Original Article

The Burden of Diabetic Foot Ulcers in Urban India: A Community Healthcare Setup-Based Study

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Abstract

Introduction: Foot ulcer is the most common cause of hospitalisation among people with diabetes (PWD). The objective of the study is to determine the incidence of diabetic foot ulcers (DFUs) in the urban community in India and its relationship with glycemic level and demographic parameters like age and sex among diabetic patients. **Methods:** A retrospective observational study was performed from January 2016 to December 2018 at an urban community set up in Mumbai. The study was conducted in a healthcare setting, providing lifelong contributory healthcare to beneficiaries of an employees' universal healthcare scheme. PWD from the community was identified using prescriptions of anti-diabetic medications. We identified patients with DFUs from electronic medical records from the hospital information system (HIS). The yearly incidence rate of DFU among PWD was estimated for the study period. The association between glycemic control and the demographic profile of patients with DFU was studied using binary logistic regression. **Results:** The study documents the average incidence of 66 DFU patients among 10,000 PWD per year in the community. Logistic regression analysis showed higher odds for the elderly age group (OR 2.863) compared to lower age for developing DFU. Similarly, poor control (HbA1c >7%) over glycemic level has a higher chance (OR 1.713) of DFU than that of optimum glycemic control (HbA1c ≤7%). Among the DFU, 15.29% of patients required amputation during the study period. **Conclusion:** The study documents the community-level incidence of DFUs among patients with diabetes. High glycemic levels and elderly age groups (≥60) are the associated risk factors for DFU.

Keywords: Community-based incidence, diabetes complications, diabetic foot ulcer, glycemic control, lower extremity amputation

Introduction

India is emerging as the diabetic capital of the world, with 69.2 million people with diabetes (PWD) in 2015, with a prevalence rate of 8.8% and a projected 123.5 million cases in 2040.[1] Uncontrolled diabetes leads to various complications, including peripheral neuropathy resulting in foot ulcerations, nephropathy and retinopathy.[2–4] Diabetic foot ulcer (DFU) is one of the leading reasons for hospitalisation among PWD.[5–7] Globally, the prevalence of DFUs is 6.3% within PWD, of which males (4.5%) constitute a higher proportion.[8] A systematic review in India found that around 25% of PWD were diagnosed with DFU. Among those, 50% required hospitalisation due to further infection, and 20% needed amputation.[9]

Diabetes is the leading cause of non-traumatic foot amputations.[10–13] DFU is the precursor for foot amputation, as most amputations start as an ulcer. An increase in DFU and its related amputations causes an additional burden to the patient and the healthcare system. It also affects the quality of life of a patient and inflicts an economic burden on the patient and family.[9,14]

To prevent DFU, regular screening is recommended to identify feet at risk of complications. Markov model-based studies have reported a reduction in healthcare costs of treating DFUs and lower extremity amputations merely by regular foot examination, risk stratification, clinician education, and

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patient education.[15,16] Studies reported about the incidence of DFUs in low-middle-income countries (LMICs) are either restricted to institutional setting-based research or relatively sparse. A community-based incidence of DFU within a defined population and with accessible, affordable and the available access to healthcare services can be useful to estimate the actual burden of the DFU in the community. We estimated the incidence of DFUs among PWD in the urban community in Mumbai. We also explore the relationship between DFUs with glycemic level and socio-demographic characteristics.

Materials and Methods

We performed a retrospective observational study from January 2016 to December 2018 at an urban community healthcare setup in Mumbai using the computerised database of Bhabha Atomic Research Centre (BARC) Hospital Mumbai. This study involves beneficiaries of a universal health coverage (UHC) scheme for the employees of BARC under the Department of Atomic Energy, Government of India. A two-tiered health system consists of thirteen primary health centres (PHCs) that function at a community level and a central referral hospital. The scheme has 100,000 beneficiaries enrolled for health coverage (working and retired employees along with their family members). All facilities (hospital and PHCs) are interlinked through a computerised hospital information system (HIS). The details about community healthcare were published earlier.[17] All the past and current clinical records and demographical details are available in the HIS for all the beneficiaries of the healthcare scheme. All the beneficiaries are availiing this scheme for a lifelong period. The Department of Surgery at BARC Hospital, with 55 beds, provides both foot protection services and tertiary care management of foot complications, and there are no particular community podiatry services.

