Prevalence of diabetic foot disease in Germany

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The reported prevalence of diabetic foot ulceration varies widely around the world. Here, the authors use a medical database to retrospectively determine the prevalence of foot ulceration, peripheral neuropathy and peripheral vascular disease in a cohort with diabetes. The relationship between ulceration and a range of known risk factors was also assessed.

Diabetic foot disease is one of the most serious and economically demanding complications that people with diabetes can develop. It is traditionally characterised by peripheral neuropathy or microangiopathy, or both, and frequently presents as acute or chronic ulceration of the foot. As a result of foot ulceration, the risk of amputation among people with diabetes is 10-times that of people without diabetes, and post-amputation morbidity and mortality are higher for those with diabetes (Kästenbauer and Irsigler, 2003).

Some epidemiological data on the prevalence of diabetic foot ulceration in various countries has been published (*Table 1*). Interpretation of such data can be difficult, with the prevalence varying between 0.5% and 13.7% of the population with diabetes in different studies. The type of diabetes (i.e. type 1 or 2), geographical location and data collection methods may influence the range of results.

The present study was undertaken to determine the prevalence of active diabetic foot disease, diabetic peripheral neuropathy (DPN) and peripheral vascular disease (PVD) in a German cohort. The relationship between diabetic foot disease and DPN, PVD, age, diabetes duration, mean HbA_{1c} and sex were also investigated.

Methods

Retrospective analysis of data from a German healthcare database – the IMS Disease Analyzer – was undertaken. The database continuously receives anonymised data from the patient records of some 3000 physicians in both primary and secondary care, representing approximately 2.4% of all practices in Germany (as at the end of 2008). The database contains longitudinal data from more than 20 million people in Germany. Their age, sex, health insurance details, inpatient treatments, sick leave, International Classification of Disease-10 German Modification (ICD-10 GM) codes for diagnosis (German Institute of Medical Documentation and Information, 2007), physician notes, laboratory results (e.g. HbA_{1c}) and drug prescription details are included. Becher et al (2009) report that the IMS Disease Analyzer database is a valid tool for epidemiological studies.

Article points

1. Some epidemiological data on the prevalence of diabetic foot ulceration in various countries has been published but the prevalence varies widely.
2. A retrospective analysis of data from a German healthcare database was undertaken to determine the prevalence of diabetic foot ulceration and its risk factors.
3. A foot ulceration prevalence of 1.2% of people with type 1 diabetes and 6.7% of people with type 2 diabetes was found.

Key words:
- Diabetic foot disease
- Diabetic neuropathy
- Peripheral vascular disease
- Prevalence

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Table 1. Prevalence of diabetic foot ulceration in published studies.

Study	Country	Sample size (*n*)	Ulcer prevalence (%)
Kumar et al (1994)	UK	811	5.3 (3.8–6.8)†
Shera et al (2004)	Pakistan	500	4.0†
Fabian et al (2005)	Poland	27 932	T1D, 0.5; T2D, 2.0
Sabag-Ruiz et al (2006)	Mexico	252	10.8†
Al-Mahroos and Al-Roomi (2007)	Saudi Arabia	1477	5.9†
Rabia and Khoo (2007)	Malaysia	200	9.5†
Iversen et al (2008)	Norway	1494	10.4 (8.8–11.9)†
Sämann et al (2008)	Germany	4778	T1D, 2.8 (2.3–3.4); T2D, 3.6 (1.9–6.0)
Vieira-Santos et al (2008)	Brasil	1374	9.0†
Wolf et al (2009)	Germany	4906	T1D, 5.1; T2D, 13.7

†Mixed type 1 and 2 diabetes population. T1D, type 1 diabetes; T2D, type 2 diabetes.

The analysis period for the present study was for records falling between 1 January 2004 and 31 December 2008.

Participants

Inclusion was based on the diagnosis of diabetes, either type 1 or type 2, according to the following criteria:

- **Type 2 diabetes:** At least one record of ICD-10 GM code E11 (non-insulin-dependent diabetes) during 2008; or at least one prescription of an antidiabetes drug (Anatomical Classification of Pharmaceutical Products [European Pharmaceutical Marketing Research Association {EPMRA}, 2007] level 3 codes: A10H [sulphonylurea]; A10J [biguanide]; A10K [thiazolidinedione]; A10L [alpha-glucosidase inhibitor]; A10M [glinide]; A10N [dipeptidyl peptidase-4 inhibitor]; A10S [glucagon-like peptide-1 receptor agonist]) during 2008.
- **Type 1 diabetes:** At least one record of ICD-10 GM code E10 (insulin-dependent diabetes); and at least one prescription of insulin (Anatomical Classification of Pharmaceutical Products [EPMRA, 2007] level 3 code: A10C [insulin]) during 2008; and no record of an ICD-10 GM code for type 2 diabetes in the past 3 years.

