# **Original Research Article**

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# Risk factors deciding the prevention and healing of diabetic foot ulcer: a prospective study in Chennai Medical College Hospital and Research Center Irungalur, Trichy, Tamil Nadu, India; a rural based tertiary medical care centre

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### **ABSTRACT**

**Background:** Diabetic foot ulcer is the one among and the most common complication of diabetes mellitus patients. Various studies from over the world for the past 2 decades discuss the important risk factors that decide the prevention and outcome of diabetic foot ulcer. In our prospective study we have discussed the risk factors focused on prevention and treatment of diabetic foot ulcer in a rural tertiary medical care centre.

**Methods:** Totally 940 patients with the clinical diagnosis of diabetic foot ulcer admitted in our hospital surgical department were studied prospectively with their clinical symptoms and signs of diabetic foot ulcer and various evaluations done for the comorbid conditions with the help of other specialty departments. All these risk factors studied in our rural based tertiary medical centre were collected in a designed format were studied and discussed in comparison to the chosen data available in various studies done at various countries.

**Results:** All the 940 patients admitted for diabetic foot ulcer who underwent a methodical evaluation for risk factor showed an elevated HbA1c more than 8 in 720 (77.5%) patients, bony involvement like osteomyelitis in 274 patients (29%), peripheral vascular disease in 421 (44.9%), neuropathy in 533 patients (56.7%), nephropathy 163 (17.34%), retinopathy in 102 (10.85%) and heart disease in 375 (39.89%).

**Conclusions:** Proper protocols to the prevention and management of foot ulcer in diabetic patients have not reached many health care centres and it is imperative to stress on the related comorbid risk factors which influence the prevention and healing of diabetic foot ulcer. Present study done at a rural tertiary health care centre is mainly focused on the incidence of risk factors which modulates and modify the diabetic foot ulcer prevention and management. This study aims to support the health professionals to identify the risk factors apart from the clinical picture of diabetic foot ulcer that may enhance the efficient management and avoid the unnecessary morbidity and mortality.

Keywords: Diabetes mellitus, Diabetic foot ulcer, HbA1c, Microangiopthy, Retinopathy

### INTRODUCTION

Diabetes mellitus (DM) is one among the major health problems showing dramatic increase as a global health threat for the past 20 years. 1,2 The epidemic incidence of diabetic mellitus has doubled from 2000 until now. 3,4

Major complications which the sufferers of diabetes mellitus come across are diabetic cardiopathy, nephropathy, neuropathy, retinopathy and diabetic foot ulcers. Over the past two decades diabetic foot ulcer is emerging as the most common complication showing definite increasing trend.<sup>5-7</sup> Altogether it is found that

about 15% of the diabetic patients will suffer from diabetic foot ulcer in their life period.<sup>8</sup>

Recent studies state that the diabetic foot ulcer is the ultimate cause for morbidity in diabetic mellitus patients and it is the more common reason for hospitalisation. About 20% of hospital admissions in diabetic mellitus patients are for diabetic foot ulcer. If not treated adequately diabetic foot ulcer can result in infection, gangrene, amputation or even death. In the literatures it is evident that approximately 50 to 70% of amputations are due to diabetic foot ulcer.

Recently it is very much discussed that multiple risk factors are involved in the formation of diabetic foot ulcer which includes<sup>11-14</sup>

- Gender male
- Advanced age of patients
- Duration of diabetes more than 10 years
- Poor glycaemic control (HbA1c level)
- Foot deformity
- Infection
- Peripheral neuropathy
- Peripheral vascular disease
- Retinopathy and nephropathy

The constellation of above mentioned factors occurring together can lead to ulcer formation under several events one among them is triad of neuropathy, foot deformity, minor trauma and the other way that determines the ulcer healing is peripheral arterial disease, infection and patient related factors. <sup>15-17</sup>

Present study is mainly confined to the risk factors that modify the prevention and management of diabetic foot ulcer. In our institution a rural tertiary health care hospital Chennai medical college hospital and research centre we utilised the services of various department like medicine, orthopaedics, cardiology, neurology, nephrology, and ophthalmology to identify the risk factors and plan for the prevention, management and follow up of the diabetic foot ulcer patients.

