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#### **RESEARCH ARTICLE**

## Risk stratification of Diabetic foot ulcers among the Patients with Diabetes mellitus at a Tertiary care Hospital

Aneena Dominic<sup>1</sup>, M J Kumari<sup>2</sup>, Dr. Suryanarayana B S<sup>3</sup>, Angeline Mary Sheela<sup>4</sup>

**1.** Msc Nursing, College of Nursing, Jawaharlal Institute of Post Graduate Medical Education and Research, Puducherry-6, India.

2. Vice Principal cum Principal (Ag), College of Nursing, JIPMER, Puducherry-6, India

3. Associate Professor, Department of Medicine, JIPMER, Puducherry-6, India

4. Sister Tutor, College of Nursing, JIPMER, Puducherry-6, India

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#### Manuscript Info

#### Abstract

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Stratification, diabetic foot ulcer, patients with diabetes mellitus, diabetic clinic

\*Corresponding Author

Aneena Dominic

**Back ground:** Diabetic foot ulcer is one of the serious complications of diabetes mellitus, which accounts for more than 85 % of non-traumatic lower extremity amputations. This study aims to stratify the level of risk for diabetic foot ulcer and to find out the factors associated with the level of risk for foot ulcer among the patients with diabetes mellitus.

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**Materials and Methods:** Descriptive cross sectional design was used in this study. Convenience sampling technique was used to select 250 diabetic patients who satisfied the inclusion criteria. Back ground variables of the patients were collected using a socio demographic and clinical variables data sheet. Stratification of foot ulcer risk was done using Scottish Intercollegiate Guidelines Network (SIGN) risk stratification system.

**Results:** Among the 250 patients with type 2 diabetes mellitus, 63 (25.2%) had neuropathy, 76 (30.4%) had foot deformities, 9 (3.6%) had absent foot pulses, 40 (16%) had previous foot ulcers and 6 (2.4%) were unable to see the foot. Using the risk stratification tool, 104 (41.6%) patients were categorized into the low-risk group for foot ulcer, 96 (38.4%) patients into the moderate risk group and 50 (20%) into the high risk group for foot ulcer. Age was found to be significantly associated with the level of risk for diabetic foot ulcer. (P: 0.001).

**Conclusions:** One fifth of the patients were categorised as high risk for the development of a foot ulcer. Screening programmes should be instituted to detect these patients earlier so that future complications can be prevented.

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### **INTRODUCTION**

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Diabetes mellitus is a major public health problem which can affect people of all ages in all countries. Diabetic foot problems are the major reason for hospital admission among the diabetic patients. It is approximated that, clients with diabetes have a lifetime risk of 15% for the development of foot ulcers. In every 30 seconds a limb is lost somewhere in the world as an impact of diabetes. It is estimated that one among every four diabetic patients are at risk for getting foot ulceration during their lifetime. Diabetic foot ulcers imposes a great economic burden on the individuals their families and also to the health care system. It has become an emergency need to detect the at risk cases of foot ulcers. Several clinical features have been shown to predict foot ulceration. Screening patients for those clinical features will be helpful in identifying at risk cases and appropriate intervention can be taken timely. Many studies were done to find out the risk factors of foot ulcers, but only few studies attempted to stratify the risk for foot ulcer among diabetic population. Studies done on stratification of foot ulcer risk among the Indian population is

scanty. With this back ground the study was conducted with the following objectives such as; to stratify the level of risk for diabetic foot ulcer among patients with diabetes mellitus and to identify the selected demographic and clinical factors associated with the level of risk for diabetic foot ulcer among the patients with diabetes mellitus.

## Materials and methods

The study was a descriptive study with cross-sectional survey design conducted in diabetes clinic of Jawaharlal Institute of Post Graduate Medical Education and Research (JIPMER), a tertiary health care institution in South India. The diabetic clinic has an average out patient attendance of 2400 per month. The institutional ethical clearance was taken before the data collection.

#### Sample

The study was conducted among the 250 diabetic patients. Both male and female type 2 diabetic patients having age above 18 years and who were able to understand English or Tamil were included in the study. Patients who were having diabetic foot ulcer at the time of the study were excluded. The data was collected by interview of the patients, review of the patients records and through foot examination. The data collection required 20-30 minutes per patient.

