Diabetic foot lesions predicting factors, view from Jabir Abu-alaiz diabetic centre in Khartoum, Sudan

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Abstract:
Diabetes mellitus (DM) is a rising epidemic worldwide. Its complications constitute a huge burden, including Diabetic Foot Lesions (DFL) which is associated with a lifetime risk of up to 25% in diabetic persons. The most common cause of non-traumatic amputation among diabetics is DFL. Long periods of hospitalization, large expenses, and loss of productivity all devastate individuals and society. This study sought to identify major predictive factors of DFL and to determine and implement preventive strategies. This case-control study was conducted in the Jabir Abu-alaiz Diabetic Center (JADC) in Khartoum, Sudan. DFL patients were enrolled as cases; diabetic patients without foot lesions were enrolled as controls in a ratio of 1:2. Frequency matching was done on demographic and confounding factors. DM duration, glycemic control, and foot care knowledge were tested using matched analysis and binary logistic regression models. Having DM longer than 10 years (p =0.01) O.R. = 1.8, 95% CI (1.15-2.8) and foot care knowledge level (p <0.0005) O.R. = 0.2,95%CI (0.9-0.4) both proved to be significant contributions to predicting development of DFL. Participants reported poor knowledge about foot care and infrequent visits to foot care clinics. Foot care knowledge and DM duration were important predicting factors for DFL. Poor foot care knowledge and practice, and infrequent foot care clinic visits were reasons to raise awareness about DFL risk factors. Advising diabetics about frequent foot care clinic visits, and for those who have had diabetes for longer than 10 years, regular feet checking would be beneficial.

Key words: Diabetes Mellitus Duration, Diabetic Foot Lesion, Foot Care Clinics, Foot Care Knowledge, Glycemic Control

INTRODUCTION
Diabetes mellitus (DM) is a rising epidemic worldwide and is associated with morbidity, mortality, insulin deficiency, and inactivity. These consequences may result from a quantitative deficiency of insulin, an abnormal insulin level, resistance to its action, or a combination of deficits.¹

DM is associated with numerous complications related to microvascular, macrovascular, and metabolic etiologies. One of those is diabetic foot syndrome (DFS), which was defined as an array of foot abnormalities, resulting from peripheral neuropathy, macroangiopathy, and other consequences of metabolic disturbances. Different causal factors may be present alone; however, they are more likely to occur in combination in patients with DM.

Neuropathy, particularly symmetric distal polyneuropathy, is the major etiological factor, and is present in 85% of the patients with a diabetic foot problem.² Neuropathy appears to be the most common causative factor, followed by ischemia, with infection and trauma being strongly associated factors.³
A clinical important manifestation of the DFS is the diabetic foot ulcer (DFU), often followed by amputation.\(^2\)

In 2002, the World Health Organization defined the diabetic foot as an infection, ulceration, and/or destruction of deep tissues associated with neurological abnormalities and varying degrees of peripheral vascular disease in the lower limb.\(^2\)

DFU is characterized by a classical triad of neuropathy, ischemia, and infection. Due to the impaired metabolic mechanisms in DM, there is an increased risk of infection and poor wound healing. These occur from a series of mechanisms which include decreased cell and growth factor response, diminished peripheral blood flow, and decreased local angiogenesis. Thus, the feet are predisposed to peripheral vascular disease, peripheral nerve damage, deformities, ulcerations, and gangrene.\(^4\)

With a lack of publications on diabetes and its complications in the Arab World, it is useful to apply the rule of 15 to understand the significance of the DFL problem. The rule of 15 states that:

- 15% of people with diabetes develop ulcers;
- 15% of ulcers develop osteomyelitis; and
- 15% of ulcers result in amputation.\(^5\)

Diabetes mellitus is a common medical problem in Sudan, and diabetic septic foot (DSF) infection is a serious complication, one associated with considerable morbidity and mortality.

