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ORIGINAL ARTICLE

History of and factors associated with diabetic foot ulcers in Norway: The Nord-Trøndelag Health Study

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Abstract

Aims: To determine the proportion of people with diabetes mellitus reporting a history of foot ulcer and to investigate factors associated with this adverse outcome. *Methods*: All inhabitants aged 20 years and older residing in a large geographic region were invited to participate in the Nord-Trøndelag Health Study, 71% (n=65,604) attended. Those reporting diabetes (n=1,972) were invited to take part in an ancillary study on diabetes. Based on 1,494 responses to the question: ''Have you had a foot ulcer that required more than three weeks to heal'', the proportion with a history of foot ulcer was estimated. *Results*: The overall proportion with a history of foot ulcer was 10.4% (95% CI 8.8–11.9%). In the final multivariate logistic regression model, significant factors for a foot ulcer history included age ⩾75 years (OR 1.8, 95% CI 1.2–2.8), height (men > 175 cm, women > 161 cm) (1.9, 95% CI 1.3–2.8), gender (male) (1.5, 95% CI 1.03–2.2), using insulin (1.6, 95% CI 1.1–2.4), and macrovascular complications (1.8, 95% CI 1.2–2.6). ***Conclusions*: The proportion of people reporting a history of foot ulcer in this population-based study exceeded the proportion of foot ulcer history reported previously. Height as a correlate has been occasionally reported in previous studies and needs further attention. Associated factors for a foot ulcer history help identify individuals who may be at particular risk of this adverse outcome.**

Key Words: *Diabetes mellitus, foot ulcer, population study, risk factors*

Background

Worldwide, the occurrence of diabetes is increasing rapidly [1]. The condition is currently a major health problem. Norway has a high occurrence of type 1 diabetes [2] and the prevalence of type 2 diabetes has been increasing [3].

Foot ulceration is a common and disabling complication of diabetes. A history of previous diabetic foot ulceration places the foot at risk of new ulceration. Foot ulcers precede approximately 85% of all diabetic lower extremity amputations and the mortality following amputation surgery is high [4]. Foot ulcers therefore represent a feared complication in people with diabetes. In the prevention of diabetic foot ulcers it is therefore important to give priority and address risk factors. Given the increasing prevalence of diabetes, the burden of complications related to diabetic foot disease is also likely to increase [5].

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Previous studies describing the proportion of those reporting a history of diabetic foot ulcer [6,7] are based on cohorts from various healthcare settings and thus may be biased with regard to patient selection. The need for population-based studies has been expressed within the international consensus group on the diabetic foot [8]. We have been able to identify only a few population studies of foot ulcer [9,10]. Furthermore, cross-sectional studies suggest that foot ulceration is more common among Caucasians than among other ethnic groups [11]. Greater understanding of factors associated with this complication will enhance efforts to identify high-risk subgroups for targeted interventions.

Aims

The aim of this study was to determine the proportion of self-reported foot ulcers that required more than three weeks to heal, in a population-based sample of people with diabetes. In addition, we aimed to identify key factors associated with this adverse outcome.

Material and methods

The study was conducted as an ancillary study to the second phase of the population-based Nord-Trøndelag Health Study (HUNT 2) carried out in one large Norwegian county during 1995–97. Details of HUNT 2 have been published elsewhere [3,12,13]. The population is stable and ethnically homogenous, with only a small percentage (3%) of people of non-Caucasian origin [12].

All inhabitants of the county aged 20 years and older at the time of screening were invited to participate (n=92,434). Each person was mailed a questionnaire along with an invitation to attend a clinical examination. Of the total number invited, 65,604 individuals (71%) attended. A total of 1,972 answered the question ''do you have or have you had diabetes?'' affirmatively and were invited to take part in the ancillary diabetes study. This involved an additional questionnaire (Q3) on diabetes-related issues including diagnosis, treatment, duration, self-care, and complications, including a history of foot ulcer. Midthjell et al. [14] reported that using this patient-administered questionnaire to collect diabetes diagnosis, types of diabetes treatment, duration of diabetes, and pharmaceutical treatment of hypertension among people with diabetes was valid for epidemiological purposes. Participants were asked to complete Q3 at home and return it by mail using a pre-stamped addressed envelope. A total of 1,692 persons with diabetes returned their questionnaires (85.8% response rate). The examination included measurements of height (without shoes to the nearest centimetre), weight (to the nearest half kilogram while wearing light clothing without shoes), and waist circumference (measured at the umbilical level). Body mass index (BMI) was calculated as kilograms per meter squared. In addition, a non-fasting sample of blood was drawn for analysis of HbA_{1c} [12]. Those who answered the question ''Have you had a foot ulcer that required more than three weeks to heal'' were included in the present study (n=1,494). Sample derivation is shown in Figure 1.

