Assessment of diabetic foot risk among diabetic patients in a tertiary care hospital, South India

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Abstract:
INTRODUCTION: Foot problems are most common among patients with diabetes, and they are an important cause of morbidity in patients with diabetes mellitus (DM). They can be prevented by following a simple foot care practice. The study objective was to stratify the level of risk for diabetic foot ulcer (DFU) among patients with diabetes by screening.

MATERIALS AND METHODS: A descriptive cross-sectional study design was adopted in this study. The sample size was 196, and a standardized INLOW'S 60-s diabetic foot screening tool was used to assess the risk of diabetic foot. Data collection was done by face-to-face interview, and diabetic foot risk (DFR) was assessed by direct observation, inspection, and palpation methods.

RESULTS: Among the 196 patients, majority required yearly foot screen in both feet. The mean and standard deviation of the level of DFR in the left foot (LF) and right foot (RF) was 4.31 ± 2.267 and 4.51 ± 2.391, respectively. There was a statistically significant association between the practice of treatment and level of foot screening recommendation in the LF with Chi-square value of $\chi^2 = 8.20$ ($df = 2$) and RF with Chi-square value of $\chi^2 = 7.95$ ($df = 2$) at $P < 0.05$ level.

CONCLUSION: Health-care providers should be made aware of the regular practice of screening the foot of diabetic patients along with health education awareness programs. It may be helpful to identify the foot ulcer risk at an early stage. It will prevent further complications of DFU and recurrence of ulcer and will reduce the economic burden to patients and their family members and the health-care system.

Keywords: Diabetes mellitus, diabetic foot ulcer, risk assessment

Introduction
Diabetes is a chronic disease that occurs either when the pancreas does not produce enough insulin or when the body cannot effectively use the insulin it produces. Insulin is a hormone that regulates blood sugar. It is a chronic condition that impairs the body’s ability to process blood glucose and is associated with abnormally high levels of glucose in the blood. Diabetes is a long-term condition which can have a huge impact on health and if not controlled, increases the risk of complications.¹⁰ According to the International Diabetes Federation report in 2019, approximately 463 million adults (20–79 years) were living with diabetes, and it will increase to 700 million by 2045.¹¹ Foot problems are common in people with diabetes.¹² The diabetic foot is a complex and serious complication of diabetes, with many negative outcomes requiring medical treatment.¹³ Diabetic complications may be disabling or even life-threatening. Diabetic foot disease is a leading cause of hospitalization and amputation. Foot problems are an important cause of morbidity in patients with diabetes mellitus (DM).¹⁴ Diabetic patients have a 15%–25% lifetime chance of developing a foot ulcer and a 50%–70% recurrence rate

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over the ensuing 5 years, and 85% of foot ulcer precedes lower-limb amputation. Worldwide, 25%–90% of amputations, especially nontraumatic lower-limb loss, are associated with diabetes.[6]

In India, diabetic foot ulcers (DFUs) affect 15% of diabetics during their lifetime. Evidence from published literature showed 100,000 leg amputations/year due to diabetes-related problems and an expense of approximately $1,960 for complete treatment of DFUs. Out of 62 million diabetics in India, 25% develop DFUs, of which 50% become infected, requiring hospitalization, while 20% need amputation. DFUs contribute to approximately 80% of all nontraumatic amputations in India, annually. The average time required for healing of DFUs is 28 weeks. Furthermore, an average patient’s income of 5.7 years is required to pay for complete DFU treatment.[7]

Diabetic foot is the main cause of nontraumatic amputation, may cause death or physical and psychical disability, has a great impact on the quality of life, and represents a high cost for society. Screening of foot in diabetes is an essential part of the examination to prevent and for early identification of the risk of foot ulcer. The aim of screening is to identify risk factors in the early stage, prevent DFU development, make timely referral for further management, and reduce amputations.[8] Diabetic foot care is one of the most ignored aspects of diabetes care in India. Due to social, religious, and economic compulsions, many people walk barefoot. Poverty and lack of education lead to the usage of inappropriate footwear and late presentation of foot lesions.