An open wound on the ankle or foot (ICD-10 GM code S91) among the population with diabetes was used to indicate diabetic foot ulceration. Episodes of active diabetic foot disease were identified by searching the database for the ICD-10 GM code S91 or physician diagnosis in the text of patient records (search terms: "diabetic foot"; "diabetic foot disease"; "diabetic gangrene"; "diabetic foot ulcer"; "diabetic foot syndrome", which are coded as "other" complications [E10.6, E11.6, E12.6, E13.6, E14.6]).

The database was searched for diagnoses of PVD, defined as a diabetes-related peripheral circulatory complication using ICD-10 GM codes E10.5, E11.5, E12.5, E13.5, E14.5 or I73.9. In Germany, PVD is diagnosed using Morbach et al's (2008) guidance, positive diagnosis being the absence of one or more of the dorsalis pedis or posterior tibial pulses (assessed by hand or ultrasound), or an ankle–brachial pressure index <0.9.

The ICD-10 GM codes E10.4, E11.4, E12.4, E13.4, E14.4 describe diabetes with neurological complications, excluding stroke, and were used in the present study to identify diagonses of DPN in the database. In Germany, DPN is diagnosed using Morbach et al's (2008) guidance, positive diagnosis being the absent or reduced perception of a tuning fork or reduced pressure sensation tested with a monofilament.

Statistical analysis

Data were analysed using SAS software (version 9.1.3; SAS Institute, Cary, NC). Descriptive analysis presented absolute and relative frequency for categorical variables. Binomial lower and upper confidence limits

Table 2. Cohort demographic and diabetic foot ulcer (DFU) data by diabetes type.

	Type 1 diabetes			Type 2 diabetes		
	Total	**DFU**	**No DFU**	**Total**	**DFU**	**No DFU**
n	3541	41	3500	27 136	1829	25 307
Age (years)†	35.6 (7.9)	40.1 (5.1)	35.5 (8.0)	67.6 (10.7)	70.4 (10.3)	67.4 (10.6)
Women (%)	48.7	31.7	51.5	47.2	41.7	47.6
Diabetes duration (years)†	11.6 (5.8)	12.5 (3.9)	11.5 (5.9)	3.0 (2.9)	4.3 (3.3)	2.9 (2.9)
HbA_{1c} (%)†	7.7‡ (1.7)§	7.3¶ (1.4)††	7.6‡‡ (1.7)§§	7.3¶ (1.3)¶¶	7.5* (1.3)¶¶	7.3¶ (1.3)¶¶

†Mean. ‡61 mmol/mol. §19 mmol/mol. ¶56 mmol/mol. ††15 mmol/mol. ‡‡60 mmol/mol. §§19 mmol/mol. ¶¶56 mmol/mol. ¶¶14 mmol/mol. *58 mmol/mol.

for prevalence were 95%. Logistic regression models were used and adjusted odds ratios calculated to evaluate the relationship between diabetic foot disease and DPN, PVD, age, diabetes duration, mean HbA_{1c} and sex.

Statistical significance was set at $P \leq 0.05$.

Results

Data were collected from 27 136 people with type 2 diabetes and 3541 people with type 1 diabetes receiving care at 82 individual healthcare institutions in Germany. Demographic data for the cohort are summarised in *Table 2*.

Diabetic foot ulceration

Diabetic foot ulceration was reported in 1.2% (95% confidence interval [CI], 0.8–1.5%) of people with type 1 diabetes and 6.7% (95% CI, 6.4–7.0%) of people with type 2 diabetes.

Diabetic peripheral neuropathy (DPN)

DPN was diagnosed in 10.0% (95% CI, 9.0–11.0%) of people with type 1 diabetes and 31.1% (95% CI, 30.5–31.6%) of people with type 2 diabetes (*Table 3*). DPN was a strong independent predictor of ulceration among people with either type 1 ($P=0.0035$) or type 2 ($P<0.0001$) diabetes (*Table 4*).

Table 3. Incidence of diabetic peripheral neuropathy (DPN) and peripheral vascular disease (PVD) in the cohort.

	Type 1 diabetes (*n*=3541)			Type 2 diabetes (*n*=27 136)		
	Total	**DFU**	**No DFU**	**Total**	**DFU**	**No DFU**
DPN (%)	10.0 (9.0–11.0†)	58.5	9.4	31.1 (30.5–31.6†)	60.1	29.0
PVD (%)	6.7 (5.9–7.6†)	56.1	6.2	25.8 (25.1–26.1†)	68.0	22.5

†95% confidence interval. DFU, diabetic foot ulcer.