We included all the health beneficiaries with diabetes of age 18 and above getting treatment during the study period. For this study, we used the operational definition of a patient with diabetes as an 'adult with age 18 years and above and receiving at least one medicine or insulin for the management of diabetes'. Pharmacy dispensing records from HIS were used to identify patients with diabetes. Women with gestational diabetes and patients on metformin for indications other than diabetes were manually identified from HIS and excluded from the study.

A DFU was defined as 'an infection, ulceration or destruction of deep tissues associated with neurological abnormalities and various degrees of peripheral vascular diseases in the lower limb'.[18] Operation theatre (OT) records and clinical progress notes from HIS were used to identify the patients with DFU. People receiving medications to control diabetes were separately identified for each year from Jan 2016 to December 2018. Similarly, 4 yearly distinct patients with DFU were identified to calculate the incidence in the community.

Individuals with DFU who had a major or minor amputation were identified based on OT records and were considered for subgroup analysis.

We considered demographic details of patients like age, sex, duration of diabetes, glycemic control using yearly average values of glycosylated haemoglobin (HbA1c) and fasting plasma glucose (FPG) as independent variables. Based on average HbA1c values, diabetes control was further categorised as optimum (HbA1c ≤7%) and poor (HbA1c >7%).[19]

Statistical analysis

We extracted data from HIS in comma-separated values format and performed the analysis using the SPSS version 25.0 (SPSS Inc., Chicago, IL, USA) and Microsoft Excel 2019 for Windows. To check the normality of the continuous data Kolmogorov–Smirnov test was conducted. Non-normal variables were presented using median and interquartile range (IQR). Categorical data are reported in absolute numbers and percentages of the group. To compare the two groups (with DFU and without DFU and with amputees and without amputees) Mann–Whitney U test for non-normally distributed variables and the Chi-squared test for qualitative variables were carried out. We estimated the yearly DFU incidence using the ratio of yearly DFU cases with yearly PWD. Logistics regression analysis was performed with DFU as a dependent variable and glycemic control and demographical parameters as independent variables. Further, we performed a subgroup analysis for feet-related amputation. We considered the *P* value below 0.05 as a statistically significant difference.

Ethical aspects

The study was approved by the institutional scientific committee as well as ethics committee during their meeting held on 13/08/2019.

Results

We found a total of 16,127 PWD during a study period of three years in our community. In this period, a total of 242 patients presented with DFU. Of these 242 patients, 37 (15.29%) required minor or major foot amputations [Figure 1].

Baseline demographic characteristics of diabetic patients with or without foot ulcers are shown in Table 1. Two out of three DFU patients were males. Nearly 63% of patients with DFU had poor glycemic control. Two out of five DFU patients had diabetes for more than five years. Median HbA1c was significantly higher for patients with DFU (8.29) compared to non-DFU individuals (7.35) (*P* value <0.001). Similarly, the age of DFU patients was significantly higher than that of non-DFU cases (*P* value <0.001). [Table 1].

During the study period of three years, a total of 1.5% of the PWD suffered from DFU. A total of 11,735, 12,014 and 12,983 patients have taken treatment for diabetes during the study years 2016, 2017 and 2018, respectively. On average, 0.66% of PWD are seen to have DFU yearly in this study. On average, 0.89% and 0.43% of diabetic males and females, respectively, were affected with DFU during the study period. Elderly patients (>60 years) were seen to be at a higher risk

Table 1: Overall participant characteristics of diabetic patients reported with and without foot ulcer in the study period of three year