Diabetic septic foot-related mortality varied among different hospitals in Sudan. Lower limb amputation among inpatients with diabetic foot in Khartoum hospitals increased in recent years. Recently, DSF accounted for 10.2% of all complications reported from private clinics in the Khartoum state.\(^6\)

According to some studies, the prevalence of DFU among the population of rural Sudan is 3.9%. It causes a high rate of bed occupancy in hospital admissions.\(^6\) The socio-economic burden from diabetes and related complications, such as amputations, are immense.\(^7\)

These include direct costs of medications, hospitalizations, treatments, and supplies.

Patients and their relatives also incur indirect costs such as time lost from work, loss of income, diversion of family resources from other basic needs, and premature death. These all have a great impact on the patient’s dependents.\(^7\)

Despite the magnitude of the DFU and its consequences (amputation) in Sudan, little research has been performed to investigate the independent roles of multiple potential etiologic factors for this complication. The number and quality of studies about DM and its complications, like DFL, are not keeping pace with its exponentially rising prevalence.

In addition to direct causes of DFL, which to some extent are agreed upon (eg, neuropathy, vasculopathy, trauma, and infection), other indirect risk factors (eg, poor foot care practice, poor glycemic control, and duration of DM) among others were not well addressed.

Although not all diabetic foot disorders are preventable, it is possible to effectively incur dramatic reductions in their incidence and morbidity through appropriate evidence-based prevention and management protocols.

This study attempted to investigate the major predicting factors for DFL in adult diabetic patients through an analytical matched case-controlled study design, with a relatively large sample size.

**MATERIALS AND METHODS**

This was an observational, hospital-based retrospective case control study. It was conducted in Jabir Abu-alaiz Diabetic Centre in the surgery and internal medicine clinics. The average number of patients was 125 patients per month in surgery and 300 patients per month in medicine. The average daily newly seen patients in the center was 6 +/- 2 patients in the surgery clinic and 12 +/- 4 patients in the medicine clinic. Participants included previously diagnosed adult diabetic patients (>18 years) in the Khartoum state in 2014. Two subgroups comprise these adults.
The diabetic patient (according to the WHO definition) is a patient diagnosed as having Type 1 or 2 DM by a fasting, 2-hour postprandial glucose tolerance test on a venous sample. Readings above the cut-off point of 126-mg/dl fasting and 200 mg/dl 2 hr postprandial (pp) suggest DM. Impaired glucose tolerant (IGT) test subjects (ie, pre-diabetic stage), those have fasting glucose level between 110-125 mg/dl or 2hr pp between 140-200 mg/dl, were excluded from the study. Diagnosis was by venous sample only (not dipstick capillary sample/not urine). Diagnosis of diabetes by HBA1c (>6.5%) was not used in this study.

The other group was comprised of DFL patients (applied for cases only). This patient, according to the above stated criteria, had a full thickness wound or ulcer on either foot surface (ie, planter or dorsal) distal to both malleoli of any surface area and/or depth not healed for more than 1 week. Lesions should be of Wagner’s class 1 or more (not 0). This definition excludes hand lesions.

The study inclusion criteria included: 1) newly diagnosed DFL patient who had a wound within 2 weeks from presentation, 2) a new DFL patient as described by any patient with recurrent wound, a healed old wound, after more than one year, and 3) patients who have had diabetes for three years.

The study exclusion criteria included: 1) patients younger than 18 years of age, 2) newly or incidentally diagnosed patients with diabetes (ie, controlled criterion), 3) patients unfit to participate in the study (ie, confused or febrile), and 4) patients with known foot lesions due to causes other than DM.

**Sampling**

The sample was calculated using the formula

\[ N = \frac{(Z)^2 \times 4p(1-p)}{d^2} \]

where \( n \) = number of study participants and:

- \( Z \) = critical ratio (at 95% C.I. its 1.96)
- \( P \) = prevalence (in this study of DFL)
- \( D \) = desired margin of error (customary 5%)

The sample size was divided for cases and controls by matching ratio of (2) so that every case was matched with 2 controls (R to 1 R=2).

