Original Article

Risk factors for diabetic foot ulcers in type 2 diabetes: a case control study, Nyeri, Kenya

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Abstract

People with diabetes have a significantly higher risk of foot ulceration, making foot complications one of the most frequent reasons for hospitalisation. We conducted a case control study with 60 diabetes patients with foot ulcers recruited as cases, and 120 diabetes patients without foot ulcers as controls. Odds ratios were calculated as measures of association for demographic, clinical, and behavioural risk factors. Stratified analysis and logistic regression were carried out. Glycaemic control, nail care, and adherence to medication were poor among the cases. Calluses on the feet (OR 3.7) and a blood pressure (BP) above 130/80 (OR 3.05) elevated risk of developing foot ulcers, while appropriate shoes (OR 0.43), examining feet regularly (OR 0.134) and having a prescribed diet and exercise plan (OR 0.30) conferred protection from foot ulcers. No fungal infections (OR 0.2) and having appropriate foot care education (OR 0.30) were significant protective factors specifically among males and females respectively. Many risk factors for diabetic foot ulceration are amenable to diabetes healthcare intervention.

Introduction

Kenya is experiencing an epidemiological transition from communicable towards non-communicable diseases.[1] Together with other developing countries, Kenya now faces a 'double burden' of disease that entails a lingering communicable diseases burden with an increase in chronic non-communicable conditions. Diabetes mellitus is one of the non communicable diseases that have been on the rise both locally and globally in the last decade.[2]

This rise in incidence and prevalence of diabetes is associated with demographic and social pattern changes that are primarily driven by globalisation and urbanisation.[3] These changes include an ageing population, excessive consumption of alcohol and cigarettes, consumption of unhealthy diets, and physical inactivity.[4,5] With this increase

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in the prevalence of diabetes has come an increase in long-term complications of diabetes, such as foot ulcers and subsequent amputations.

It has been estimated that 10 to 15 % of diabetes patients will develop a foot ulcer at some point in their lives[6] and that the risk of lower extremity amputation is 15 to 46 times higher in people with diabetes than in those without diabetes.[7,8] Consequently, foot complications are one of the most frequent reasons for hospitalisation in diabetes, accounting for up to 25% of all admissions.[9,10] Diabetic foot ulcers precede 84 % of all lower limb amputations.[11]

The socio-economic burden incurred due to diabetes and related complications such as amputations are immense.[12] These include direct costs of medication, hospitalisation, cost of treatment, and supplies. Patients and their relatives also incur indirect costs that may include time lost from work, loss of income from the patient and relatives, diversion of family resources from other basic needs, and premature death that has a great impact on the patient's dependents.

The objective of this case control study was to compare the characteristics of diabetes patients with foot ulcers and those without, to determine the risk and protective factors for diabetes foot ulcers in type 2 diabetes patients.

Patients and methods

This was a case control study. Diabetes patients with foot ulcers were compared with patients without foot ulcers as controls, to determine risk or protective factors for foot ulceration. The sample size was 180, 60 being cases and 120 being controls. Cases were recruited from the Nyeri Provincial General Hospital diabetes clinic and from the surgical wards using a systematic sampling method. For every case identified, two controls matched for sex were sampled.

Ethical approval was obtained from the Ethics Review Committee of the Kenya Medical Research Institute (KEMRI). Informed consent and/or assent were obtained from all participants/guardians/caretakers before the interviews. At entry into the study, participants underwent an interview, a physical examination, and laboratory testing to determine past and present risks of foot ulceration and to elicite exposure to social, demographic, and behavioural risk factors of foot complications.

The physical examination involved an examination of the foot for ulcers, dryness, deformities, previous ulcers and amputations, and general indicators of proper foot care. An ulcer was defined as history of a lower extremity full-thickness skin defect, characterised as per the Wagner

classification.[13] Assessment for peripheral sensory neuropathy was done using a 10 g Semmes-Weinstein mono filament with insensitivity at four out of the ten sites plus loss of the vibratory sense to a 128Hz tuning fork, considered as a sign of peripheral sensory neuropathy.[12,14,15]

Peripheral vascular disease (PVD) was assessed by evaluating the dorsalis pedis (DP) and posterior tibial (PT) pulses on the same limb with a hand held Doppler. An ABI of <0.8 in either foot (calculated as the higher of the DP or PT arterial systolic Doppler blood pressure divided by the higher brachial arterial Doppler blood pressure in both arms) was considered as an indication of PVD.[12] Blood glucose levels were analysed and a glycosylated hemoglobin (HbA_{1c}) using A1cNow® (Metrika, Inc., Sunnyvale, CA).

Odds ratios were calculated as measures of association for demographic, clinical and behavioural risk factors. Stratified analysis and logistic regression were carried out and the Chi-square-corrected (Yates) used as the test for significance. An Epi Info™ 3.5.4 statistical package was used.

Results
General characteristics
There were 36 (60%) females and 24 (40%) males among the cases and 72 (60%) females and 48 (40%) men among the controls. The total number of men was 72 (40%) while women were 108 (60%). Ages ranged from 32 to 93 years. The mean age was 57±12 and in the controls 58±12.