#### Description of the tool

Demographic data included age, gender, education, occupation, marital status, income, residential area and the source of foot care information. The clinical variables included duration of diabetes mellitus, type of treatment, habit of smoking, family history of diabetes, complications and comorbidities of diabetes mellitus such as retinopathy, nephropathy, coronary artery disease, stroke, hypertension, compliance, HbA1c level and recent blood sugar level. Scottish Inter collegiate Guidelines Network (SIGN) risk stratification tool for diabetic foot ulcer was used to find out the level of risk for diabetic foot ulcer. The tool was designed to assess for five factors, peripheral neuropathy using 10g monofilament, assessment of foot pulses, foot deformities, physical or visual disability and history of previous foot ulcers.

#### Data Collection Procedure

Informed consent was taken from the participants after explaining the study. By convenience sampling technique, 250 patients who fulfilled the inclusion criteria were selected. Good rapport was maintained with the patients and proper instructions were given. The data regarding demographic and clinical parameters were collected using back ground proforma. Foot assessment was performed by the investigator. Semmes- weinsten monofilament (10gms/5.07) was used to assess for peripheral neuropathy. Each filament was placed perpendicular to the plantar surface of the foot so that it bent with a constant force of 10 g. The patients were advised to close their eyes and yes /no response was elicited in response to monofilament sensation. The monofilament sensation was tested in ten sites (base of the great toe, second and fifth toe, base of 1st, 3rd and 5th metatarsal heads, the heel, lateral aspect of foot arch, medial aspect of foot arch and dorsal surface of the foot). An absence of protective foot sensation at more than 4 sites was considered as neuropathy sign. Evidence of peripheral vascular disease was assessed by the palpation of foot pulses both dorsalis pedis and posterior tibial. Absence of foot pulses both dorsalis pedis and posterior tibial pulses in one foot was considered as the risk. Information regarding previous foot ulcer and amputation was collected from the patient. The patients were asked for the ability to reach and see the foot. Foot was examined for the presence of deformities also. After foot examination, the patients were categorized into three groups ( low risk, moderate risk and high risk for foot ulcer) as per the SIGN risk stratification system.

#### Statistical analysis

Data analysis was performed in SPSS version 19. Both descriptive and inferential statistics were used for analyzing the data. The baseline characteristics were presented as frequencies and percentages. To describe the association of level of risk for foot ulcer with demographic and clinical parameters chi-square test was performed. The comparison of continuous variables such as HbA1c, duration of diabetes mellitus and age with level of risk was done using ANOVA.

## RESULTS

The distribution of demographic variables of the study participants showed that 185 (74%) patients had age above 50 years. Majority of the study participants, 150 (60%) were females. Pertaining to education, 71 (28.4%) had no formal education, 23 (9.2%) had primary education, 137 (54.8%) had secondary education, and 19 (7.6%) had education above higher secondary level. Regarding occupation, majority 158 (63.2%) patients were unemployed and 92 (36.8%) were employed. Majority 245 (98%) patients were married. Pertaining to the residence 165 (66%) patients were from rural area. Regarding the income most of the patients 225 (90%) had monthly income less than Rs. 2000. Regarding foot care information 181 (72.4%) had not received foot care information.

Regarding the distribution of clinical variables of diabetic patients, majority 86 (34.4%) patients had a duration of diabetes mellitus for 5-10 years. Pertaining to the type of treatment 42 (16.8%) patients were getting insulin treatment and 104 (41.6%) patients were getting OHA and the remaining 104 (41.6%) patients were getting both insulin and OHA. Pertaining to the habit of smoking 230 (92%) had no habit of smoking. Regarding family history 112 (44.8%) patients had the family history of diabetes mellitus. Regarding complications and co morbidities of diabetes mellitus 64 (25.6%) had retinopathy, 25 (10%) had nephropathy, 56 (22.4%) had CAD, 139 (55.6%) had hypertension. Majority 159 (63.6%) patients were not compliant to treatment. Pertaining to the HbA1c value majority 119 (47.6%) had a value higher than 8%. Regarding blood sugar value, most of the patients 184 (73.6%) had blood sugar in the range of 151-300 mg/dl.

#### Table 1: Distribution of level of risk for diabetic foot ulcer among patients with diabetes mellitus

N=250Level of risk for diabetic foot ulcerFrequency (N)Percentage (%)Low risk10441.6Moderate risk9638.4High risk5020

Table 1 shows that among 250 diabetic patients, 104 (41.6%) patients were in the low risk group for diabetic foot ulcer, 96 (38.4%) patients were in the moderate risk group and 50 (20%) patients were in the high risk group for diabetic foot ulcer.