DFU leads to amputation, which results in permanent disabilities throughout life. This disability can be prevented by creating awareness on proper foot care by health-care providers. Early identification of DFU may prevent further complications and economic burden to the individual, family, and health-care system. Hence, the investigator is interested to assess the level of risk and the recommended screening period and create awareness on the prevention of DFU among diabetic patients. DFU can be prevented by following simple foot care practices. The study objectives were to stratify the level of risk for DFU among patients with diabetes, to identify the selected demographic and clinical factors associated with the level of risk for diabetic foot among patients with diabetes, and to create awareness on the prevention of DFU among diabetic patients.

Materials and Methods

Descriptive cross-sectional study design was adopted in this study. Inclusion criteria of the study were patients who were above 18 years of age; those who have attended diabetic outpatient department, in JIPMER; both gender; and diabetics with other comorbid illness. The exclusion criteria of the study were patients who were having DFU, those who were critically ill, and those who were unable to communicate throughout the study period. The sample size was 196 with an expected percentage of diabetic patients who may develop foot ulcer as 15% at 5% absolute precision with 5% level of significance, and systemic random sampling techniques were used to select the study participants. The study tool consists of two parts: part 1: sociodemographic data including age, gender, religion, educational qualification, income, marital status, sources of health information, and clinical data such as present illness, duration of illness, family history of DM, treatment, diet control, habit of smoking, alcoholism, and comorbidity. Part 2 includes the standardized INLOW’S 60-s diabetic foot screening tool. The foot screening focused on skin, nails, foot deformity, footwear, temperature – cold and hot, range of motion, sensation-monofilament testing, foot sensations, pedal pulses, dependent rubor, and erythema. The diabetic foot assessment was stratified as Category – 0 – no risk, which means presence of diabetes, no loss of protective sensation (LOPS), peripheral arterial disease (PAD) or deformity, and patients in this category were recommended screening for every 12 months; Category – 1 – moderate risk, which includes patients with LOPS – screening recommended for every 6 months; Category – 2 – high risk, which includes patients with LOPS ± PAD/deformity/evidence of pressure/onychomycosis, – screening recommended for every 3–6 months; and Category – 3 – very high risk, it includes patients with the presence of diabetes with a previous history of ulceration/amputation, – screening recommended for every 1–3 months; and urgent risk means those with ulcer ± infection, active Charcot, and PAD (gangrene and acute ischemia) – recommended urgent care.

Data collection was initiated after obtaining clearance from the institute’s ethical committee (human study) in JIPMER. Patients who fulfilled the inclusion criteria were recruited and were then explained the study, its purpose, and risks and benefits in their own language and then a written informed consent was obtained. Data collection was done by face-to-face interview, and diabetic foot risk (DFR) assessment screening was done by direct observation, inspection, and palpation methods. Diabetic foot care is a neglected aspect in diabetic management; many studies reveal that most of the diabetic patients are unaware of diabetic foot care and the preventive strategies of foot ulcer. Hence, the investigator aimed to impart education intervention and counseling to patients by using PowerPoint presentation with video clipping on DFU preventive strategies. The education intervention focused on treatments of diabetes, common complications
of diabetes, risk factor and causes of DFU, warning signs and symptoms of DFU, complications of DFU, education on diabetic foot care, including nail care, foot care, foot inspection, selection of footwear, and leg exercises. The patients were provided with educational intervention and counseling face to face in Tamil language.

The distribution of demographic variables including sociodemographic data such as age, gender, and religion and clinical data such as duration of illness, family history of diabetes, and practice of treatment was expressed as frequency and percentages. The level of DFR among diabetic patients with left foot (LF) and right foot (RF) was expressed as frequency, percentage, mean, and standard deviation. The correlation of level of DFU risk among diabetic patients with their selected demographic and clinical variables was carried out using Pearson’s correlation test. The data were analyzed using SPSS version 23 (Licensed by IBM corporation. City: Puducherry, State: Puducherry, Country: India). The statistical analysis for association of level of DFR (RF and LF) among diabetic patients with their selected demographic and clinical variables at 5% level of significance and $P < 0.05$ was considered statistically significant.