The duration of time the respondents had lived with diabetes ranged from 1 to 31 years (mean 8 years). On average 74 (41%) had never been admitted due to their diabetes, while 43 (24%) and 33 (18%) had been admitted once or twice respectively. There were 30 (17%) who had been admitted more than three times before.

Glycaemic control
Overall, mean HbA_{1c} was 8.5%, with cases alone having a mean of 9.1% compared with 8.3% in controls, the difference being significant (p = 0.015).

When a cut-off of 7.5% for HbA_{1c} as per the Kenya National Clinical Guidelines for diabetes management[16] was employed, 64% were above this threshold. This comprised 70% of cases and 61% of controls. When the random blood glucose (RBG) results were analysed, 51% had a level above 8.0 mmol/l, while 31% were still over the 10.0 mmol/l threshold.

Blood pressure (BP)
The median systolic BP was 130 mmHg, with that of the cases being 143 mmHg and that of the controls 130 mmHg. For diastolic BP, the median was 80 mmHg, with that of the cases being 88 mmHg and controls 80 mmhg. There were 36(60%) of cases and 36(30%) of controls with a BP over 130/80 mmHg, indicating significant long-term cardiovascular complication risks.[17,18]

Body mass index (BMI)
The BMI ranged from a 16.6 to 47.3 kg/m². The mean BMI for all the respondents was 27.6 with a median of 27.1. The mean BMI among the cases was 28.5 and was not significantly different from the mean among the controls at 27.3 (p=0.08).

Risk factors determination
Bivariate analysis
Several factors as listed on Table 1 were found to be significantly associated with foot ulcers as either risk factors (OR>1, p value <0.05) or protective factors.

Stratified analysis and logistic regression
After generating the risk and protective factors identified in Table 1 (over page), they were taken through stratified analysis by age groups and sex, and later fed into a logistic regression model (see Table 2). This generated two risk factors and three protective factors for diabetic foot ulcers. Those with an elevated BP were more at risk of developing foot ulcers than those with a blood pressure below 130/80 mmHg (OR 3.05, CI 1.13–8.19). Having callus on the feet elevated the risk of developing foot ulcers (OR 3.7 ,CI 1.24–11.18) while wearing appropriate shoes reduced the risk of foot ulcers by 43% (OR 0.4, CI 0.24–0.61). Those who examined their feet regularly were protected from ulcers by 13% (OR

Table 2 Factors significantly associated with foot ulcers after logistic regression

Variable	Crude Odds Ratio	Adjusted Odds Ratio	95% confidence interval		p value
			lower	upper	
All patients					
BP above 130/80	3.500	3.056	1.139	8.197	0.026
Callus on feet	3.632	3.728	1.242	11.187	0.019
Examines feet regularly	0.357	0.133	0.028	0.638	0.018
Proper footwear	0.495	0.430	0.241	0.616	0.026
Diet and exercise prescribed	0.399	0.301	0.099	0.915	0.004
Males					
Absence of fungal infection	0.372	0.194	0.194	0.714	0.041
Previously healed ulcer	4.618	3.589	1.477	8.722	0.005
Female					
Callus on feet	3.632	13.206	1.917	90.965	0.009
Educated on foot care	0.234	0.302	0.122	0.752	0.017