The participants who reported having diabetes were given an appointment for a follow-up visit with collection of a fasting blood sample to determine diabetes type; 74.8% returned for this follow up. They were classified as having type 1 or type 2 diabetes, based on a combination of 3 factors: (1) measures of fasting C-peptide glutamic acid dearboxylase antibodies (anti-GAD), (2) fasting glucose, and (3) for those taking insulin, time from diagnosis to start of insulin treatment [12]. As recommended by the WHO [15] persons with latent autoimmune diabetes of the adult (LADA) were combined with those classified as type 1 diabetes mellitus. Participants with gestational diabetes mellitus were excluded.

Those reporting diabetes received tubes for three consecutive first morning urine samples. From the 1,494 participants, a majority (94.1%) provided these three urine samples. Written instructions were included on how to collect urine, and a prepaid, addressed envelope for returning the tubes was included. The urine samples were analysed for albumin and creatinine [12]. Albumin/creatinine ratio (ACR) $\geq$2.5 mg/mmol in at least two of the three urine samples was used to define microalbuminuria (MA) [16].

Other variables included age, dichotomized at $<$75 yrs vs $\geq$75 yrs, marital status (unmarried, widowed, divorced, or separated vs. married or cohabiting) and education (compulsory education [$<$10 years] vs. high education [$\geq$10 years]). Height was dichotomized at the median for each gender. Complications were categorized as microvascular (microalbuminuria, self-reported eye problems due to diabetes), macrovascular (history of stroke, myocardial infarct, angina pectoris, peripheral surgery) and any lower limb amputations (amputation of toes, calf/knee, and femur).

The HUNT study was approved by the Norwegian Data Inspectorate and the Regional Committee for

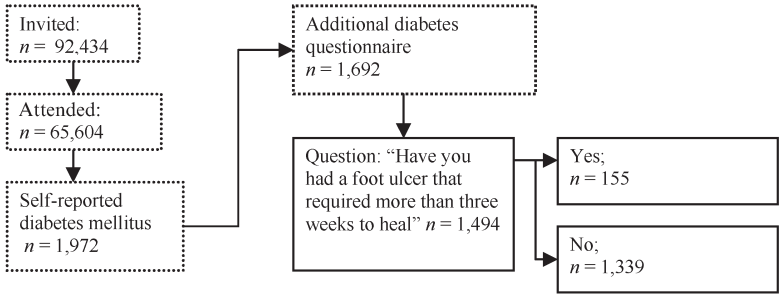

Figure 1. Study participants.

Medical Research Ethics. Participation was voluntary, and each participant signed a written consent form. The study complied with the Declaration of Helsinki. The current analyses were exempted from full review by the Duke University Medical Center Institutional Review Board.

Statistical methods

In the interest of parsimony, we decided to limit the number of independent variables included in the logistic regression model. Categorical and continuous variables were dichotomized as described above and in Table II. Dichotomized cut-off points were generated based on published risk estimates [17–22]. Dichotomized cut-off points for age and smoking were based on traditional cut-off points. Those who did not answer the question about insulin use but answered that they used tablets for their diabetes were assigned "did not use" for insulin use.

To compare sample members by foot ulcer history, *t*-tests, chi-squared tests, and a Mann–Whitney test were used to generate point estimates (see Table I) for bivariate analyses. The Mann–Whitney test was used instead of two-sample *t*-test when the assumption of normality was not met. Logistic regression was used to generate odds ratios for independent correlates that were associated with foot ulcer history (see Table II). For bivariate and multivariate models, odds ratios (ORs) and 95% confidence intervals (95% CI) are reported.

Four increasingly complex models were developed by adding one set of variables at a time. The model in Table II is exploratory and the addition of variable sets (i.e. demographic, lifestyle, clinical, and complication variables, respectively) shows how much the effect estimates changed as each variable set is added. Collinearity was assessed using condition index. SPSS version 13.0 was used. Statistical significance was assessed with a two-sided *p*-value of 0.05.