Since the prevalence of DFL was unknown in Sudan, by substituting data from a study done in Nairobi Kenya in the above formula a prevalence of DFL = 4.5% (0.045)\(^8\) was obtained, and the estimated sample size was about 264. To account for unexpected issues, the sample size was decided to be 270 total subjects, 90 cases and 180 controls, by the ratio of case: control of 1:2.

Since no consistent frame was found, the initially presented patients represented a convenience sample. For those who presented, a probability systematic interval random sample was applied.

The first participant was randomly selected from a list of the daily newly presenting patients in both surgery and medicine clinics. Additional participants were selected systematically, after a fixed interval, by identifying every other participant in the surgery clinic and every second participant in the medicine clinic. The average time of data collection was 45 days (>6 weeks). Our final study sample included 88 cases and 182 controls.

**Data Collection Methodology**

A structured, pre-designed, pre-tested, pre-coded, close-ended interview administered questionnaire was used for data collection. The questionnaire was pilot tested on a random sample of JADC patients, using a Cronbach alpha scale (0.65). Two physicians in the surgery clinic and two physicians in the medicine clinic collected data through direct patient interviews, and reviewing past records and center registries. All physicians were trained on using the tool.

Physicians also used a 10 gram monofilament, with 128 Hz tuning fork devices to check and grade neuropathy. A hand held Doppler device was used in the ultrasound department to measure Ankle Brachial Pressure Index (ABPI) and grade vasculopathy. All of the devices were the same and used on all participants in a consistent manner to maintain and maximize internal validity.
Ethical Consent

All participants verbally agreed to informed consent after they received study explanation and their concerns were clarified. The designated ethical clearance committee gave study approval, and the JADC Director gave study permission.

Variables

Demographic variables included age, sex, residency, education, and income.

Education and income variables were combined to represent an estimate of the socio-economic status. Since most of the formulae and/or equations in the literature were difficult to apply on patients presented to JADC (ie, expenditure per day, income per capita), the author created a simple formula to produce the intended variable. This categorical variable was assigned as follows:

- 1 - Illiterate or primary education + income < 750 SD (low S.E. status)
- 2 - Secondary or university education + income 750-2000 SD (average S.E. status)
- 3 - Post university education + income > 2000 SD (high S.E. status)

In situations where education was not aligning with income, as above, more weight was given to education. Although this was not a precise method, it could give an estimation for socio-economic status.

Other study variables included DM duration, DM family history, glycemic control according to the past three months results (modified from standardized questionnaire and scale),\(^9\) and past and current smoking habits.

Both independent and dependent study variables were used. The primary dependent (outcome) variable was the development of DFL (ie presence or absence of wound). Independent variables included foot care knowledge and attitude and practice (in terms of barefoot walking; frequent checks; application of moisturizing formulas, cleaning, and drying; and podiatric clinic visits). An investigator designed a scale that used predetermined scores against which knowledge of participants was assessed and scored. This scale was tested with a Cronbach value (0.64).

Variables used in the foot care knowledge assessment scale are listed in Table 1.

Table 1. Foot care knowledge.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Mean</th>
<th>Std. Deviation</th>
<th>N</th>
</tr>
</thead>
<tbody>
<tr>
<td>Foot inspection</td>
<td>.11</td>
<td>.315</td>
<td>19</td>
</tr>
<tr>
<td>Washing feet</td>
<td>.32</td>
<td>.478</td>
<td>19</td>
</tr>
<tr>
<td>Moisturing</td>
<td>.53</td>
<td>.513</td>
<td>19</td>
</tr>
<tr>
<td>Barefoot walking</td>
<td>.16</td>
<td>.375</td>
<td>19</td>
</tr>
<tr>
<td>Footwear</td>
<td>.53</td>
<td>.513</td>
<td>19</td>
</tr>
</tbody>
</table>

Other variables that were studied included:

- Features of neuropathy (ie, paresthesia, numbness, fall of shoes out while walking).
- Loss of protective sensation defined as lack of sensation with 10-gm monofilament test on foot planter surface and/or vibration sensation with 128-HZ tuning fork on malleolli.
- Features of vascular insufficiency in term of past diagnosis of vascular insufficiency disease and ABPI grade (0.9-1.1= normal, <0.9 or >1.1= abnormal).
- Perfusion assessment included pedal assessment (dorsalis pedis/posterior tibial arteries).
- Peripheral arterial disease regarded present if ABPI was less than 0.9 and/or both pedal pulses were absent.