**Results**

Demographic and clinical variables of the 196 diabetic patients were analyzed in that 112 (57.1%) patients were in the age group between 40 and 60 years, 111 (56.6%) patients were female, majority of the patients (96.9%) were Hindu, 87 (44.4%) patients had studied up to 10th standard, 153 (78%) patients reported no regular income, most of the patients (99.5%) were married, 153 (78.1%) patients were receiving health-related information from mass media, 112 (57.1%) patients were having diabetes < 10 years, 104 (53.1%) patients had a family history of DM, 108 (55.1%) patients were under oral anti-hyperglycemic agent treatment, 177 (90.3%) patients were following diet control that including restricting maximum intake of carbohydrate-rich foods and sugar intake, 186 (94.9%) patients undergo monthly checkup, 194 (99%) patients were not having the habit of smoking, and 195 (99.5%) patients were not having the habit of alcoholic consumption.

Table 1 reveals that out of the 196 patients, majority required yearly foot screen in both feet. The mean and standard deviation of the level of DFR in the LF and RF was $4.31 \pm 2.267$ and $4.51 \pm 2.391$, respectively. There was a positive correlation of DFR between the LF and RF among diabetic patients with “r” value of 0.922 and $P = 0.001$, which are highly statistically significant.

Table 2 depicts that there was a statistically significant association between the practice of treatment and level of foot screening recommendation in the LF with Chi-square value of $\chi^2 = 8.20 (df=2)$ and RF with Chi-square value of $\chi^2 = 7.95 (df=2)$ at $P < 0.05$ level. The other demographic variables did not show a statistically significant association with the level of DFR among diabetic patients.

**Discussion**

The present study was undertaken to perform DFR assessment among diabetic patients in JIPMER. The first objective of the study was to stratify the level of risk for DFU among patients with DM. Table 3 shows the assessment of DFR status of diabetic patients in which majority of the patients’ skin were of intact and healthy, were unkempt, and were of ragged nails. Most of the patients used inappropriate footwear, their foot temperature was warm, had a full range of hallux, and had monofilament sensation detected in ten sites. Most of the patients reported that they had one of the neuropathic symptoms such as numbness, tingling, burning sensation, and feeling of insect crawling. Pedal pulse was able to palpate in all patients, was warm, and none of the patients had dependent rubor and erythema. Table 1 reveals that majority of the patients (84.2% and 82.1%) had no risk (Category – 0) of diabetic foot and they required screening yearly once; 15.3% and 17.3% of the patients had moderate risk (Category – 1) in the LF and RF, respectively, and they were recommended with screening every 6 months; and 1 (0.5%) patient had high risk (Category – 2) in both feet and hence was recommended screening every 3 months.

**Correlation of level of diabetic foot risk (left foot and right foot) among diabetic patients**

The mean and standard deviation of DFR (LF and RF) was $4.31 \pm 2.267$ and $4.51 \pm 2.391$, respectively, and the correlation of level of DFR (LF and RF) among patients indicated a positive correlation with $r = 0.922$ and $P = 0.001$, which are highly significant. There is a positive correlation of DFR between the left foot and right foot with “r” value of 0.922 and $P = 0.001$, which are highly statistically significant.
Table 2: Association of demographic level of diabetic foot risk among diabetic patients with their selected demographic and clinical variables (n=196)

