

# A Study of Factors Predicting Severity and Outcomes of Foot Ulcers in Diabetes Mellitus in RMMCH.

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## Abstract

- Background:** Diabetes is a major contributing factor in up to 70% of lower limb amputations. Foot damages such as ulceration, infection, gangrene are one of the important cause of hospital admission in patients with diabetes mellitus. The burden of diabetic foot disease and ulceration is set to increase further due to the co-existence of contributory co morbidities.
- Aim:** To assess various prognostic factors involved in the development of foot ulcers in type 2 diabetic patients presenting in Rajah Muthiah Medical College Hospital, Chidambaram. To understand the role of factors involved in the complications arising out of diabetic foot. To correlate the severity of infection with the organism grown from the wound culture of diabetic foot.
- Material and Methods:** In this case study 50 patients were studied. This study was conducted from October 2016 to September 2018. The protocol for the study was approved both by the Department Of General Surgery and the Ethical Review Committee of Rajah Muthiah Medical College Hospital, Chidambaram.
- Results:** Findings were tabulated according to age and other clinical aspects.
- Conclusion:** Factors influencing the outcome and long duration of bedridden state in diabetic foot ulcer disease studied were age, male gender, duration of diabetes and tobacco smoking. Limb Salvage was considered possible in patients who had isolated microangiopathy (nephropathy, retinopathy), foot ischaemia or neuropathy. Conditions where amputation rather limb salvage were more pointed towards patients having dyslipidaemia, hypertension and infection of the foot, poor glycaemic control, site and number of ulcers in foot. It was evident that good prognosis can be achieved with diabetic foot lesions by optimizing glycaemic control, using combination antibiotic chemotherapy, vigorously correcting co morbid conditions.

## Introduction

The theme for World Health Day 2016 is HALT THE RISE: BEAT DIABETES, For 2018 = SAVE THE FOOT.

## Background

- Diabetic incidence and prevalence are on the rise
- Diabetic foot ulcer is a preventable complication of diabetes
- Limb Salvage

According to the World Health Organization's 'The World Health Statistics 2012' report, India has the largest

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number of diabetics in the world and is now being called the "Diabetic Capital of the World". It is estimated that there were 69.1 million cases of diabetes (8.7%) in India in 2015. This will mean that every fifth diabetic in the world would be an Indian. Diabetic foot is a term for foot problems in patients with diabetes mellitus (DM) because of arterial abnormalities and diabetic neuropathy, as well as a tendency toward delayed wound healing, infection, or gangrene of the foot. It occurs in 15% of all patients with diabetes and precedes 84% of all lower leg amputations. There are two main types of ulcers: neuropathic and ischemic. In patients with diabetes, pure ischemic ulcers are less common, and the vast majority of ulcers are mixed neuroischemic.

The management of DFUs includes,

1. Good glycaemic control
2. Control of infection
3. Extensive Debridement

4. Wound dressing
5. Offloading
6. Newer methods of treatment
7. MRI Study of diabetic foot

Prevention is the first step towards solving diabetic foot problems. It is estimated that a leg is lost to diabetes somewhere in the world every 30 seconds.

### Aim and Objectives

- To assess various prognostic factors involved in the development of foot ulcers in type 2 diabetic patients presenting in Rajah Muthiah Medical College Hospital, Chidambaram.  
To understand the role of factors involved in the complications arising out of diabetic foot.
- To correlate the severity of infection with the organism grown from the wound culture of diabetic foot
- To decrease the risk of developing foot ulcers and its complications in people with diabetes.
- To promote early problem detection and in attaining timely intervention.

### Material and Methods

A total of 50 patients with diabetes mellitus from inpatients and outpatients were screened by meticulous clinical examination, especially inspection and palpation for diabetic foot ulcer. Fifty of the total number screened satisfied the inclusion criteria for the study. Diabetic foot ulcers were operationally defined as a breach on the normal skin occurring as induration, ulceration or change of colour on the foot for duration equal to or more than one week. Only patients with active foot ulceration (s) were included in the study.

For each of the recruited subjects, a history was obtained, and it detailed the patient's demographics including the age, gender and marital status. Smoking, alcohol use, occupation, presence of trauma at onset of ulcer was noted. History regarding the diabetes including duration of disease (estimated from year of diagnosis), and the mode of treatment form either the patient or available hospital records were documented. The presence of neuropathic pain was noted.

A physical examination was then performed. Height, weight, Blood Pressured was recorded. Both feet were examined and the site, state and the stage of foot ulcers were documented. The presences of the high-risk non-ulcer lesions were also described. The lesions were staged based on the Meggitt-Wegner classification.

Peripheral neuropathy was assessed by elucidating the presence or absence of vibration sense using the 128Hz

tuning fork on the medial and lateral malleoli and documented. The pressure sensation was done. Then neurological disability scoring (NDS) system was used to each foot. Range of neuropathy score: 0 - 10

- 0 - 2 = No neuropathy
- 3 - 5 = Mild neuropathy
- 5 - 8 = Moderate Neuropathy
- >9 = Severe Neuropathy

### Peripheral Vascular Disease

The dorsalis pedis and posterior tibial arterial pulses were palpated with the patient in supine position and graded as present or absent. Lower limb Arterial Doppler study had been done in the patients at time of inclusion and re-visit.