# **METHODS**

Patients presenting with diabetes mellitus and diabetic foot ulcer at General Surgery outpatient department were included in the study. About 940 patients who were admitted in the general surgical ward, Chennai medical college hospital and research centre, Irungalur, Trichy, Tamil Nadu were selected for the study.

A prospective study was conducted in the selected patients and the detailed particulars are recorded in a designed format which included the clinical details like age, sex, duration of ulcer, duration of diabetic mellitus, foot deformity, infection, glycaemic control and other comorbid conditions like peripheral vascular disease, neuropathy, retinopathy and nephropathy.

Patients admitted in the hospital for diabetes mellitus and diabetic foot ulcer from September 2012 to August 2016 were included in the study. Follow up made for minimum 1 year.

Nine hundred and forty patients admitted for diabetic foot ulcer were included in the prospective study and most of them were followed up to 1 year.

### Inclusion criteria

- All patients with clinical finding of diabetic foot ulcer.
- All age group from 18 to 80 years
- Both male and female patients were included.
- Patients with ulcer below the ankle.

### Exclusion criteria

- Patients with recurrent diabetic foot ulcer.
- Patients who had undergone surgical intervention like amputation, split skin grafting in the past.
- Patients recently detected diabetes mellitus.
- Non-cooperative patients for complete evaluation of other co-morbid conditions.

Patient's history pertaining to name, age, sex, duration of ulcer, duration of diabetes and investigation reports regarding HbA1c, pus culture and sensitivity, x-ray of affected part, renal function test, echo cardiogram were recorded in the prescribed performa.

With regard to neuropathy the clinical practice of defining loss of foot sensation was documented with monofilament light touch pain and vibration perception test. We used pulse palpability and recording ABPI as defining peripheral vascular disease involvement methods. In cases where there is clinical evidence of vascular occlusion the arterial Doppler scan was done.

The bony deformity (charcots foot) and bony change were made only by plain radiograph. The characteristic radiographic signs like osteomyelitis, osteolysis, osteopenia, subluxation, dislocations, and fragmentation of sub chondrial bone were read in the plain radiograph itself.

Opinions were also sought for the evidence of Nephropathy (microalbiminuria >300 and elevated serum creatinine) and Retinopathy (macular odema and micro aneurysms on fundus examination).

### **RESULTS**

Totally 940 patients were taken up for present study. Among them the age incidence was from 20 to 40 years 68 patients (7.2%), from 41 to 60 years 406 patients

(43.19%), from 61 to 80 years 342 patients (36.38 %) and in >80 years age group 124 patients (13.19%) were affected Figure 1. It shows that the age group 41 to 80 years were mostly (79.57%) affected.

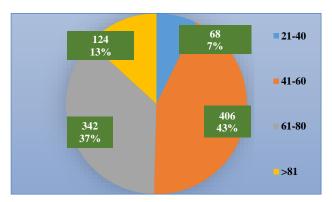


Figure 1: Age distribution in the incidence of diabetic foot ulcer.

Among the 940 patients male were 526 (55.9 %) and female 414 (44.1%). Figure 2. The greater incidence of diabetic foot ulcer in men may be due to genetic factor, hormonal factor, habits (smoking) and risk taking jobs.

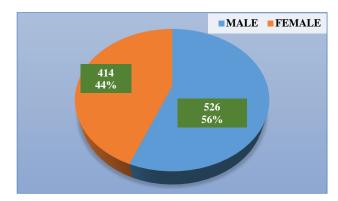


Figure 2: Sex incidence.