| Demographic and clinical variables | Recommended screening for diabetic patients |  \( \chi^2 \) | df |  \( P \) |
|-----------------------------------|---------------------------------------------|-------------|-----|-----|
|                                   | Every year (no risk), \( n \% \) | Every 6 months (moderate risk), \( n \% \) | Every 3 months (high risk), \( n \% \) |
| Age (years)                       |                                             |             |     |     |
| 20-40                             | 10 (90.9)                                   | 1 (9.1)     | 0   | 1.50 (LF) | 4 | 0.826 | 0.617 |
| 40-60                             | 95 (84.8)                                   | 16 (14.3)   | 17 (15.2) | 2.65 (RF) | 4 |       |     |
| 60-80                             | 60 (82.2)                                   | 57 (78.1)   | 13 (17.8) | 0   |       |     |
| Gender                            |                                             |             |     |     |
| Male                              | 73 (85.9)                                   | 12 (14.1)   | 16 (18.8) | 0.95 (LF) | 2 | 0.620 | 0.615 |
| Female                            | 92 (82.9)                                   | 18 (16.2)   | 18 (16.2) | 0.97 (RF) | 2 |       |     |
| Religion                          |                                             |             |     |     |
| Hinduism                          | 159 (83.7)                                  | 30 (15.8)   | 34 (17.9) | 1.16 (LF) | 4 | 0.884 | 0.854 |
| Christianity                      | 1 (100)                                     | 0           | 0   | 1.34 (RF) | 4 |       |     |
| Islam                             | 5 (100)                                     | 0           | 0   |       |     |     |     |
| Educational qualification         |                                             |             |     |     |
| Illiterate                        | 54 (80.6)                                   | 12 (17.9)   | 13 (19.4) | 4.38 (LF) | 8 | 0.821 | 0.885 |
| SSLC                              | 23 (88.5)                                   | 3 (11.5)    | 4 (15.4) | 3.68 (RF) | 8 |       |     |
| +2                                | 9 (75)                                      | 3 (25)      | 3 (25) | 0   |       |     |
| Below 10th                        | 75 (86.2)                                   | 12 (13.8)   | 14 (16.1) | 0   |       |     |
| Graduate                          | 4 (100)                                     | 0           | 0   |       |     |     |     |
| Income in rupees                  |                                             |             |     |     |
| <2000                             | 7 (77.8)                                    | 2 (22.2)    | 0   | 0.749 (LF) | 6 | 0.993 | 0.992 |
| 2000-5000                         | 22 (84)                                     | 4 (16)      | 5 (20) | 0.80 (RF) | 6 |       |     |
| >5000                             | 8 (88.9)                                    | 1 (11.1)    | 1 (11.1) | 0   |       |     |
| Nil                               | 129 (84.3)                                  | 23 (15)     | 26 (17) | 1.75 (10.6) |     |     |
| Marital status                    |                                             |             |     |     |
| Married                           | 164 (84.1)                                  | 30 (15.4)   | 34 (17.4) | 0.189 (LF) | 2 | 0.910 | 0.897 |
| Unmarried                         | 1 (100)                                     | 0           | 0   | 0.21 (RF) | 2 |       |     |
| Source of health information      |                                             |             |     |     |
| Newspaper                         | 7 (87.5)                                    | 1 (12.5)    | 1 (12.5) | 9.80 (LF) | 6 | 0.133 | 0.180 |
| Television                        | 125 (81.7)                                  | 28 (18.3)   | 31 (20.3) | 8.88 (RF) | 6 |       |     |
| Network                           | 1 (100)                                     | 0           | 0   | 0   |     |     |     |
| Verbal                            | 32 (94.2)                                   | 2 (5.9)     | 2 (2.9) | 1.29 (10.6) |     |     |
| Duration of illness               |                                             |             |     |     |
| <10 years                         | 96 (85.7)                                   | 16 (14.3)   | 18 (16.1) | 9.26 (LF) | 6 | 0.159 | 0.324 |
| 10-20 years                       | 60 (81.1)                                   | 13 (17.6)   | 14 (18.9) | 6.96 (RF) | 6 |       |     |
| 20-30 years                       | 9 (100)                                     | 0           | 1 (11.1) | 0   |     |     |     |
| >30 years                         | 0                                           | 1 (100)     | 1 (100) | 0   |     |     |     |
| Family history of DM              |                                             |             |     |     |
| Yes                               | 84 (80.7)                                   | 19 (18.3)   | 19 (18.2) | 2.46 (LF) | 2 | 0.292 | 0.593 |
| No                                | 81 (88)                                     | 11 (12)     | 15 (16.3) | 1.04 (RF) | 2 |       |     |
| Practice of treatment             |                                             |             |     |     |
| OAG agent                         | 98 (90.7)                                   | 12 (11.1)   | 0   | 8.20 (LF) | 2 | 0.017* | 0.019* |
| Insulin                           | 67 (76.1)                                   | 20 (22.8)   | 22 (25) | 7.95 (RF) | 2 |       |     |
| Practice of diet control          |                                             |             |     |     |
| Restricting maximum intake of carbohydrate-rich food (a) | 0 | 0 | 0 | 0 | 0.111 (LF) | 2 | 0.946 | 0.929 |
| Restricting maximum sugar intake (b) | 0 | 0 | 0 | 0 | 0 | 0.14 (RF) | 2 |     |     |
| Both (a) and (b)                  | 149 (84.2)                                  | 27 (15.3)   | 31 (17.5) | 1.06 (10.6) |     |     |
| No dietary restrictions           | 16 (84.2)                                   | 3 (15.8)    | 3 (15.8) | 0   |     |     |     |
| Practice of health checkup        |                                             |             |     |     |
| Monthly once                      | 156 (83.9)                                  | 32 (17.2)   | 1 (0.5) | 0.376 (LF) | 4 | 0.984 | 0.981 |
| 6 months once                     | 8 (88.9)                                    | 7 (77.8)    | 2 (22.2) | 0.41 (RF) | 4 |       |     |
| Yearly once                       | 1 (100)                                     | 0           | 0   | 0   |     |     |     |