Narration	Patients with diabetes enrolled over a period of 3 years (2016-18)			
	Without DFU	With DFU	Overall	*P*
Total number of patients	15,885 (98.5%)	242 (1.5%)	16,127	
Sex				
Male	7,914 (49.82%)	165 (68.18%)	8,079 (50.1%)	<0.001
Female	7,971 (50.18%)	77 (31.82%)	8,048 (49.9%)	
Age group				
18-40 years	918 (5.78%)	6 (2.48%)	924 (5.73%)	<0.001
41-60 years	6,417 (40.4%)	76 (31.4%)	6,493 (40.26%)	
>60 years	8,550 (53.82%)	160 (66.12%)	8,710 (54.01%)	
Glycaemic control using HbA1c				
Optimum control (≤7%)	5,207 (38.95%)	57 (27.14%)	5,264 (38.77%)	<0.001
Poor control (>7%)	8,161 (61.05%)	153 (72.86%)	8,314 (61.23%)	
Duration of diabetse				
≤5 years	9,940 (68.25%)	143 (59.09%)	10,083 (68.1%)	0.002
>5 years	4,625 (31.75%)	99 (40.91%)	4,724 (31.9%)	
Independent variables (Median (IQR))				
Age	62 (53-70)	66 (56-73)	62 (53-70)	<0.001
HbA1c	7.35 (6.7-8.5)	8.29 (6.9-9.88)	7.35 (6.7-8.5)	<0.001
FPG	129.62 (111.75-155)	140.5 (116-184.28)	129.75 (111.9-155.3)	<0.001

DFU: diabetic foot ulcer, HbA1c: glycosylated haemoglobin, FPG: fasting plasma glucose

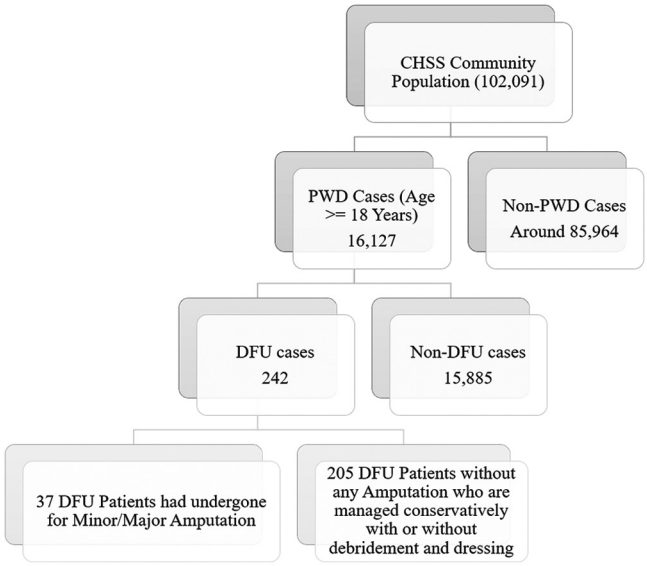

Figure 1: Patient flow diagram

of DFU compared to the younger age individuals throughout the three years of the study period. PWDs who had diabetes for more than five years had higher incidence of DFU than those who had diabetes for less than or equal to five years. Similarly, poor glycemic control was associated with a higher proportion of incidence cases than that optimum glycemic control. We found a decreasing trend in the yearly DFU incident cases. [Table 2].

Table 3 describes the risk factors for DFU. The elderly age group is seen to have 2.83 times higher odds of foot ulcers compared to the younger age group patients. Similarly, males (OR 2.158) were seen to be at a higher risk of DFU compared to females. Further, long duration of diabetes (OR 1.488), poor glycemic control level (OR 1.713) and high FPG (OR 1.395) indicated the overall risk factors for DFU.

In the subgroup analysis of patients who had ever been examined for DFU, we found that 37 (15.29%) of them underwent amputations during the study period. Among amputees, males were higher in proportion than females. Increasing age and poor glycemic control were the risk factors for amputations [Table 4].

Discussion

The current study documented a yearly average DFU incidence rate of 0.66% among PWD in the community. Of these DFU cases, 15.29% of patients needed either major or minor amputations during the study period. The yearly incidence of DFU reported in the present study is lower than that of reported rates in the literature. A community-based study reported 1.93% of new foot ulcers during an average one-year follow-up period.[20] Another cohort study from China has found that 8.1% of diabetic patients developed new ulcers in their feet during the follow-up period of one year.[6] The institutional-based study from Northwest Ethiopia has reported an incidence rate of 4 cases per 100 diabetic cases.[21] A population-based diabetic foot cohort study reported a 5.62% cumulative incidence of DFU for two years which is much higher than this present study.[22]

Studies have reported higher vulnerability among males in the elderly age group. Further risk enhances among those with a history of smoking and alcoholism.[23,24] In a similar line, the

Table 2: Incidence of the diabetic foot ulcer (DFU) among people with diabetes (PWD) in the community

