

Physical assessment	Yes (%)	No (%)
1. Appearance of Feet- Normal	88 (36.2)	155 (63.8)
Deformities	32 (13.1)	211 (86.9)
Dry skin, callus	113 (46.5)	130 (53.5)
Infection	49 (20.2)	194 (79.8)
Fissure	12 (4.9)	231 (95.1)
Ingrown nails	24 (9.9)	219 (90.1)
2. Ulceration present	16 (6.6)	227 (93.4)
3. Ankle Reflexes reduced/absent	49 (20.2)	194 (79.8)
4. Vibration perception at great toe absent/decreased	125 (51.4)	118 (48.6)
5. 10gm SW Monofilament test reduced/absent	92 (37.9)	151 (62.1)

Table-4: Shows Classification of diabetic foot syndrome according to IWGDF Risk Classification System (n=243)

Risk Category	Characteristics	n(%)
Category 0	No peripheral Neuropathy	80 (32.9)
Category 1	Peripheral Neuropathy	103 (42.4)
Category 2	Peripheral Neuropathy with PAD and/or a foot deformity	37 (15.2)
Category 3	Peripheral Neuropathy and a history of foot ulcer or lower extremity amputation	23 (9.5)

Table-5: Showing association between Clinico-social determinants and DFS (n=243)

C-S Factors	Diabetic Foot Syndrome		Total n (%)	χ^2 (df)	p value
	Yes (%)	No (%)			
Age Group					
≤40 years	12 (40.0)	18 (60.0)	30 (100.0)		
41-60 years years	103 (67.3)	50(32.7)	153 (100.0)	14.5 (2)	0.001
≥61 Years	48 (80.0)	12 (20.0)	60 (100.0)		
Sex					
Male	96 (61.5)	60 (38.5)	156(100.0)		
Female	67 (77.0)	20 (23.0)	87 (100.0)	6.1 (1)	0.009
Residence					
Urban	120 (67.4)	58 (32.6)	178(100.0)		
Rural	43 (66.2)	22 (33.8)	65 (100.0)	0.03(1)	0.484
Educational Status					
Illiterate	20 (83.3)	4 (16.7)	24 (100.0)		
Up to Class V	7 (63.6)	4 (36.4)	11 (100.0)		
Class VI- X	55 (64.0)	31 (36.0)	86 (100.0)	3.3 (3)	0.343
>Class X	81 (66.4)	41 (35.6)	122 (100.0)		
Addiction (current Smoker)					
Yes	66 (74.2)	23 (25.8)	89 (100.0)		
No	97 (63.0)	57 (37.0)	154 (100.0)	3.2 (1)	0.049
Family History of T2DM					
Yes	75 (67.0)	37 (33.0)	110 (100.0)		
No	88 (67.2)	43 (32.8)	131 (100.0)	0.001 (1)	0.540
Duration of Diabetes					
0-5 years	53 (52.5)	48 (47.5)	101 (100.0)		
6-10 years	46 (70.8)	19 (29.2)	65 (100.0)		
≥ 11 years	64 (83.1)	13 (16.9)	77 (100.0)	19.1(2)	0.000
Treatment Regimen					
Insulin+ OHA	46 (79.3)	12 (20.7)	58 (100.0)		
OHA only	117 (63.2)	68 (36.8)	185 (100.0)	5.1(1)	0.016
Waist Circumference					
Normal	32 (45.1)	39 (54.9)	71 (100.0)		
High(Male>90;Female>80)	131 (76.2)	41 (23.8)	174 (100.0)	22.0(1)	0.000
BMI (Kg/m²)					
Underweight (<18.5)	2 (40.0)	3 (60.0)	5 (100.0)		
Normal (18.5-24.9)	53 (46.1)	62 (53.9)	115 (100.0)	48.7 (3)	0.000
Overweight (25.0-29.9)	78 (86.7)	12 (13.3)	90 (100.0)		
Obese (≥ 30.0)	30 (90.9)	3 (9.1)	33 (100.0)		
Hypertension					
Yes	98 (91.7)	22 (8.3)	120 (100.0)		
No	65 (52.8)	58 (47.2)	123 (100.0)	22.8(1)	0.000
Hypercholesterolemia					
Yes	41 (73.2)	15 (26.8)	56 (100.0)		
No	122 (65.2)	65 (34.8)	187 (100.0)	1.2(1)	0.171
Ischemic Heart Disease					
Yes	21 (84.0)	4 (16.0)	25 (100.0)		
No	142 (65.1)	76 (34.9)	118 (100.0)	3.6(1)	0.042
Hypothyroidism					