Contd...
Table 2: Contd...

| Demographic and clinical variables | Recommended screening for diabetic patients | \( \chi^2 \) | df | \( P \) |
|-----------------------------------|--------------------------------------------|-------------|-----|------|
|                                   | Every year (no risk), \( n \) (%)          | LF | RF | LF | RF | LF | RF |
| Habit of smoking                  |                                            | 0.380 (LF) | 2   | 0.827 | 0.803 |
| Yes                               |                                            | 0.43 (RF)  | 2   | 0.910 | 0.897 |
| No                                |                                            | 1.08 (LF)  | 2   | 0.292 | 0.608 |
|                                   |                                            | 0.10 (RF)  | 2   | 0.754 | 0.326 |
| Habit of alcoholic consumption    |                                            | 0.189 (LF) | 2   | 0.666 | 0.414 |
| Yes                               |                                            | 0.19 (RF)  | 2   | 0.637 | 0.427 |
| No                                |                                            | 0.91 (LF)  | 2   | 0.340 | 0.557 |
|                                   |                                            | 0.01 (RF)  | 2   | 0.916 | 0.916 |

*P<0.05 significant. LF=Left foot, RF=Right foot, DM=Diabetes mellitus, OAG=Oral Anti-glycemic

Table 3: Assessment of diabetic foot risk among the diabetic patients (n=196)

| Assessment parameters | Components                                      | LF, \( n \) (%) | RF, \( n \) (%) |
|-----------------------|-------------------------------------------------|-----------------|-----------------|
| Skin                  | Intact and healthy                              | 103 (52.55)     | 95 (48.46)     |
|                       | Dry with fungus or light callus                 | 73 (37.24)      | 73 (37.24)     |
|                       | Heavy callus buildup                            | 6 (3.06)        | 5 (2.55)       |
|                       | Open ulceration or history of previous ulcer    | 14 (7.14)       | 23 (11.73)     |
| Nails                 | Well kept                                       | 39 (19.89)      | 39 (19.89)     |
|                       | Unkempt and ragged                              | 112 (57.14)     | 112 (57.14)    |
|                       | Thick, damaged, or infected                     | 45 (22.95)      | 45 (22.95)     |
| Deformity             | No deformity                                    | 190 (96.93)     | 186 (94.89)    |
|                       | Mild deformity                                  | 6 (3.06)        | 9 (4.59)       |
|                       | Major deformity                                 | 0               | 1 (0.51)       |
| Foot wear             | Appropriate                                     | 56 (28.57)      | 55 (28.06)     |
|                       | Inappropriate                                   | 140 (71.42)     | 141 (91.13)    |
|                       | Causing trauma                                  | 0               | 0              |
| Temperature - cold    | Foot warm                                       | 124 (63.26)     | 122 (62.24)    |
|                       | Foot was cold                                   | 72 (36.73)      | 74 (37.75)     |
|                       | Foot was warm                                   | 195 (99.48)     | 195 (99.48)    |
|                       | Foot was hot                                    | 1 (0.51)        | 1 (0.51)       |
| Temperature - hot     | Foot was warm                                   | 188 (95.19)     | 187 (95.40)    |
|                       | Foot was hot                                    | 8 (4.08)        | 9 (4.59)       |
| Range of motion       | Full range to hallux                            | 188 (95.19)     | 187 (95.40)    |
|                       | Hallux limitus                                  | 8 (4.08)        | 9 (4.59)       |
|                       | Hallux rigidus                                   | 0               | 0              |
|                       | Hallux amputation                               | 0               | 0              |
| Sensation - monofilament testing | 10 sites detected                                   | 181 (92.34)     | 180 (91.83)    |
|                       | 7 to 9 sites detected                           | 4 (2.04)        | 5 (2.55)       |
|                       | 0 to 6 sites detected                           | 11 (5.61)       | 11 (5.61)      |
| Sensation of foot     | Replied no to numbness, tingling, burning sensation, and feel of insect crawling | 82 (41.83) | 81 (41.32) |
|                       | Replied yes to any one of the sensation questions | 114 (58.16) | 115 (58.67) |
| Pedal pulses          | Present                                         | 196 (100)       | 196 (100)      |
|                       | Absent                                          | 0               | 0              |
| Dependent rubor       | No                                              | 196 (100)       | 196 (100)      |
|                       | Yes                                             | 0               | 0              |
| Erythema              | No                                              | 196 (100)       | 196 (100)      |
|                       | Yes                                             | 0               | 0              |