	Yearly Incidence		
	2016	2017	2018
PWD patients	11,735	12,014	12,983
Total DFU patients	87 (0.74%)	80 (0.67%)	75 (0.58%)
Sex			
Male	61 (1.02%)	54 (0.89%)	50 (0.77%)
Female	26 (0.45%)	26 (0.44%)	25 (0.39%)
Age Group			
18-40 years	3 (0.57%)	2 (0.43%)	2 (0.37%)
41-60 years	20 (0.44%)	31 (0.67%)	24 (0.47%)
>60 years	64 (0.96%)	47 (0.68%)	49 (0.67%)
Duration of diabetes			
≤5 years	45 (0.69%)	52 (0.75%)	46 (0.58%)
>5 years	42 (0.97%)	28 (0.66%)	29 (0.69%)
Average HbA1c			
Optimum control (≤7%)	16 (0.66%)	13 (0.45%)	11 (0.34%)
Poor control (>7%)	47 (0.88%)	48 (0.89%)	49 (0.80%)

Table 3: Association of diabetic foot ulcer with demographic and glycemic parameters

	Unadjusted		Adjusted	
	Odds Ratio (95% CI)	*P*	Odds Ratio (95% CI)	*P*
Sex				
Female	reference			
Male	2.158 (1.644-2.834)	<0.001	2.082 (1.531-2.832)	<0.001
Age Group				
18-40 years	reference			
41-60 years	1.812 (0.787-4.172)	0.162	1.131 (0.485-2.635)	0.776
>60 years	2.863 (1.264-6.487)	0.012	1.894 (0.827-4.34)	0.131
Duration of diabetes				
≤5 years	reference			
>5 years	1.488 (1.149-1.927)	0.003	1.374 (1.018-1.853)	0.038
HbA1c				
Optimum control (≤7%)	reference			
Poor control (>7%)	1.713 (1.261-2.326)	0.001	1.439 (0.985-2.103)	0.06
FPG				
≤126	reference			
>126	1.395 (1.049-1.854)	0.022	1.206 (0.85-1.709)	0.294

HbA1c: glycosylated haemoglobin, FPG: fasting plasma glucose

present study reported that 68% of DFUs were males. However, no difference was seen in the mean age of the patients of either sex. In the Indian scenario, males are the prime earners in most families and are mostly involved in outdoor activities than females. So, they are more prone to leg injuries and hence more vulnerable to diabetic foot-related problems.

Higher chances of DFU complications in the elderly (>60 years) compared to younger age groups (≤ 60 years) can be accounted for by various age-related issues. Studies conducted in Thailand and India have shown a significant association between older age and DFU.[25,26] The longer duration of diabetes was significantly associated with the increasing risk of DFU (OR 1.488) [Table 3]. Studies performed in Jordan and China also highlighted the association of increased duration of diabetes.[6,24]

Poor glycemic level (HbA1c >7%) was seen to have a crucial impact on the risk factor of DFU in the present study. In the present study, the binary logistic regression has shown a significant relationship between higher glycemic levels and the risk of amputation. Compared to optimum control glycemic level (HbA1c ≤7%), poor control glycemic level (HbA1c >7%) patients have a 1.439 times higher risk for DFU when adjusted to other confounding factors. [Table 3] Uncontrolled glucose level increases the severity of the ulcer. Studies have reported issues in wound healing delays and more extended hospitalisation due to poor glycemic control.[27–29] The development of neuropathy can be controlled significantly by maintaining glycemic levels at normal levels.[30]

The present study documented 15.29% amputations among DFU cases. Of these amputees, 68% were males, and 66% belonged to elderly age (>60 Years). There was no significant age difference observed between amputees and non-amputees. The included number of amputees was smaller hence the power of sample size is reduced leading to no difference in the mean age of the two groups. Systematic review and meta-analysis reported that males are at a higher risk of amputation than females.[31] Another systematic review has documented that HbA1c levels ≥8% are associated with lower extremity amputations in patients with DFUs.[32] Studies reported various significant risk factors for amputation among DFU patients, which include peripheral arterial disease, poor glycemic control, hypertriglyceridemia and hypertension.[33,34] The present study has documented significantly high glycemic levels among amputees (median HbA1c = 10.43) than that of non-amputees (median HbA1c = 8.11) for females. Frequent screening of glycemic levels can help patients and treating doctors detect complications in the early stage.[35] The Indian scenario of seeking diabetic foot help is much more different than that of Western countries. In India, delays are often evident in the standard treatment guidelines. These delays are mainly because of factors like accessibility, affordability, lower awareness and poor knowledge about the consequences of untreated conditions.[36] In developing countries, such delays pertaining to appropriate care for chronic conditions like DFU are high, which may further lead to exponential growth in the overall treatment costs.[4]