Data Management and Analysis

The prime investigator performed data sorting, editing, and cleaning, as well as the field data check. SPSS version 22 was used for analysis, and results were presented in tables, graphs, and percents. Point estimates were determined (ie, odd ratios); interval estimates such as confidence intervals were also calculated, and significance tests were calculated (ie, P-values).
Confounding Variables

Matching was performed between cases and controls using possible confounding variables such as age, sex, family history, neuropathy, and vasculopathy as fixed (matching) variables.

Matching was done in three stages in stepwise fashion on three alternating variables (foot care knowledge, DM duration, and glycemic control) by fixing two and testing for one in each stage on top of the already five previously mentioned fixed variables.

Binary logistic regression and modeling were also performed. Significance was reported from alpha <0.05 and 95% confidence intervals were stated.

RESULTS

The total study included 270 patients, comprised of 88 cases (diabetics with foot lesions) and 182 controls (diabetics without foot lesions) in 1:2 ratio. Five participants declined study participation, two in the surgery clinic (cases) and three in the medicine clinic (controls), resulting in a >98 percent response rate.

Almost half of the subjects in this study (around 46%) were older than 55 years of age. The other half comprised the following cohorts, in descending order: between 46 and 55 years of age, followed in descending order by the range of (46-55) years then (36-45) years till the least group (18-25) years (Figure 1).

Table 2 shows the frequency distributions of sex, socio-economic status, and residence within each group of cases and controls.

Table 2. Frequency distribution of base-line characteristics in percentages among cases and controls in DFL study in JADC in 2014/2015.

<table>
<thead>
<tr>
<th>Variables</th>
<th>Controls</th>
<th>Cases</th>
</tr>
</thead>
<tbody>
<tr>
<td>Frequency / percentage</td>
<td>88 (32.6%)</td>
<td>182 (67.4%)</td>
</tr>
<tr>
<td>Sex (M=male / F=female)</td>
<td>M=67%, F=33%</td>
<td>M=47.8%, F=52.2%</td>
</tr>
<tr>
<td>S.E. status (low / average / high)</td>
<td>64.8%, 31.8%, 3.4%</td>
<td>44%, 50%, 6%</td>
</tr>
<tr>
<td>Residence (U=urban / R=rural)</td>
<td>U=62.5%, R=37.5%</td>
<td>U=83%, 17%</td>
</tr>
</tbody>
</table>

S.E. status = socio-economic status.

Foot care knowledge and practice were found significantly different between cases and controls, unlike attitude, which is almost similar in both groups (Table 3).

Table 3. Test of significance (chi square test) of case/control status vs. foot care knowledge, attitude, and practice.

<table>
<thead>
<tr>
<th>Variables</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case/control status vs. foot care knowledge</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>Case/control status vs. foot care attitude</td>
<td>0.662</td>
</tr>
<tr>
<td>3 Case / control status vs. foot care practice</td>
<td>&lt;0.0001</td>
</tr>
</tbody>
</table>
Figures 2, 3, 4, 5, and 6 show the distribution among cases and controls.

Figure 2. Distribution of foot care knowledge among cases in DFL study in JADC in 2014 and 2015.

Figure 3. Distribution of foot care knowledge among controls in DFL study in JADC in 2014 and 2015.

Figure 4. Distribution of foot care attitude among case and controls in DFL study in JADC in 2014 and 2015 (important=98%; not important=2%).

Figure 5. Distribution of foot care practice among cases in DFL study in JADC in 2014 and 2015 (yes=25%; no=75%).