Characteristics/risk factors	Cases Exposed #	%	Cases Non-exposed #	%	Controls Exposed #	%	Controls Non-exposed #	%	Crude odds ratio	95% CI Lower	Upper	p value
Female sex	36	60%	24	40%	72	60%	48	40%	1.000	0.531	1.882	0.871
Low formal education	42	70%	18	30%	79	66%	41	34%	1.210	0.620	2.363	0.694
Diabetes duration above 5 years	43	72%	17	28%	78	65%	52	35%	1.362	0.693	2.675	0.370
Never admitted to hospital before	16	27%	44	73%	58	48%	62	52%	0.388	0.197	0.763	0.005
Blood pressure above 130/80	36	60%	24	40%	36	30%	84	70%	3.500	1.832	6.687	0.000
Not having a previously healed foot ulcer	37	62%	23	38%	31	26%	89	74%	0.216	0.112	0.420	0.000
No gaps in taking medicine	17	28%	43	72%	65	54%	55	46%	0.334	0.172	0.651	0.002
Access to a glucose meter	4	7%	56	93%	32	27%	88	73%	0.196	0.066	0.585	0.003
HbA$_{1c}$ above 7.5%	42	70%	18	30%	73	61%	47	39%	1.502	0.774	2.915	0.297
Poor nail care	50	83%	10	17%	81	67%	39	32.%	2.407	1.105	5.247	0.038
Previous amputation	8	13%	52	87%	2	2%	118	98%	9.070	1.863	44.22	0.004
Not educated on appropriate foot wear	44	73%	16	27%	47	39%	73	61%	4.270	2.165	8.427	0.000
Not a member of a diabetes support group	31	52%	29	48%	40	33%	80	67%	2.138	1.135	4.025	0.027
No home glucose testing	47	78%	13	22%	71	59%	49	41%	2.495	1.222	5.095	0.017
No diet prescribed by nutritionist	42	70%	18	30%	56	47%	64	53%	2.667	1.381	5.151	0.005
Has a prescribed exercise plan	52	87%	8	13%	94	78%	26	22%	1.798	0.759	4.256	0.252
Current or past smoking	23	38%	31	62%	41	34%	79	66%	1.198	0.630	2.278	0.699
Signs of neuropathy	30	50%	30	50%	35	29%	85	71%	2.429	1.279	4.611	0.009
Callus on the feet	46	77%	14	23%	57	47%	63	52%	3.632	1.808	7.294	0.000
Never had their feet examined by clinician	54	90%	6	10%	87	72%	33	27%	3.414	1.342	8.685	0.012
Examines their feet regularly	20	33%	40	67%	70	58%	50	42%	0.357	0.187	0.683	0.002
Unaware of cause of diabetes ulcers	45	75%	15	25%	63	53%	56	47%	2.667	1.342	5.297	0.007
Poor nail care	50	83%	10	17%	81	67%	39	32%	2.407	1.105	5.247	0.038
Moved to oral agents from insulin	17	28%	43	72%	19	16%	101	84%	2.102	0.997	4.428	0.075
Wearing good/appropriate shoes	13	22%	47	78%	43	36%	77	64%	0.495	0.241	1.016	0.077
Wear shoes always	46	77%	14	23%	88	73%	32	27%	1.195	0.580	2.460	0.760
Customised shoes not needed	29	48%	31	52%	84	70%	36	30%	0.401	0.211	0.760	0.007
Knowledge foot care	44	73%	16	27%	47	39%	73	61%	4.271	2.165	8.427	0.000
Not taught nail care	51	85%	9	15%	85	71%	35	29%	2.333	1.037	5.248	0.057
Appropriate nail care	50	83%	10	17%	81	67%	39	32.%	2.407	1.105	5.247	0.038
Examines his/her feet regularly	20	33%	40	67%	70	58%	50	42%	0.357	0.187	0.683	0.002
Absence of fungal infection	31	52%	29	48%	89	74%	31	26%	0.372	0.194	0.714	0.004
Diet and exercise prescribed	7	12%	53	88%	24	20%	96	80%	0.301	0.099	0.915	0.004

Table 1 Frequency of risk factor exposures among diabetic foot ulcer cases and controls

13.3, CI 0.03–0.64). Patients with a diet and exercise plan prescribed were also protected from developing ulcers (OR 0.3, CI 0.1–0.92). When the model was applied to the different sexes, absence of fungal infections of the feet and previously healed ulcer were the most significant factors for men (OR 0.2, CI 0.19–0.7). Having callus on the feet (OR 13) and being educated on appropriate foot care and footwear (OR 0.3) were the most significant risk and protective factors.

Discussion

Most of our patients were in their fifth and sixth decades.[19] The level of education varied with a quarter having not received any formal education. This reflected a group from a largely rural agricultural area with a significant number of respondents working as farmers. In view of this work and that most did not always wear shoes, it reflected a significant exposure to foot injuries.

Overall rate of glycaemic control was sub-optimal, particularly in cases. Complications of diabetes in our population were similar to other reported groups.[20] Peripheral neuropathy was found in 35% and was more common in cases than controls. This was significant as peripheral neuropathy is a significant risk factor for developing diabetic foot ulcers.[12] The rates of peripheral neuropathy among the controls compared well with rates in other studies on diabetes patients without foot ulcers, e.g. Zambia 61%, Tanzania 26%, South Africa 28%, Uganda 46%, Ethiopia 50%, Sudan 37% and Malawi 59%. [21]

The mean BMI of 27.6 kg/m² implies that many were either overweight or obese. This indicates a significant risk for long-term complications of diabetes.[22] Raised BMI was more common in our foot ulcer patients. The odds of having an ulcer without appropriate shoes was (2.23 CI 1.07,4.6). This meant that diabetes patients not wearing proper shoes had a risk of developing foot ulcers that was 2.23 higher than those who wore the right kind of shoes. For patients with deformities, proper customised shoes should be worn to reduce the risk of shoes breaking the skin and forming ulcers. This is a significant challenge given that 37% of all respondents needed customised shoes owing to deformities.

We found that not wearing appropriate shoes more than doubled the risk of foot ulceration (OR 2.2). Other factors significantly associated with the risk of foot ulcers were an elevated BP and having callus on the feet. The latter is a marker of peripheral neuropathy, which is a significant risk of foot ulceration.[23]

As well as appropriate footwear, regular foot examination reduced the risk of foot ulceration, as did a prescribed diet and exercise plan; suggesting that diabetes education in general may be a protective factor. Between the sexes, fungal infection, as well as past ulceration, were positive risk factors for men. Callus was a particularly strong risk factor in women.

Overall, this study demonstrated important risk factors for foot ulceration in a diabetic population, many of which are amenable to healthcare intervention.

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