## Figure 1: Distribution of risk factors for diabetic foot ulcer among the patients with diabetes mellitus.

N=250



Figure 1 shows the distribution of risk factors for diabetic foot ulcer among the patients with diabetes mellitus. Among the 250 patients 63 (25.2%) had neuropathy, 76 (30.4%) had foot deformities, 9 (3.6%) had absent foot pulse, 40 (16%) had previous foot ulcers, 6 (2.4%) were unable to see the foot and 56 (22.4%) had no risk factors.

# Table 2: Comparison of age in relation to the level of risk for foot ulcer among the patients with diabetes mellitus

Level of risk for diabetic foot ulcer	N	Mean	SD	Statistical Significance
	1	1120mi	2	Statistical Significance

N=250

Low risk	104	53.68	10.9	
Moderate risk	96	59.13	9.7	F=6.85
High risk	50	57.14	10.8	P=0.001*

\*denotes significance at P < 0.05

Table 2 illustrates the comparison of age in relation to the level of risk for foot ulcer among patients with diabetes mellitus. Age was significantly associated with the level of risk for diabetic foot ulcer. (P value <0.05)

## Discussion

In a prospective observational study conducted by Leese G.P.et al., (2006) most of the participants (64%) were categorized into low risk group, 23% into the moderate risk group, and 13% were categorized into the high risk group based on the assessment of five clinical variables. In the present study also majority (41.6%) of the patients were categorized into low risk group for foot ulcer. Pal, R. et al., (2011), Mugambi et al., (2009) also reported a large number of low risk patients like the present study. The study results are consistent with a study done in Botswana in that, both these studies were female dominated and age of the patients were in the range of 19-85 years. Age was significantly associated with the level of risk for foot ulcer with P value: 0.001.

In a study conducted in Ireland by Hurley et al., (2013), the prevalence of neuropathy was 23-25% and the prevalence of absent foot pulses was 18-39%. The percentage of moderate risk and high risk cases were respectively 25% and 11%. The findings are consistent with the prevalence of neuropathy in the present study which was 25.2%. But the prevalence of absent foot pulses in the current study is 3.6%. This may be because the present study was done in less number of patients when compared to the Ireland study where the sample size was 563. The present study also shows a higher number of moderate and high risk cases than Ireland study. This difference can be explained that in the present study, majority of patients were in their fifties and sixties and most of the patients were non-compliant to treatment.

The succeeding objective of the study was to find out the factors associated with the level of risk for foot ulcer. In this study demographic parameters like gender, education were not found to be associated with foot ulcer risk, which was found to be associated in other studies. This may be due to a large female population in this study.

Factors like low education level, being on insulin treatment, habit of smoking, duration of diabetes mellitus, HbA1c greater than 7%, lack of health education were found to be the risk factors of foot ulcer in a Palestine based case control study done by Hussen A.O.et al., (2015). In this study also age was found to be associated with the level of risk for foot ulcer. This can be explained that the elderly population poses a diminished ability to perform self-care including foot care. They will also have poor vision.

Musa H.G. et al., (2015), Al Kafrawy et al., (2014) found out that poor glycemic status, habit of smoking and duration of diabetes mellitus are associated with the development of foot ulcers. But these variables were not found to be associated with the level of risk for foot ulcer in the current study. The study findings shows that mean HbA1c value of the high risk group was marginally higher when compared to the low risk group. But this difference was not found to be statistically significant. This may be due to the fact that only recent HbA1c values were collected in this study and complications are determined by long term diabetic control not recent control.

In this study the mean duration of diabetes mellitus was higher among the high risk category when compared to the low and moderate risk group but this difference was not found to be statistically significant. This can be explained that it is difficult to establish the onset of diabetes mellitus especially among type 2 diabetic patients.

The present study had some limitations. The study setting was limited to the diabetic clinic and being a cross sectional study no follow up assessment was done for the study subjects.

## Conclusions

This study revealed that 50 (20%) diabetic patients attended diabetic clinic were at high risk for the development of foot ulcers. The risk for diabetic foot ulcer increases with an increase in age (P.001). The findings of this study shows the importance of screening programs in identifying the high-risk cases of foot ulcers. As most of the risk factors can be identified by simple measures, proper intervention can be taken at the right time.

#### Conflict of Interest: Nil

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