Peripheral vascular disease (PVD)

PVD was present in 6.7% (95% CI, 5.9–7.6%) of people with type 1 diabetes and 25.8% (95% CI, 25.1–26.1) of people with type 2 diabetes (*Table 3*). In multivariate analysis, PVD was independently associated with ulceration among people with type 2 diabetes (95% CI, 3.4–4.9%; *P*<0.0001; *Table 4*). PVD approached significance for independent association with ulceration among people with type 1 diabetes (*P*=0.0552; *Table 4*).

Other risk factors

Diabetic foot ulceration was also found to be independently associated with diabetes duration (*P*<0.0001) and mean HbA_{1c} >7.5% (>58 mmol/mol; *P*=0.0189) among people with type 2, but not type 1, diabetes (*Table 4*).

Table 4. Multivariate analysis of diabetic foot ulcer risk factors.

	OR	95% CI	*P*-value
	Type 1 diabetes (*n*=3541)		
Age†	1.13	0.98–1.25	0.1148
Male sex	2.56	0.67–9.76	0.1690
DPN	6.32	1.84–21.77	0.0035*
PVD	3.32	0.97–11.32	0.0552
HbA_{1c}>7.5%†‡	0.49	0.15–1.68	0.2575
Diabetes duration†	0.93	0.69–1.24	0.6106
	Type 2 diabetes (*n*=27 136)		
Age†	1.01	1.00–1.01	0.1997
Male sex	107	0.90–1.26	0.4398
DPN	3.10	2.57–3.73	<0.0001*
PVD	4.10	3.41–4.94	<0.0001*
HbA_{1c}>7.5%†‡	1.08	1.01–1.15	0.0189*
Diabetes duration†	1.13	1.10–1.16	<0.0001*

*$P \leq 0.05$, significant. †Mean. ‡>58 mmol/mol. CI, confidence interval; DPN, diabetic peripheral neuropathy; OR, odds ratio; PVD, peripheral vascular disease.

Discussion

The prevalence of diabetic foot ulceration in Germany shown here (1.2%, type 1 diabetes; 6.7%, type 2 diabetes) is consistent with rates reported elsewhere in the literature. In a study of 4778 people in Germany, Sämann et al (2008) found the prevalence of ulceration to be 3.6% (95% CI, 1.9–6.0%) among people with type 1 diabetes and 2.8% (95% CI, 2.3–3.4%) among those with type 2 diabetes. In the KORA Survey (Icks et al, 2006) some 5% (95% CI, 2–10%) of people with type 2 diabetes had a foot ulcer.

DPN and PVD incidence

The prevalence of DPN in population-based studies reported elsewhere is approximately 30% (Shaw and Zimmet, 1999; Veves and Malik, 2000; Vinik et al, 2000), which corresponds closely to the 31.1% prevalence among people with type 2 diabetes found in the present study.

The prevalence of PVD among people with type 2 diabetes in the present study (25.8%) was higher than the figures reported elsewhere. Kumar et al (1994) determined the prevalence of PVD among people with type 2 diabetes to be 11% (95% CI, 9.1–13.7%). In an Australian cohort (Tapp et al, 2003), the prevalence of PVD was estimated to be 13.9% among those with known diabetes, and 6.9% in those newly diagnosed with the condition.

In the present study, a significant relationship between ulceration, DPN and PVD was observed among people with either type 1 or type 2 diabetes. DPN (Al-Mahroos and Al-Roomi, 2007; Nather et al, 2008) and PVD (Rabia and Khoo, 2007; Iversen et al, 2008; Gershater et al, 2009) have been reported elsewhere to be significant risk factors for diabetic foot ulceration.

Other ulceration risk factors

Various studies report other significant risk factors for diabetic foot ulceration, including older age (Iversen et al, 2008; Sämann et al, 2008; Wolf et al, 2009), male sex (Basit et al, 2004; Iversen et al, 2008), longer duration of diabetes (Sämann er al, 2008; Gershater et al, 2009; Wolf et al, 2009) and higher mean HbA_{1c} (Wolf et al, 2009). Longer duration of diabetes and a mean HbA_{1c} level of >7.5% (>58 mmol/mol) were significantly associated with ulceration among people with type 2 diabetes in the present study.

Study limitations

Due to the nature of data collection in the present study, some diagnoses of type 1 and type 2 diabetes, diabetic foot disease, DPN and PVD could have been missed. Thus, the actual incidence of these conditions could be higher than shown here. Conversely, ICD-10 DM miscoding could have inflated the number of diagnoses for each of the investigated conditions. Furthermore, it was not possible to investigate the impact of a range of other variables on ulcer incidence (e.g. podiatry access, foot self-care, foot deformities) as the database did not hold information on all elements of patient care and behaviour.

Conclusion

The results of this database study suggest that the prevalence of active diabetic foot disease in this German cohort is relatively low, but that the prevalence of risk factors for ulceration are high. Preventive efforts to avoid diabetic foot diseases should target these risk factors. ■

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