Limitations

The present study has some limitations. First the common barriers to healthcare like access, affordability and availability

Table 4: Risk factors for amputations

	With amputation (row%)	Without amputation (row%)	Overall (col%)	*P*
Overall count	37 (15.29%)	205 (84.71%)	242	
Sex				
Male	28 (16.97%)	137 (83.03%)	165 (68.18%)	0.288
Female	9 (11.69%)	68 (88.31%)	77 (31.82%)	
Age group				
18-40 years	(0.00%)	6 (100%)	6 (2.48%)	0.853
41-60 years	11 (14.47%)	65 (85.53%)	76 (31.4%)	
>60 years	26 (16.25%)	134 (83.75%)	160 (66.12%)	
Duration of diabetes				
≤5 years	21 (14.69%)	122 (85.31%)	143 (59.09%)	0.754
>5 years	16 (16.16%)	83 (83.84%)	99 (40.91%)	
HbA1c				
Optimum control (≤7%)	2 (3.51%)	55 (96.49%)	57 (23.55%)	0.016
Poor control (>7%)	28 (18.3%)	125 (81.7%)	153 (63.22%)	
Not available	7 (21.88%)	25 (78.13%)	32 (13.22%)	
Age (Median (IQR))				
Overall	64 (58-70)	66 (56-73)	66 (56-73)	0.142
Male	64 (55-71.5)	66 (55-74)	65 (55-74)	0.578
Female	67 (63-69)	66.5 (57-72)	67 (58-71)	0.170
HbA1c (Median (IQR))				
Overall	9.03 (7.9-10.32)	8.14 (6.79-9.83)	8.29 (6.9-9.88)	<0.001
Male	8.74 (7.8-9.77)	8.15 (6.9-9.67)	8.29 (7-9.67)	<0.001
Female	10.32 (8.05-12.22)	8.11 (6.73-10.13)	8.34 (6.73-10.32)	0.013

HbA1c: glycosylated haemoglobin

were nearly eliminated for the community as they are availing the health facility in line with the UHC scheme. Few attritions may be possible in the present study as patients who opt to get treated outside on their own are beyond the scope of this work. However, considering the dedicated community healthcare setup in close proximity to the city, a negligible number of patients might have taken the treatment outside. Undiagnosed diabetics in the community are beyond the reach of this study. Second, the diabetic neuropathy, risk factors like smoking, drinking, and associated comorbid conditions of an individual may influence the development of feet ulcer in the patient. We were not able to consider these parameters in the present study due to non-availability of retrospective data in HIS. Third, the study population belongs to the urban middle-class community, which may not be representative of the urban population. However, results can be considered in similar contexts with age-sex adjustment for the required population dividend.

Early identification of the 'foot at risk' can save the life-long disability and further burden on health service resources. Through careful inspection, physical examination of the foot and patient education, unnecessary amputation can be avoided by early and appropriate intervention on foot ulcers. Knowledge about the management of diabetics and its complications is essential education for patients. The findings of this study will be helpful for policymakers and even physicians to identify the risk factors for DFU, and they can make necessary efforts to minimise the complications and minimise the economic burden.

Conclusion

The present study documents the community-level incidence of DFUs among patients with diabetes. We found that 15.29% of individuals underwent major or minor amputations among those who presented with diabetic foot-related ulcers. Advanced age, duration of diabetse and poor glycemic levels are associated risk factors for the development of foot ulcers. Organised screening programmes for diabetic foot neuropathy and related awareness may help to attend to complicated conditions. Further research will be helpful in determining the effectiveness of a diabetic foot prevention program and in reducing amputations and related hospitalisations.

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Author contributions

PP, SM, and AG have participated in the concept and design of the work. PP and PB have done the analysis and interpretation of the data. PP, SM, AG, and PB have drafted the manuscript. All the authors have critically reviewed the article and approved the final version of the article.

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Conflicts of interest

There are no conflicts of interest.

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