Figure 6. Distribution of foot care practice among controls in DFL study in 2014 and 2015.
This following section describes base-line characteristics of the subsamples after matching. Matched analysis was done on age, sex, family history, neuropathy, and vasculopathy, as fixed matched on variables. Duration of DM, glycaemic control, and foot care knowledge were risk factors that were studied and were matched sequentially (two were matched and one was not matched) in 3-stepwise fashion stages.

Out of 88 cases and 182 controls, only suitably matched subjects in certain variables were included and analyzed accordingly:

- Stage 1: matched on glycaemic control and DM duration - Table 4
- Stage 2: matched on glycaemic control and foot care knowledge - Table 5
- Stage 3: matched on DM duration and foot care knowledge - Table 6

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency Among Cases (%)</th>
<th>Frequency Among Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (&gt;55, 46-55, 36-45) yrs.</td>
<td>54.4, 27.8, 14.4</td>
<td>56.2, 28.8, 11</td>
</tr>
<tr>
<td>Family history (Yes, No)</td>
<td>73.3, 26.7</td>
<td>78.1, 21.9</td>
</tr>
<tr>
<td>Sex (male, female)</td>
<td>66.7, 33.3</td>
<td>64.4, 35.6</td>
</tr>
<tr>
<td>Neuropathy (Yes, No)</td>
<td>82.2, 17.8</td>
<td>79.7, 20.3</td>
</tr>
<tr>
<td>Vasculopathy (Yes, No)</td>
<td>17.8, 82.2</td>
<td>13.5, 86.5</td>
</tr>
<tr>
<td>Duration of DM (&lt;5, 5-10, &gt;10) yrs.</td>
<td>12.2, 26.7, 61.1</td>
<td>15.1, 30.1, 54.8</td>
</tr>
<tr>
<td>Glycaemic control (Poor, average, good)</td>
<td>57.8, 32.2, 10</td>
<td>52.1, 35.6, 12.3</td>
</tr>
</tbody>
</table>

Table 4. Frequency distribution of matched variables under DFL study (stage 1) 73 controls were found matched to 73 cases on fuzz tolerance (0.5).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency Among Cases (%)</th>
<th>Frequency Among Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (&gt;55, 46-55, 36-45) yrs.</td>
<td>54.4, 27.8, 14.4</td>
<td>56.2, 23.3, 15.1</td>
</tr>
<tr>
<td>Family history (Yes, No)</td>
<td>73.3, 26.7</td>
<td>72.6, 27.4</td>
</tr>
<tr>
<td>Sex (male, female)</td>
<td>66.7, 33.3</td>
<td>61.6, 38.4</td>
</tr>
<tr>
<td>Neuropathy (Yes, No)</td>
<td>82.2, 17.8</td>
<td>79.5, 20.5</td>
</tr>
<tr>
<td>Vasculopathy (Yes, No)</td>
<td>17.8, 82.2</td>
<td>13.7, 86.3</td>
</tr>
<tr>
<td>Foot care knowledge (poor, average, good)</td>
<td>85.6, 13.3, 1.1</td>
<td>84.9, 13.7, 1.4</td>
</tr>
<tr>
<td>Glycaemic control (Poor, average, good)</td>
<td>57.8, 32.2, 10</td>
<td>53.4, 34.2, 12.3</td>
</tr>
</tbody>
</table>

Table 5. Frequency distribution of matched variables under DFL study (stage 2) 73 controls were found matched to 73 cases on fuzz tolerance (0.5).

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency Among Cases (%)</th>
<th>Frequency Among Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age (&gt;55, 46-55, 36-45) yrs.</td>
<td>54.4, 27.8, 14.4</td>
<td>60.9, 21.7, 14.5</td>
</tr>
<tr>
<td>Family history (Yes, No)</td>
<td>73.3, 26.7</td>
<td>73.9, 26.1</td>
</tr>
<tr>
<td>Sex (male, female)</td>
<td>66.7, 33.3</td>
<td>60.9, 39.1</td>
</tr>
<tr>
<td>Neuropathy (Yes, No)</td>
<td>82.2, 17.8</td>
<td>81.2, 18.8</td>
</tr>
<tr>
<td>Vasculopathy (Yes, No)</td>
<td>17.8, 82.2</td>
<td>14.5, 85.5</td>
</tr>
<tr>
<td>Foot care knowledge (poor, average, good)</td>
<td>85.6, 13.3, 1.1</td>
<td>84.1, 14.5, 1.4</td>
</tr>
<tr>
<td>Duration of DM (&lt;5, 5-10, &gt;10) yrs.</td>
<td>12.2, 26.7, 61.1</td>
<td>15.9, 33.3, 50.7</td>
</tr>
</tbody>
</table>