Results

Among respondents with diabetes, the proportion reporting a history of foot ulcer requiring three or more weeks to heal was 10.4% (155/1,494) (95% CI 8.8–11.9%). Height, waist circumference, less than one hour of physical activity per week, HbA_{1c}, insulin treatment, duration of diabetes, self-reported stroke, peripheral vascular surgery, any lower limb amputation, MA, and eye problems related to diabetes were significantly associated with a history of foot ulcer (Table I).

Among those (1,118) classified as having either type 1 or type 2 diabetes, 13.1% and 8.0% respectively, (OR=1.73, 95% CI 1.07–2.78) reported a history of foot ulcer. Persons with "classic" type 1 diabetes (10.6% [10/94]) reported a lower proportion of foot ulcer than LADA patients (15.4% [16/104]); this difference was not statistically significant (OR 1.5, 95% CI 0.7 – 3.6).

In Table II, results of logistic regression analyses used to examine associations between various independent variables and foot ulcer history are presented. In the first simple multivariate model, age and height above the median were significantly associated with foot ulcers; these associations remained significant after controlling for lifestyle and clinical variables and for the presence of vascular complications.

Association between lifestyle variables, clinical variables, and foot ulcers

As shown in models 2 and 3 (see Table II), men and women having waist circumferences $\geqslant$102 and $\geqslant$88 cm, respectively, were significantly more likely to report a history of foot ulcer.

Those using insulin were 1.6 times as likely to report a history of foot ulcer. Although duration of diabetes did not contribute significantly in the final model, the use of insulin remained significantly associated with having a foot ulcer.

Table I. Description of the total diabetic study population, and for persons reporting or not reporting a foot ulcer.[a]

Characteristics	Total diabetic population n=1,494	Reporting foot ulcer n=155	Not reporting foot ulcer n=1,339	p-value[b]
Social demographic characteristics				
Age (years)	65.8 (SD 13.6)	67.2 (SD 14.0)	65.6 (SD 13.6)	0.157
Sex male (%)	50.5	56.8	49.7	0.097
Marital status (single/alone) (%)	38.9	45.8	38.1	0.064
Education (<10 years) (%)	62.7	66.2	62.3	0.367
Height (cm)	168 (SD 9.7)	170.2 (SD 9.7)	167.9 (SD 9.7)	0.008
Lifestyle characteristics				
BMI (kg/m^2)	29.0 (SD 4.8)	29.3 (SD 5.3)	28.9 (SD 4.8)	0.396
Waist (cm)	95.3 (SD 12.0)	98.2 (SD 12.3)	95.0 (SD 12.0)	0.002
Physical inactivity[c] (%)	28.5	37.2	27.5	0.026
Current smokers (%)	16.2	11.1	16.8	0.070[d]
Former smokers (%)	33.5	34.0	33.5	
Never smokers (%)	50.3	54.9	49.7	
Clinical characteristics				
HbA_{1c} (% units)	8.1 (SD 1.8)	8.4 (SD 2.0)	8.1 (SD 1.7)	0.015
Insulin (%)	33.0	43.5	31.8	0.004
Duration of diabetes (years) (median)	6.0	10.0	6.0	0.001
Ever used anti-hypertensive medication (%)	47.0	52.3	46.4	0.170
Subgroups of diabetes[e]				
Type 1 (classic type 1/LADA) (%)	17.7	26.0	16.9	
Type 2 (%)	82.3	74.0	83.1	
Microvascular complications				
Microalbuminuria[f] (%)	28.6	40.0	27.3	0.001
Eye problems due to diabetes (%)	13.2	24.8	11.9	0.0001
Any microvascular complication (%)	35.0	47.7	33.5	0.0001
Macrovascular complications				
Self-reported stroke (%)	5.7	12.2	5.0	0.0001
Self-reported myocardial infarction (%)	12.9	15.3	12.6	0.345
Self-reported angina pectoris (%)	18.9	22.0	18.5	0.307
Peripheral vascular surgery (%)	3.5	10.7	2.7	0.0001
Any macrovascular complication (%)	29.3	43.2	27.6	0.0001
Any lower limb amputations (%)	1.1	5.2	0.7	0.0001

[a]Numbers represent percentages, means (SD) or median; total population n varies somewhat depending on the actual completion of the different tests/questionnaires (missing range 0–338); [b]p-value for comparing the groups: reporting vs not reporting a foot ulcer; [c]22.5% missing; excluded from multivariate analyses; [d]p-value reflect test of current smokers vs. all others (never+former); [e]25.2% missing; excluded from multivariate analyses; [f]MA is defined as ACR≥2.5 mg/mmol in at least two of three urine samples.