Yes	36 (85.7)	6 (14.3)	42 (100.0)		
No	127 (63.2)	74 (36.8)	201 (100.0)	7.9 (1)	0.003

IV. Discussion

In this study, the prevalence of Diabetic Foot Syndrome (DFS) was found to be 67.1%. According to “the International Working Group on Diabetic Foot (IWGDF) Risk Classification System”, 32.9% were category 0 (normal) and remaining 67.1% had foot risk. 42.4% of study participants foot were in risk category 1, 15.2% were in the risk category 2 and 9.5% were in the risk category 3. Several other studies from India as well as from other countries reported the prevalence of DFS and peripheral from 42.0%-52.0%¹⁸⁻²¹. Higher prevalence of DFS and Diabetic Peripheral Neuropathy (DPN) in our study may be due to the selective referral of high risk and complicated cases at IDGDC. In a study done by Lawrence A Lavery et al. the prevalence of Category 3 foot was found to be 10.8%²⁰. However, D’Souza M et al reported a much lower 18.3% prevalence of DPN²². Numbness of feet was the most common symptom, reported by 56.8% of study participants. Burning sensation in feet, too sensitive to touch and pricking sensation in feet was reported by 50.2%, 40.3% and 37.0% of study participants respectively. Numbness of feet as the most common symptom of DPN was also reported by Vibha S.P et al¹⁸. Pain during walking (65.4%) followed by pricking sensation in feet (63.0%) as most common symptoms was reported by D’souza M et al²². About 2/3rd of the study participants had abnormal looking feet. Most common abnormality present was dry feet/callus in 46.5% of study participants, followed by infection, deformity; ingrown nails and fissure were present in the feet of 20.2%, 13.1%, 9.9% and 4.9% of study participants respectively. A higher prevalence of 74.5% foot abnormality was reported by Vibha SP et al¹⁸. Most common abnormality in their study was dry feet/callus followed by infections, which are similar to our study findings. In this study, the prevalence of Peripheral Artery Disease (PAD) as reflected by reduced Ankle-Brachial Index (<0.9) was found to be 14.8%. A 36.0% prevalence of PAD in among diabetes patients was reported by Shukla V et al. However, a lower prevalence 3.5%²⁴ and a higher prevalence 42.6%²⁵ of PAD using Ankle Brachial Index were reported by other studies.

Increasing age was significantly associated with DFS and DPN. Similar association of advancing age with DFS and DPN were reported by Vibha SP et al¹⁸, D’souza M et al²², Dipika Bansal et al²⁶ and Sailesh K shahi et al²⁷.

DPN and DFS were significantly associated with female sex. Solanki JD et al²⁸ and Ali Z²⁹ reported similar significant association between female gender and DPN. However, few other studies reported significant association with male gender²². Smoking is an established risk factor for DFS and was significantly associated with DFS in this study too. Similar significant association of smoking with DFS was also reported by various studies²⁶⁻²⁷. Treatment with insulin was significantly associated with DFS which may attribute to the long standing and complicated nature of insulin treated cases. Similar findings were reported by Vibha SP et al¹⁸. In this study a significant association between High Waist Circumference and High BMI was found. This may be due to the fact that obesity can hamper long term Glycemic control which may in turn is a risk factor for DFS. However, few researchers did not report any significant association between DFS and Obesity³⁰⁻³¹. Hypertension and ischemic heart disease significantly favored the occurrence of DFS. This finding is in agreement with various other studies^{18, 26-28}. While the effect of hypothyroidism on DFS is not well established and conflicting, we found a significant association between hypothyroidism and DFS. A study from China also reported significant association between hypothyroidism and Diabetic peripheral neuropathy³².

Results of the study cannot be generalized as the study has been conducted in a Specialty Unit which is bound to get more complicated cases.

V. Conclusion

There is high prevalence of Diabetic Foot Syndrome and diabetic peripheral neuropathy. Most of the risk factors like obesity, smoking, hypertension are modifiable. Control of modifiable risk factors may prevent or delay the progression of DFS and subsequent lower limb amputation.

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