

E-ISSN:2320-3137

# **Research Article**

# AN OBSERVATIONAL STUDY ON THE CORRELATION OF THE SEVERITY OF DIABETIC FOOT ULCER DISEASE WITH THE SOCIO-DEMOGRAPHIC PROFILE AND CONCOMITANT PRESENCE OF HYPERTENSION AND DYSLIPIDEMIA IN AN URBAN POPULATION OF INDIA

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#### Abstract

The study is to determine the common risk factors affecting the diabetic foot ulcer disease with its implications and the severity of the disease in relation to the socio-economic status, level of education, concomitant hypertension anddyslipidemiawith particular correlation to the incidence of amputation. The study was done in 53 patients admitted in the surgical ward of a large private medical college hospital in Kolkata, India over a period of one year. The selected patients were randomly selected as per criteria of modified Kuppuswamy's socio-economic scale 2007 for the urban population in India, with education level from primary school (up to Class VIII) to post-graduation. The severity of the ulcers were determined by Wagner classification and the patients were managed either conservatively or surgically (wound debridement or amputation). It has been found from this study that the incidence and severity of diabetic foot ulcer is more in patients with lower socio-economic status and low education level, especially in females. 86.79% of the patients developed the foot ulcer after a minor trauma, friction or injury due to a foreign body, apparently may be due to the habit of walking bare foot and ignorant about optimum foot care. A strong correlation is found in patients suffering from hypertension (58.49% of the total patients) and the severity of the foot ulcer disease. Dyslipidemia as determined by serum LDL level in our study, was found to be abnormal in 86.79% of patients which may be a significant prognostic indicator for the development and severity of diabetic foot ulcer disease. Surgical intervention had to be done in 62.26% of patients and ultimately 28.30% of them undergone amputation, mostly in Wagner Stage IV foot ulcers. The incidence of amputation was highest in female patients with low education level and socio-economic status.

**Key words:** Diabetic foot ulcer, , education level and diabetic foot disease, hypertension and diabetic foot disease, serum LDL and diabetic foot disease, socio-economic status and diabetic foot ulcer disease.

## INTERNATIONAL JOURNAL OF MEDICAL AND APPLIED SCIENCES E-ISSN:2320-3137



E-ISSN:2320-3137

## INTRODUCTION

Diabetes mellitus, one of the major risk factor accounting for premature morbidity and mortality, largely due to its complications. India being the diabetic capital of the world, currently has more than 35 million people affected by the disease, with future estimation of about 80 million people in 2030 [1].

One of the most significant complication of diabetes mellitus is the disease affecting the foot, which often lead to amputations and was found to be quite common in the developing countries like India [1]. Life time risk to a person with diabetes for developing a foot ulcer could be as high as 25%. Diabetic foot ulcers result from the simultaneous action of multiple contributing causes. The major underlying causes are noted to be peripheral neuropathy and ischemia from peripheral vascular disease. Moreover, smoking, hypertension, and hyperlipidemia are other factors that are common in diabetic patients and contribute to the development of PAD.Cumulatively, this leads to occlusive arterial disease that results in ischemia in the lower extremity and an increased risk of ulceration in diabetic patients [21]. Diabetic neuropathy can lead to loss of sensation of distal extremities like foot. It is not a single disease and encompasses several neuropathic syndromes, of which the commonest is peripheral symmetrical polyneuropathy. Advanced peripheral neuropathy results in insensitivity facilitating trauma, altered proprioception and small muscle wasting, leading to altered weight loading under the foot on standing and walking. Late the foot can secondarily become infected, often with polymicrobial invasion [2]. The alarming fact in India is that the incidence of foot disease and subsequent amputation remains very high, accounting for up to 20% of diabetes-related hospital

admissions. Amputations among people with diabetes far exceeds that of non-diabetic subjects with almost five out of six amputations occur in diabetes. The vast majority of all diabetic related amputations are preceded by foot ulcers [1]. This can be easily attributed to several practices prevalent in India, such as bare foot walking, inadequate facilities for diabetes care, low socio-economic status and more importantly ignorance and illiteracy [3]. The significant risk factors for a patient with diabetes requiring amputation are lower extremity ischemia, neuropathy, a history of foot ulcer, elevated HbA1c and retinopathy. The indicators for lower extremity amputations in diabetics include septic gangrene, peripheral arterial occlusion, non-healing ulcer, severe soft tissue infection and osteomyelitis.

It was documented that the recurrence of foot infection was common among diabetic patients in India which is about 52% [4].

## AIMS AND OBJECTIVES:

(1) Determination of the impact of the socio-demographic indicators such as age, sex, occupation, education level and monthly family income on the development of diabetic foot ulcers.

(2) Assessing the impact of the socio-demographic indicators with special reference to economic condition and education level, on the severity and location of the diabetic foot ulcer.

(3) Observing the impact of concomitant hypertension and dyslipidemia on the incidence and the severity of the ulcer and treatment pattern.