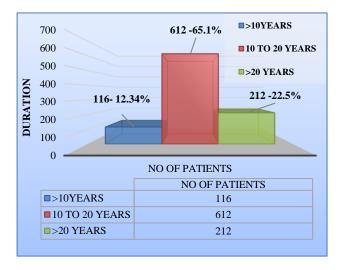


Figure 3: Duration of diabetes mellitus and development of diabetic foot ulcer.

The duration of diabetes mellitus was <10 years in 116 patients (12.34%), 10 to 20 years 612 (patients 65.1%) and >20 years in 212 patients (22.5%) (Figure 3). The development of diabetic foot ulcer was more when the duration of diabetes was more than 10 years because of the onset of complications like neuropathy, peripheral vascular disease, microangiopathy and bony changes.

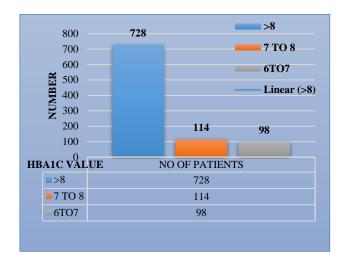


Figure 4: Serum levels of HbA1c and the incidence of diabetic foot ulcer.

The serum levels of HbA1c was >8% in728 patients (77.5%), 7 to 8% in 114 (12.1%) and 6 to 7% in 98 (10.4%) (Figure 4). It is clearly evident that uncontrolled diabetes shown by raised HbA1c level >8% was the prime cause for diabetic foot ulcer.

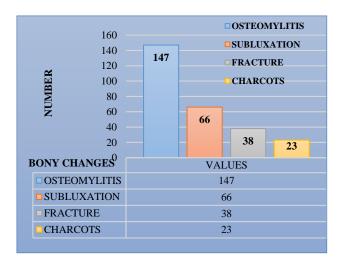


Figure 5: Bony lesions affecting the healing of diabetic foot ulcer.

Among the 940 patient's bony lesions were found in 274 patients (29%) such as osteomyelitis in 147 (15.6%), subuxation in 66 (7%), fracture in 38 (4%) and Charcots joint in 23 (2.4%) (Figure 5). In the management of diabetic foot ulcer not only the soft tissue infection but also the combined bony involvement should be considered.

The incidence of diabetic foot ulcer increases as the age advances and the duration of diabetes mellitus increases due to comorbid conditions. In present study group of 940 patients the association of comorbid conditions like peripheral vascular disease was seen in 421 patients

(44.9%), peripheral neuropathy in 533 patients (56.7%) and coronary heart disease in 375 (39.89%). The evidence of retinopathy was seen in 102 patients (10.85%) and nephropathy in 163 patients (17.3%) (Table 1).

Table 1: comorbid conditions affecting the healing of diabetic foot ulcer.

Comorbid conditions	Neuropathy	Retinopathy	Nephropathy	CHD	PVD
Patients	533	102	163	375	421
Percentage	56.7	10.85	17.34	39.89	44.9

### DISCUSSION

Diabetic foot ulcer the emerging commonest complication of diabetes mellitus when effectively managed at the early stages can prevent and reduce the unacceptable amputations and mortalities. Review of recent literatures is focussed on several risk factors that determine the development and severity of diabetic foot ulcer such as male gender, duration of diabetes, advanced age of the patient, poor glycaemic control (HbA1c much elevated), foot deformity ,infections and other comorbid conditions like peripheral vascular disease, peripheral neuropathy, cardiovascular diseases, nephropathy and retinopathy.

The incidence of diabetic foot ulcer in men and women did not show much difference in a cohort study by Gershater MA et al.<sup>19</sup> In another study by Jeffeoade WJ, et al men to be much more affected.<sup>20</sup> In present study out of 940 patients 526 were men (55.9%) and 414 were women (44.1%). The greater incidence of diabetic foot ulcer in men may be due to genetic factor, hormonal factor (oestrogen has protective action against development of peripheral vascular disease), habits (smoking) and risk taking jobs.<sup>20-22</sup>

In most of the reviews it was found that the diabetic foot ulcer was mostly seen in patients above the age of 50 years because of the advancing age, the progress of peripheral vascular disease and neuropathy increases leading to diabetic foot ulcer.<sup>23</sup> In present study the age group 40-60 (43.19%) and 60-80 (36.38 %) and totally 79.59 % above the age of 40.