LF=Left foot, RF=Right foot

The second objective of the study was to identify the selected demographic and clinical factors associated with the level of risk for DFU among patients. The demographic variable of practice of treatment showed a statistically significant association with the association between the level of DFR (RF and LF) among diabetic patients with Chi-square value of \( \chi^2 = 8.20 \) (df = 2) at \( P < 0.05 \) level. The other demographic variables did not show statistically significant association with the level of DFR (RF and LF) among diabetic patients.

In the present study, majority of the patients were unaware of the healthy foot care practice and had poor...
knowledge on foot care. In the present study, educational intervention and counseling were given to patients by using PowerPoint presentation with video clipping on DFU preventive strategies. The education intervention focused on treatment of diabetes; common complications of diabetes; risk factor and causes of DFU; warning signs and symptoms of DFU; complications of DFU; and diabetic foot care including nail care, foot care, foot inspection, selection of footwear, and leg exercises. The patients were provided with educational intervention and counseling face to face in Tamil language.

A similar result was found by Muhammad-Lutfi et al.’s study which also emphasized and empowered the diabetic population on diabetic foot care. They did a study on the knowledge and practice of diabetic foot care at a tertiary medical center. The study findings revealed that the majority of patients admitted for diabetic foot infections had poor knowledge and practice of diabetic foot care. Education regarding foot care strategies should be emphasized and empowered within the diabetic population. A total of 157 patients were included in their study with a mean age of 56.33 years (31–77). There were 72 males (45.9%) and 85 females (54.1%), with the majority of them being Malays (154 patients, 98.1%). Majority of the patients (58%) had poor foot care knowledge, while 97 patients (61.8%) had poor diabetic foot care practice as compared to the median score. Based on the Chi-square test of relatedness, there was no significant association between knowledge and practice with any of the variables.

At Tikur Anbessa Specialized Hospital Diabetes Centre, a hospital-based cross-sectional study was conducted. A total of 200 patients participated. By using the 60-s foot screening tool, they assessed the risk factors of acquiring DFU. The study revealed that among the 200 participants, 145 were female and the median age was 50 years. Similar to this study, the present study showed that 112 (57.1%) patients belonged to the age group between 40 and 60 years and 111 (56.6%) were female.

This study was conducted in a diabetic outpatient department only, which is the limitation.

**Conclusion**

Majority of the patients had poor knowledge and practice of diabetic foot care. Good knowledge and practice regarding diabetic foot care will reduce the risk of diabetic foot complications and, ultimately, amputation. Health-care providers are suggested to enhance regular screening along with health education awareness programs. It may help to identify the foot ulcer risk at the early stage. It will prevent further complication of DFU and recurrence of ulcer and reduce the economic burden to patients and their family members and the health-care system.

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**Conflicts of interest**
There are no conflicts of interest.

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