The other dermatological and/or high-risk lesions looked for were dryness, cracks, fissures, ingrown and/or improperly trimmed nails, oedema, foot deformities e.g., hammer toes, pes cavus and/or corns. X-rays were done to stage the ulcers of the patients.

Using the clinical information obtained, the type of the foot lesion was determined and classified as neuropathic, ischaemic or neuroischemic. Foot ulcers were categorized as ischaemic when peripheral vascular disease was present but the neurologic disability was less than or equal to 2; neuropathic when there was neurological disability more than or equal to 3 but no obvious peripheral vascular disease and neuroischemic when both neurological disability and evidence of peripheral vascular disease were present.

After the history and full clinical assessment of the patients in fasted state for about 10hours, venous blood drawn and sent for fasting blood sugars and lipid assays. Also, blood was sent for glycosylated haemoglobin (HbA1c) values. The results were then reported in percentage as per assay test recommendation as: HbA1c < 7% - good metabolic control

- >7 to <10% - fair control
- >10% - poor metabolic control

A pus swab was obtained from the ulcers and was delivered to the lab within half an hour. The data was summarized in tabular form and is presented in the form of diagrams, tables, bar charts and histogram as appropriate. Qualitative data were entered in form of percentages and where appropriate associations were made.

### Discussion

The study was conducted in Rajah Muthiah Medical College and Hospital, Chidambaram, TamilNadu. The

figures are comparable to other studies, but if the differences are significant, this is due to a regional variation in prevalence of diabetes mellitus and the local operating risk factors of diabetic foot ulcer disease.

The mean age of patients with diabetes was found to be 55 years. Peak age of incidence of diabetic ulcers was 51 – 60 years. Margueritte et al [1] in Seattle, USA, found a comparable mean of 60 years and a study done by P.N. Nyamu et al [2] in Kenyatta National Hospital, Nairobi, found a mean age of incidence as 56.9 years. This comparable mean age may suggest certain time – dependent risk factors in the evolution and course of diabetic foot ulcer disease which are common to diabetes in whatever environment. Age of onset of diabetes is also different in continents.

Men with diabetes are more likely to suffer amputation than women. According to Gayle E. Reiber et al [3] a consistently higher ulcer rate was found in males than in females. The estimated amputation rate in diabetic subjects are higher for males than for females. This is a uniform finding in most U.S. hospital discharge studies, with 1.4-2.7 times excess risk for males compared with females [4,5]. In 1990, the age-adjusted amputation rate for diabetes, computed from NHDS and NHIS data, was 61% higher in males than females (10.3 per 1,000 versus 6.4 per 1,000) [6]. This amputation risk was more pronounced in younger males. In our study, the male to female ratio is 3.1: 1 approximately and the prognosis is worse in male of age more than 50 years and in females more than 45 years.

The mean duration of diabetes in this study is 10.52 years comparable to 7.98 years, 13 years and 5 years in Margueritte et al [1] in Seattle, USA study, P.N. Nyamu et al [2] in Kenyatta National Hospital, Nairobi study, McLigeyo and Otieno's study on diabetic foot ulcers<sup>7</sup> respectively. The variation in results may be due to difference in quality of diabetes care at various centres. Better diabetes care can prolong the onset of ulceration. This study revealed that the longer the duration of diabetes, the higher the risk of occurrence of infection and amputation. This is in correlation with study conducted by Nelson RG, Gohdes DM [7]. There is an increased association with atherosclerosis, peripheral neuritis in patients with longer duration of diabetes and poor glycemic control.

Hypertension is a risk factor in the disease process of diabetic foot ulceration. Control of hypertension has been well shown to reduce cardiovascular mortality. In our study, 30 out of 50 patients who were hypertensive have undergone amputation and hence it can be regarded as a poor prognostic factor. In a study conducted by Ogbuawa

et al [8], they found hypertension to be an independent risk factor for macrovascular disease and subsequent foot ulceration. A lot of other studies conducted previously had conflicting results with some failing to show any association between blood pressure and diabetic foot ulcers [5,9,10]. In accord with the haemodynamic hypothesis early hyperaemia and capillary hypertension promote more sinister late functional abnormalities with increasing duration of diabetes. These late functional abnormalities include loss of autoregulation and reduced hyperaemic responses which interact with loss of neurogenic flow regulation, disturbed endothelial function, and abnormal rheology to produce the familiar clinical picture of the diabetic foot [4]. Both essential hypertension and diabetes mellitus affect the same major target organs. The common denominator of hypertensive/diabetic target organ-disease is the vascular tree. As it can be seen that both the systemic diseases affect the vascular tree the patients with diabetic foot ulcer would have poor wound healing.

The Framingham study suggests that smoking in diabetic foot patients, at least, has the same adverse effect on macro-vascular disease as they do in non-diabetics. In my study, 28 out of 50 patients gave the history of smoking in whom higher levels of amputations were attempted with poor prognosis. Smoking affects the small blood vessels and make the wounds heal slower.