The duration of diabetes is also indicted to the incidence of diabetic foot ulcer and if it is more than 10 years there is 70% chances of developing the ulcer present.<sup>24</sup> In present study in 87.6% of patients diabetic foot ulcer developed when the duration was > 10 years.

The primary reason for diabetic foot ulcer is mainly the inadequate glycaemic control.<sup>25</sup> In a diabetic patient over a period of years the best indicator for sugar control is HbA1c[26] .The UK Diabetic prospective study 1998

shows that for every 1% increase in HbA1c there is an increase of 25 to 28% relative risk of peripheral neuropathy and peripheral vascular disease which was the primary cause for diabetic foot ulcer. Good glycaemic control reduces the risk of diabetic foot ulcer. Present study reveals that 82% of the patients with diabetic foot ulcer had elevated HbA1c level >8 at the time of admission; the reason being the failure to take the drugs regularly or have stopped the drugs switching onto other modes of treatment.

Because of defective sensation in the feet due to peripheral neuropathy minor injuries were left unnoticed and infection develops leading to diabetic foot ulcer. In a study approved by Regional Ethical Review Board in Lund it was stated that in the development of diabetic foot ulcer neuropathy constituted 59% as the cause.<sup>29</sup> The formation of callous ulcer is also more in peripheral neuropathy. In present study 56.7% of the patients found to have peripheral neuropathy.

In the management of diabetic foot ulcer not only the soft tissue infection but also the combined bony involvement such as osteomyelitis, charcots joint if present should be considered. The characteristic bony changes apart from osteomyelitis include osteolysis, osteopenia, subluxations, dislocations and fragmentation subchondral bone. 30,31 The bony changes seen in present study are osteomyelitis 15.6%, subluxation 7%, fracture 4% and charcot joint 23%. Surgical correction of these bony lesions should be done simultaneously for better healing of the ulcer.

The association of peripheral vascular disease in diabetic foot ulcer patients results in neuroischaemic or ischaemic ulcers with resultant chronic infection. A study by Prompers L et al tells that 49% of diabetic foot ulcer patients had signs of peripheral vascular disease.<sup>32</sup> Another study by Bild DE et al showed a strong relation of diabetic foot ulcer with peripheral vascular disease going for amputation.<sup>33</sup> Looking into present study 44.9% had clinical and investigatory evidence of peripheral vascular disease and 39.9% had coronary heart disease.

The pathology in diabetic foot ulcer is microangiopathy in foot apart from atherosclerotic peripheral vascular disease. Since the same micro angiopathic changes are seen in kidney and retina of diabetic patients as diabetic nephropathy and retinopathy respectively; their presence can be taken up as a predictor of development of diabetic foot ulcer. An aretinopathy and 163 patients (17.34%) had nephropathy. Hence in patients with diabetic nephropathy or retinopathy development of foot ulcer can be anticipated and the preventive measures and advises can be taught to the patients and appropriate treatment started.

### **CONCLUSION**

In diabetic patients the foot ulcer when goes for amputation whether it is neglect or lack of knowledge about the related risk factors like neuropathy, peripheral vascular disease, bony lesions, nephropathy or retinopathy which were when identified and treated simultaneously can avoid morbidities and mortalities to an appreciable extent. In present study we analysed the incidence of these risk factors in our rural set up tertiary care hospital and utilised the services of speciality department to reduce the morbidity and mortality in diabetic foot ulcer patients. Present study is mainly focused to enlighten the rural based hospital professional for better handling in the prevention and management of the diabetic foot ulcer patients.

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Ethical approval: The study was approved by the

Institutional Ethics Committee

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