E-ISSN:2320-3137

### **MATERIALS AND METHODS:**

This is an observational study done in 53 patient saged between 28 to 83 years presented with clinically infected foot ulcers who were admitted in the surgical ward of a teaching hospital in Kolkata, India over the period of one year.

The criteria for including the patients in our study are as follows: (1) all the patients were diabetic (2) on Insulin therapy during the hospital stay (3) had wound swab for bacterial culture taken on the first day of admission.

The following patients were excluded from our study: (1) Age less than 18 years (2) Pregnant mother (3) Patients on oral antihypoglycemic agents only (4) Acutely ill patients (5) The patients who had not given consent to being part of our study.

The foot ulcers in diabetic patients are classified into six grades based on Meggit Wagner classification – Grade 0 to Grade 5 [5]. Our criteria for inclusion are patients with foot ulcer of grade II or more.

Wagner classification for diabetic foot ulcers	
GradeDescription of ulcer	
0	intact skin in patients who are at risk
I	superficial ulcers with exposed subcutaneous tissue
II	exposed tendon and deep structures
III	ulcers extend to the deep tissue and have either associated soft tissue abscess
IV	ulcers include feet with partial gangrene
V	feet ulcers with more extensive gangrenous tissue

The patients were identified, an informed written consent form was handed over to the patient and the methodology of the study was explained in their own language with adequate explanation.

After getting the signed informed consent from the patient, data collection process was started.

A proforma was developed for recording the vital parameters in this regard. The socio-economic status was judged from the level of education and monthly family income. Medical history regarding mode of development of the foot ulcer, its location and severity according to Wagner classification was taken for all the subjects. Details regarding duration of the diabetes mellitus and hypertension (if present) and personal habits like preference for walking bare foot were taken.

Blood circulation to the affected limbs were assessed by peripheral USG-Doppler study while the involvement of underlying bones were noted from standard X-ray plates. The wound swabs were taken in all the cases and subjected to the microbiological studies. The outcome of the foot

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ulcer was assessed from the duration of hospital stay, pattern of treatment received and the exact level of amputation (if any).

## **RESULTS AND DISCUSSIONS:**

The total number of patients were 53; out of which 32 were male and the rest were female. The youngest patient was a female aged about 28 years and the oldest one was a male aged about 83 years. Gershater *et al.* [6] also found a higher prevalence in men than women in developing foot ulcers. Doupis *et al.* [7] reported that men may have more risk factors and risk for trauma and infection. In contrast, Edmonds and Foster [8] found no difference between sexes in the prevalence of ulcers.



The male: female ratio is 1: 0.66. Stage IV foot ulcer disease was more common in females, most probably due to the combination of low level of education and socio-economic status. Of the 21 female patients, 16 (76.19%) were homemakers who were not financially independent and may be one of the reason of seeking treatment in the late stage of the foot ulcer disease (Stage III & IV).Females had poorer glycemic control compared to the males. Women still remain underprivileged in this environment where upon most of them depend on Husbands for maintenance. This may extend to healthcare as well. [9].

A considerable number of patients were retired persons but they mostly presented with Stage II and III foot ulcer disease. The others category consisted of primary school teachers, clerks, technical persons, small businessman and junior executives. 13 (86.67%) of them presented with late stage disease due to concomitant presence of either hypertension, dyslipidemia or both.

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E-ISSN:2320-3137



Most of the patients with Stage IV foot disease were in the age group of 40 - 60 years due to the detection of Type II diabetes mellitus for the first time with little awareness about the complications of diabetes. The older patients (above 61 years) who were mostly retired or homemakers presented with the Stage III foot disease more commonly as many of them were financially handicapped.



26.42% of the patients studied up to Class VIII (primary school level) and out of them 71.43% were females who had the habit of walking bare footed and were less aware of the complications of diabetes mellitus. All of these patients presented with severe foot ulcers (Wagner Stage III &IV) which indicates the association of severity of diabetic foot ulcer with the low level of

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education. 20.75% of the patients studied up to Class X (secondary school level) and a substantial number of the patients (41.50%) either graduates or post-graduates but they had less severe foot ulcers (50% of them presented with Wagner Stage II) even though they were long time diabetics (more than 5 years), may be due to higher education and more awareness regarding the complications of diabetes mellitus and none of them had the habit of bare foot walking, which again indicates the direct relation of education and social habits with the severity of diabetic foot ulcer. Subjects with low level of education were found to have a higher risk of developing ulcers possibly due to the less likelihood of seeking treatment and the interest in life style adjustments. In fact low level of education has been suggested for increasing prevalence of DM in the rural sector of Sri Lanka and DPN in UAE, both contributing to foot ulceration [10].

Delbridge et al. [11] noted a significant relationship between the level of patient understanding of diabetes mellitus and diabetic foot problems and the development of foot lesions in a cohort of 80 diabetic patients. Bachmann et al. [12] measured education in terms of schooling received and reported more severe complications amongst patients who had received less education. The less educated were also more likely to be seen as non-compliant by health professionals and used less hospital care.Indeed, education is usually seen as the key to better health as it facilitates an individual to better utilize health information and treatment [9,12,16,22].