Table 6. Frequency distribution of matched variables under DFL study (stage 3) 70 controls were found matched with 70 cases on fuzz tolerance (0.5).
The risk factors above were tested in a statistical model by binary logistic regression equation after being tested by chi square test as shown in Table 7 and Table 8.

Table 8 also shows that out of three, only two independent variables made a unique statistically significant contribution to the model. Those are:

- Duration of diabetes (p-value=0.01), O.R. = 1.8, 95% CI (1.15-2.8)
- Foot care knowledge (p-value < 0.0005), O.R.=0.2, 95%CI (0.9-0.4)

These results indicate a directly proportional relationship between DM duration and DFL development. Foot care knowledge was protective against the outcome, indicating an inverse relationship with DFL development.

The frequency distribution of the variables previous foot care clinic visit and diabetic foot wear in cases and controls are shown in Table 9. These variables are almost equally distributed, and the following analysis findings reflected both cases and controls combined.

Table 9. Frequency distribution in cases and controls in DFL study in JADC in 2014 and 2015.

<table>
<thead>
<tr>
<th>Variable</th>
<th>Frequency Among Cases (%)</th>
<th>Frequency Among Controls (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Previous foot care clinic visits</td>
<td>23, 77</td>
<td>29, 70</td>
</tr>
<tr>
<td>Diabetic foot wear</td>
<td>33, 67</td>
<td>36.3, 63.7</td>
</tr>
</tbody>
</table>

- 72% of participants reported no previous foot care clinic visits (Figure 7).

Table 7. Test of significance (chi square test) for the 3 stages.

<table>
<thead>
<tr>
<th>Stage</th>
<th>Variables</th>
<th>p-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>DFL vs. foot care knowledge</td>
<td>&lt;0.0001</td>
</tr>
<tr>
<td>2</td>
<td>DFL vs. DM duration</td>
<td>0.009</td>
</tr>
<tr>
<td>3</td>
<td>DFL vs. glycaemic control</td>
<td>0.564</td>
</tr>
</tbody>
</table>

DFL = diabetic foot lesion

Table 8. Shows outcome of binary logistic regression model.

<table>
<thead>
<tr>
<th></th>
<th>B</th>
<th>S.E.</th>
<th>Wald</th>
<th>Df</th>
<th>p</th>
<th>Exp (B)</th>
<th>95% C.I. for EXP(B)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Lower</td>
</tr>
<tr>
<td>Duration of DM</td>
<td>.590</td>
<td>.229</td>
<td>6.642</td>
<td>1</td>
<td>.010</td>
<td>1.804</td>
<td>1.152</td>
</tr>
<tr>
<td>Glycemic control</td>
<td>-.317</td>
<td>.252</td>
<td>1.588</td>
<td>1</td>
<td>.208</td>
<td>.728</td>
<td>.444</td>
</tr>
<tr>
<td>Foot care knowledge</td>
<td>-1.643</td>
<td>.390</td>
<td>17.706</td>
<td>1</td>
<td>.000</td>
<td>.193</td>
<td>.090</td>
</tr>
</tbody>
</table>
• Those who reported previous visits, 60% reported a frequency as one or fewer visits, with frequencies (2 to 3), and (>3)/month) 20% each (Figure 8).

![Figure 8. Frequencies of foot care clinic visits for cases and controls in DFL study in JADC in 2014 and 2015.](image)

• Of those who reported never visiting a foot care clinic, 72% said they did not hear about it at all, 16% reported it was not important, and the remainder reported not visiting because of no time or no money (Figure 9).