Association between macro- or microvascular complications and foot ulcers

In the bivariate analyses, the proportion with a foot ulcer history was twice as high among those reporting macrovascular complications compared with those who did not. In the final multivariate model macrovascular complications remained significantly associated with increased odds of a foot ulcer. Microvascular complications contributed though not independently as an associated factor (Table II).

Discussion

In this population-based study, 10.4% reported a foot ulcer that required three weeks or more to heal. Compared with other studies based on known diabetes, the proportion with history of foot ulcer in our study is high [7,9–11]. The lower rates of foot ulcer history identified in previous population-based studies may be due to the fact that these studies were conducted in different healthcare settings and may not have been representative of the general diabetic patient population. A possible explanation is that some in the general diabetic patient population have had foot ulcers which have healed without encountering the healthcare system. Even patients with less serious foot ulcers, not treated by a physician but still reporting that this required more than three weeks to heal, are probably vulnerable for the occurrence of new and serious ulcers and should be identified for more intensive follow-up compared with those not reporting a foot ulcer history.

Significant correlates of report of foot ulcer history were male gender, age older than 75 years, height above the median, using insulin, and presence of macrovascular complications (see Table II). Height

Table II. History of foot ulcer in subgroups: Bivariate and multivariate models showing relative odds of foot ulcer.

	Proportion[a] (%)	Unadjusted OR (CI)	Model 1 OR (CI)	Model 2 OR (CI)	Model 3 OR (CI)	Model 4 OR (CI)[b]
Demographic	n=1,393[c]		n=1,393[c]	n=1,393[c]	n=1,393[c]	n=1,393[c]
Age <75 yrs	8.3%	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]
Age≥75 yrs	13.2%	1.7 (1.2–2.4)	2.1 (1.4–3.1)	2.0 (1.4–3.0)	2.2 (1.4–3.2)	1.8 (1.2–2.8)
Height ≤175/161 cm	7.6%	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]
Height >175/161 cm	11.7%	1.6 (1.1–2.3)	1.9 (1.3–2.8)	1.9 (1.3–2.7)	1.9 (1.3–2.7)	1.9 (1.3–2.8)
Female	8.3%	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]	Ref.[d]
Male	10.8%	1.4 (0.9–1.9)	1.4 (0.99–2.1)	1.6 (1.1–2.4)	1.7 (1.1–2.4)	1.5 (1.03–2.2)
Lifestyle						
Not current smoker	10.1%	Ref.[d]		Ref.[d]	Ref.[d]	Ref.[d]
Current smoker	7.3%	0.7 (0.4–1.2)		0.7 (0.4–1.2)	0.7 (0.4–1.2)	0.7 (0.4–1.2)
Waist <102/88 cm	8.5%	Ref.[d]		Ref.[d]	Ref.[d]	Ref.[d]
Waist≥102/88 cm	10.9%	1.3 (0.9–1.9)		1.5 (1.005–2.1)	1.5 (1.03–2.2)	1.4 (0.9–2.0)
Clinical						
Duration ≤10 yrs	8.4%	Ref.[d]			Ref.[d]	Ref.[d]
Duration >10 yrs	11.9%	1.5 (1.03–2.1)			1.2 (0.8–1.9)	1.2 (0.8–1.8)
No insulin	8.1%	Ref.[d]			Ref.[d]	Ref.[d]
Insulin	12.7%	1.7 (1.2–2.4)			1.6 (1.1–2.5)	1.6 (1.1–2.4)
Vascular complications						
No microvascular complications	8.1%	Ref.[d]				Ref.[d]
Microvascular complications	12.4%	1.6 (1.1–2.3)				1.3 (0.9–1.9)
No macrovascular complications	7.6%	Ref.[d]				Ref.[d]
Macrovascular complications	14.6%	2.1 (1.4–3.0)				1.8 (1.2–2.6)

[a]History of reported foot ulcer in the different subgroups. [b]Condition index=6.5. [c]Only persons with complete information on all risk factors were included. [d]Reference category.

emerged as a factor strongly associated with foot ulcer history, with higher risk associated with a height of over 175 cm for males and 161 cm for females (median values). Some studies have shown height to be associated with neuropathy [10,23]. Height is associated with the length of axons and longer axons are more prone to metabolic disturbances [10]. Norwegians are relatively tall and may have a higher risk of neuropathy, which may have contributed to higher levels of foot ulcers. The results of a study showing that Asians have about one-third the risk of foot ulcers compared with Europeans lends some support to this possibility [11].