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The monthly family income (MFI) has been classified into five groups as per Kupppuswamy's socio-economic scale (modified 2007), rounded to the next thousand. All of the patients with MFI of Rs.3000 – 5000 and Rs.5000 – 7500 were admitted with either Wagner Stage IV(50% of total patients) or Stage III (50% of total patients) foot ulcer disease. Whereas for MFI of above Rs.20001, only 1 patient each were admitted with Stage IV and Stage III and the rest with Stage II foot ulcer disease. It shows that the severity of the diabetic foot ulcer is directly related to the MFI; less the MFI, higher is the incidence of severity of the foot ulcer. A family monthly household income of less than LKR 15000 was another factor identified in this study which increases the risk of developing an ulcer (OR: 23.3; 95% CI 1.5-34.0). This finding is supported by a national study showing that DPN is associated with residence in rural areas and with a low household income suggesting that the extreme poor may be having less opportunity for health services [10]. Low average monthly income has been associated with worse diabetic outcomes as it determines the ability to obtain medication and services that improve health. Oladele and Barnett [13] found a strong association between the level of social class and preventive practices.



<u>Association with hypertension:</u> The patients in this study who had blood pressure more than 130/80 mm of Hg were considered to be suffering from hypertension. 31 (58.49%) patients had hypertension and most of these patients had also low blood flow to the lower extremity of the affected side as detected by USG-Doppler study. 13 male patients (42.63% of total male patients) and 7 female patients (33.33% of the total female patients) presented with Stage IV foot ulcer, which indicates concomitant hypertension increases the severity of the disease. Hypertension, in our study, was the most common comorbid condition among diabetic foot patients. Several studies generally support the concept that hypertension accelerates the development of peripheral vascular disease in certain populations.

The presence of other risk factors such as hypercholesterolemia, smoking, diabetes, and male sex appears to markedly accentuate the effects of hypertension on the development of this process [14]. Ogbuawa et al [15] found hypertension to be an independent risk factor for macrovascular disease and subsequent foot ulcer.

Association with dyslipidemia: The serum LDL level was considered as the parameter of dyslipidemia in our study. The normal level was taken to be less than 70 mg/ml. All patients were subjected to the estimation of serum LDL level and46 patients (86.79% of total patients) was found to have high level of LDL who presented with the late stage (Stage III & IV) of the foot ulcer disease. Out of them 23 (50%) presented with Stage IV disease which indicates hypercholesterolemia may be a potential risk factor in the development of diabetic foot ulcer with increasing severity.

The importance of glycemic control in patients with diabetes is well known but neurological



E-ISSN:2320-3137

studies suggest that dyslipidemia is actually a more significant contributor to the development of peripheral neuropathy in the same patient population (Andrea M. Vincent et al.) [16].

Diabetic dyslipidemia plays an important role in the progression of vascular complications of diabetes. It involves all classes of lipoproteins. There is an elevated oxidized LDL form that has a decreased metabolic clearance and an increased toxicity to endothelial cells [14]. Cholesterol, LDL and TG level increases in DFU patients. It was also found that HDL level decrease with the increase of HbA1C level in patients with DFU. Another important finding is that, In case of foot ulcer patient HbA1c, Creatinine, Cholesterol, LDL and triglycerides level were found higher than those of patients without foot ulcer where it was opposite in case of HDL [17].



Volume 4, Issue 1, 2015

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E-ISSN:2320-3137



Young et al. noted that Asian patients were much more likely to have toe amputations while Native American patients had the highest percentage of below knee amputations. Young et al. noted that Asians had a 69% lower risk of amputation when compared with whites [18].

15 patients (28.30%) had undergone amputation of toes (from one toe to a maximum of three toes) in Stage III and IV foot ulcer disease. Out of them 8 were female patients (53.33%) as they presented with late foot ulcer disease. Two of them were young females (28 and 32 years respectively) with Stage IV disease. Amputation was more common in female patients with low socio-economic status who were admitted with late stage foot ulcer disease.

## **CONCLUSION:**

From the study, it is observed that the severity of diabetic foot ulcer disease is related to the socio-demographic indicators in the urban population of India. In univariate analyses, diabetic foot problems were characterized by older age, male preponderance, longer duration of diabetes, smoking, poorer glycemic control, more insulin users, hypertension, hyperlipidemia, higher diastolic and systolic blood pressure, lower education level, and living in rural areas [19]. Both low education level and poor economic status are constantly related with the more severe forms of diabetic foot ulcer disease and poor prognosis. Moreover concomitant existence of hypertension and dyslipidemia increased the severity of the disease with higher incidence of amputation. Hypertension and dyslipidemia have been noted asthe risk factors for diabetic neuropathy, ischemic neuropathy and foot ulcers [20].

Health education and more importantly creating awareness among the general population, especially diabetic patients, regarding the complications of diabetes mellitus is essential for the optimum management of diabetic foot ulcer disease.



### **Conflict of interest and funding:**

The authors have not received any funding or benefits from industry or elsewhere to conduct this study.

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