![Figure 9. Reasons for not visiting foot care clinic previously for cases and controls in DFL study in JADC in 2014 and 2015.](image)

DISCUSSION

DFLs represented a rising epidemic among both developed and developing countries. Since they are associated with tremendous morbidity and mortality consequences, multiple studies have addressed issues such as predicting factors to prevent DFL.

This study sampled 88 cases and 182 controls from JADC in an approximate ratio of 1:2. The baseline characteristics of the studied sample showed that most of participants were older than 55 years of age. This finding was not surprising since DM is a chronic disease with the majority of diabetics being older with Type 2 DM. Gender distribution revealed that the overall sample had a greater number of males than females. The same gender ratio was exhibited in the cases, but controls had more females than males.

Studies in the literature show that the prevalence of DFL was greater in males than females. This finding was similar to other studies, it might suggest a relationship between gender and DFL development. This relationship could be explained by the fact that males are more prone to outdoor activities and occupational movement in comparison to females. This might be the cause of recurrent trauma and injury to the feet. However, other studies reported a reverse ratio.

Regarding socio-economic status, most of the studied sample had low or average socio-economic status, with a smaller fraction classified as having high socio-economic status. This fact showed the increased burden of DM and its complications on all of the individuals, the society, and the government. This finding resembled a previous Nigerian study.

Considering the cases, the highest proportion had low socio-economic status (65%). In the controls, the highest proportion (50%) had an average socio-economic status. This resembles that found in several other studies. This finding may also suggest an association between socio-economic status and DFL development, and could be explained by the fact that poor people are usually less educated about DM and its complications. Therefore, they are less aware of how to prevent DFL. Financial issues also might play a major role in why people with lower incomes sought less medical advice early on or adhered to prescribed treatment recommendations. Most participants in this study were from urban locations, mostly from the Khartoum state and nearby towns. This was almost the same finding from the other study in which it was reported up to 72% of those with DFL were urban residents.

When comparing cases to controls, 37% of
cases were from rural areas, in contrast to 17% from controls. This suggested an association between residence and development of DFL. It resembles the finding in the Ethiopian study. This could be explained by the fact that rural residents typically hold jobs as manual workers, farmers, and herdsmen who have more exposure to field trauma and injury, whereas urban residents typically hold office jobs. The above observations might suggest that further research on the roles of certain demographic factors (ie, gender, socio-economic status, and residence) in developing DFL would be valuable.

On the other hand, most cases were classified as having poor knowledge about foot care, in comparison to controls. This difference proved to be statistically significant. The level of foot care knowledge proved to have significant contribution to developing DFL, according to a tested model. This represented an expected finding since an inverse relationship exists between level of foot care knowledge and probability of developing DFL. Poor foot care knowledge found among cases was one of the major causes in developing DFL. Controls also had relatively poor knowledge, although not the same as cases. This indicated that other factors, apart from foot care knowledge, played a role in DFL development.

Both cases and controls considered foot care knowledge as important, but when considering foot care practice remarkable differences were observed. Foot care practice among controls was noted to be double that of the cases. This in itself explains why DFL easily occurs among cases. This finding highlights the importance of foot care practice among diabetics in preventing and minimizing the occurrence of DFL. Data shows that controls had a high probability of not developing DFL because of their higher level of foot care practice adherence. This resembles what was stated in another Middle Eastern study from Gaza. This contrasted an Ethiopian study which reported DFS care practice and favorable attitude foot self care to be 55% and 44% respectively.

Matching was used in the analysis stage of the study with variables thought by the investigator to be confounding. Effort was therefore made to make cases and controls comparable groups in a frequency-matching pattern. Those five matching variables were fixed: (age / sex / family history /neuropathy/ vasculopathy). Thereafter, alternating predicting variables in the study (ie, foot care knowledge, DM duration, and glycemic control) were added in a sequentially matched analysis. Identical matching was difficult to achieve due to time and resource limitations, but an acceptable matching level was attained. (Fuzz tolerance of 0.5).