In the observation of wound healing rates with high HbA1c, it was observed that patients with low HbA1c values had faster healing. My study shows 21 patients had high HbA1c of which 76.9% showed poor wound healing rates and underwent subsequent amputation. This is in correlation with Andrea L. Christman et al [3] study which showed that individuals with HbA1c of 5.6% had a wound healing rate of 0.35 cm<sup>2</sup> per day whereas those with HbA1c 11.1% had a healing rate of 0.001 cm<sup>2</sup> per day. This suggests that a relationship exists between faster wound healing rate and low HbA1c levels. Many physiological factors that are thought to contribute to poor wound healing in diabetic foot individuals include decreased or impaired keratinocyte and fibroblast migration and proliferation, cytokine and growth factor function, and angiogenic response, and response to infection [7]. Many of these mechanisms involve hyperglycaemia. Hyperglycaemia reduces keratinocyte migration and proliferation [11]. Also, it adds to the oxidative stress with the production of reactive oxygen species [11]. In my study, of the 23 out of 32 patients who underwent amputation, 3 cases underwent forefoot amputation, 7 underwent below knee amputation, 1 underwent above knee amputation, 12 underwent toe amputations.

In my study, dyslipidaemia in diabetic foot patients is found to be a poor prognostic factor as it delayed wound healing significantly. Dyslipidaemia directly did not influence the diabetic foot as such, but it played an important role in the development of peripheral vascular disease which in turn affected the outcome of diabetic foot. This finding is in correlation with a study done by P.J. Palumbo et al [13], where they found that age, sex, diabetes, hyperlipidaemia, hypertension, and cigarette smoking are significant risk factors for LEAD. In patients with diabetes, vascular disease, ABI, current smoking, and arm systolic blood pressure were identified as significant independent risk factors for LEAD.

Several analytic studies have provided evidence for an association between neuropathy and lower extremity amputations. In the cohort study of Pima Indians [15] and in the Seattle VA case-control study [14] it is observed that impaired vibratory perception was a statistically significant risk factor for amputation after controlling for age, sex and diabetes duration. In the latter, the significance of this predisposing condition in terms of population-attributable risk percent was high because of the higher prevalence of hypoesthesia among cases (78%) than among controls (18%). Foot sensory neuropathy emerged as the most predictive of foot ulcer risk in our population.

According to a study conducted by Robert J. Hinchliffe et al; they concluded that both peripheral neuropathy and peripheral arterial disease predispose to the development of ulcers and to their slow healing.

Neuropathy inhibits healing partly by increasing forces on certain parts of the foot while walking (because of motor neuropathy and wasting of the small muscles of the foot) and by a loss of protective behaviour (because of reduced sensation). Peripheral arterial disease inhibits healing though its impact on local blood flow and a disruption of the processes needed for re-epithelialization. In another study conducted by Robert G. Frykberg et al [9], it has been concluded that peripheral arterial disease (PAD) rarely leads to foot ulcerations directly. However, once ulceration develops, arterial insufficiency will result in prolonged healing, imparting an elevated risk of amputation. Additionally, attempts to resolve any infection will be impaired due to lack of oxygenation and difficulty in delivering antibiotics to the infection site. Therefore, early recognition and aggressive treatment of lower extremity ischemia are vital to lower limb salvage. In my study it has been found a major percentage of patients with associated peripheral vascular disease had underwent amputation.

Wagner's classification score may be different for a surgeon as compared to physician because the diabetic foot patients come with advanced disease to a surgeon and for this reason patient with grade 0, 1, 2 are lesser and those with grade 3, 4, 5 are more in our study. The standard treatment for diabetic foot according to Wagner's classification is prevention for grade 0, antibiotics and good glycaemic control for grade 1. In grade 2 patients need hospitalization, as they need surgical intervention along with antibiotics and glycemic control. Grade 3 requires debridement and some sort of amputation. In grade 4, aggressive debridement and amputation while in grade 5 the preferred treatment is below knee amputation. Initial aggressive and radical debridement with daily surgical follow-up is the mainstay in the treatment of diabetic ulcers in nearly 90% of our patients. Patients with Grade 3, 4, 5 underwent amputation indicating grade of ulcer at presentation is a predictive factor for plan of treatment.

## Conclusion

- Factors influencing the outcome and long duration of bedridden state in diabetic foot ulcer disease studied were age, male gender, duration of diabetes and patients who smoke tobacco.
- Limb Salvage was considered in patients who had isolated microangiopathy (nephropathy, retinopathy), foot ischaemia or neuropathy. But, when these factors were associated with systemic diseases, severe fasting hyperglycaemia, evident bone destruction and super added infection, the outcome of treatment was adverse.
- Adverse factors which influence the prognosis drastically and where extreme sedulousness might be warranted for limb salvage were dyslipidaemia, hypertension and infection of the foot, poor glycaemic control, site and number of ulcers in foot.
- It was evident that good prognosis can be achieved with diabetic foot lesions by optimizing glycaemic control, using combination antibiotic chemotherapy, vigorously correcting co morbid conditions.

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