HbA_{1c}, insulin, and duration of diabetes were associated with a history of foot ulcer in the bivariate analyses. Due to strong inter-correlations among these three variables, and based on previous research [6,10,24], priority was given to duration and insulin use in the multivariate model. Consistent with previous research [6,10] insulin use was statistically significant in the final model, but long duration of diabetes (>10 years) was not.

We found that macrovascular complications of diabetes relate significantly to a history of foot ulcer. This is strongly supported by the recent American Diabetes Association statement on preventive foot care in diabetes [21,22]. Macrovascular complications probably reflect disease severity. In busy clinical practices, with limited time available during practitioner–patient encounters, macrovascular complications probably receive primary focus, and the state of the feet may easily be overlooked. However, the presence of macrovascular complications should indicate careful foot inspection.

Surprisingly, smoking was not independently associated with foot ulcer in our study. No significant differences in smoking status were found between those with and without a foot ulcer, either in the bivariate or multivariate models. However, there were relatively few smokers among those reporting a foot ulcer. Previous research is mixed in reporting the relationship between smoking and foot ulcers [20,25]. Our study had significantly more smokers and perhaps more morbidity among study participants not answering the foot ulcer question. We were not in a position to evaluate whether these results might be due to higher mortality rates in the foot ulcer sample.

In order to assess the validity of the findings, among those with diabetes, we compared those who completed the foot ulcer question with those who did not (see Figure 1). There were no differences in distribution of diabetes subtype, education, BMI,

diabetes duration, or HbA_{1c} level. Those who did not complete the foot ulcer question were more likely to be older, shorter, female, single, current smokers, to have a larger waist circumference, and were more likely to have MA or a history of stroke than those who participated. This implies that the reported proportion of foot ulcers in this population may even be an underestimate.

A strength of this study is that, in spite of some missing data on diabetes subgroups, this is the only study of diabetic foot ulcers to have distinguished between type 1 and LADA. The high proportion of foot ulcers reported among persons with LADA (15.4%) suggests particular vulnerability for foot ulcer development and need for special attention to this group, and calls for additional research.

One study limitation associated with using cross-sectional data is that history of foot ulcer and potential factors associated with a history of foot ulcer are reported simultaneously, although some of the potential factors are time invariant (e.g. gender and height). Second, ''history of foot ulcer'' is based on self-reported data and not clinically verified. However, self-reported data have been deemed reliable in other large research studies [26,27]. Third, data provide no means for evaluating whether group differences in foot ulcer history relate to the quality of primary healthcare or the completeness of reporting. Fourth, missing or incomplete information on outcome and correlates prevented inclusion of diabetes type and physical inactivity in the multivariate model. Finally, some participants may have erroneously reported other types of ulcers, such as venous leg ulcers, as a foot ulcer. However, the term ''foot ulcer'' (''fotsår'') is probaby less ambiguous in Norwegian than in English. In spite of these limitations, this population-based study should provide a reasonable representation of the proportion with a history of diabetic foot ulcer in Norway.

Traditionally preventive care has had a relatively low priority. Foot inspection and care also appears to have a low priority in diabetes care, despite the significant suffering and costs related to foot ulcer development [28]. In everyday clinical practice Lavery et al. [29] provide several reasons why the diabetic foot is often ignored by healthcare professionals. The process leading to ulceration is still not well understood. For the average primary care physician with a caseload containing a few hundred diabetic patients, foot ulcers are a relatively uncommon event [29]. Nurses in the community may be in a good position to screen all diabetic patients to prevent ulcers or to detect them early. The factors identified in this study may help nurses move from general screening of diabetic patients to in-depth examination of more vulnerable subgroups at particular risk of foot ulcers.

Conclusions

The proportion of respondents with diabetes reporting a history of foot ulcer was higher in this Norwegian population than has been reported elsewhere [7,9–11]. Even patients with less serious foot ulcers, which have healed without encountering the healthcare system, are probably more susceptible to the occurrence of new and serious ulcers and should be identified for more intensive follow-up compared with those not reporting a history of foot ulcer. Associated factors such as age, height above the median, male gender, using insulin and, macrovascular complications give support to previous research, although height as an associated factor has occasionally been reported in previous studies and needs further attention.

Our study findings may be helpful to formal providers working in primary care contexts, as they initiate strategies to detect and to prevent foot ulcers among persons with diabetes. The factors associated with a history of foot ulcer in this study may support efforts to tailor primary healthcare interventions for diabetic patients who are particularly vulnerable to foot ulcer development.

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