As expected, matching variables could not in this study because both cases and controls by definition had to be similar in this regard. As shown by the tested model, foot care knowledge and DM duration were significant factors associated with DFL. The odds ratio (OR) of foot care knowledge was 0.2, 95%CI (0.09-0.4), indicating that participants with adequate foot care knowledge were only 20% prone to developing a wound in comparison to those with inadequate knowledge. Therefore, it was a protective factor by 80% in this sample. Observing an inverse relationship between foot care knowledge and DFL development was logical and predictable since diabetics with a high level of knowledge were more likely to practice healthy foot care.

Also, diabetics who have had the condition for longer than 10 years, on average, are nearly twice as likely to develop DFL than other diabetics. This represents a logical outcome from a culmination of multiple risk factors that eventually lead to DFL. All stem from long-term persistent and poorly controlled hyperglycemia, leading to multiple complications, including DFL.

Our results revealed many participants reported poor knowledge about foot care when assessed by the scale. However, when it was explained to them at the end, participants were practicing some of the procedures as usual habits unintentionally (ie, bare foot walking avoidance, and moistening feet with creams). This fact might complicate the assessment of real knowledge, attitude, and practice of foot care in
Glycemic control was assessed using a modified scale adopted from international scale (DSMC)\(^9\) to replace the lack of HBa1c level recorded in a lot of studied participants. This modified scale was not used before on a large scale and it may not reflect the real level intended to be measured. That may explain why glycemic control failed to attain significant contribution to the model, if it was at all.

On the other hand, although previous foot care clinic visit variable was matched between the two groups it was a partial restriction, as subjects might report visiting or not. Most of those who reported previously visiting a foot care clinic, did so in response to following instructions from their health care providers (in JADC), not from their own recollection or prompting. This suggests that intrinsic knowledge and drive for foot care clinic visiting might be poorer than reported in this study.

On the other hand, those who reported they had not previously visited a foot care clinic mentioned that they did not hear about it at all, and some reported financial issues, no money, or no time were the reasons. These findings indicated that a large proportion of our diabetic population lack information about foot care clinics, and an effort should be made to raise knowledge about those clinics, their uses, benefits, and importance. No similar findings nor conclusions were found in the searched literature.

This study faced some limitations. One of them was information bias in the form of recall bias, as is common in all case control studies. The investigator tried as much as possible to verify any information, if records existed. Also, selection bias might represent one of the threats to validity in this study, as included samples might not perfectly represent the source population. Some variables were difficult to assess by objective measures (ie, socio-economic status, glycemic control) so it is recommended that future studies use more objective measures.

Matching was not perfect due to time and resource limitations. Individually matched larger size case control studies, funded with larger amounts, are recommended in the future.

One of limitations of this study was that it was facility-based. DM and its DFL complications became widespread in the community, and so future research is recommended to be community-based.

One of the main study findings was that foot care knowledge (according to criteria specified in this study) was a major factor in developing DFL. Therefore, health care providers and policy makers should invest more time to raising knowledge among high-risk diabetics. Moreover, diabetics knowing that having DM for 10 years or more increases the risk of developing DFL, they should be encouraged to check their feet and visit foot care clinics more frequently.

**CONCLUSIONS**

In conclusion, this study found that males, those with low socio-economic status, and those residing in rural areas are more prone to developing DFL. Those who have DM for longer than 10 years are significantly associated with DFL. On the other hand, the level of foot care knowledge proves to be a predictive factor for developing DFL.

The study found that the majority of participants did not previously visit a foot care clinic, and they did not hear about it at all. Those who reported having previously visited a clinic before, had done so only once.

For diabetic patients, foot care knowledge was a significant protective factor for developing DFL. Therefore, acquiring knowledge is important, and diabetics with a long history of DM need to raise their threshold for promoting feet health, prevention, and protection from DFL.

Also, health care providers can educate diabetic patients about DFL, its possible causes and risk factors, and how to detect and protect them from lesions. They can also encourage their diabetic patients with a history of DFL to regularly visit foot care clinics and practice healthy home foot care.
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