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# Decreasing incidence of foot ulcer among patients with type 1 and type 2 diabetes in the period 2001–2014

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## ABSTRACT

**Aim:** Diabetic foot ulcer (DFU) is a serious complication to diabetes. The aim was to study the incidence of first DFU among patients with type 1 (T1DM) and type 2 diabetes (T2DM), stratified according to etiology: neuropathic, neuro-ischemic or ischemic, over a period of 14 years (2001–2014).

**Methods:** DFU incidence rates were calculated from electronic patient record data from patients with T1DM and complicated T2DM from a large specialized diabetes hospital with a multidisciplinary foot clinic in Denmark. Poisson regression was used to model incidence of first DFU according to calendar year, diabetes type and etiology.

**Results:** Among 5640 patients with T1DM 255 developed a DFU, corresponding to an incidence of 5.8 (95% confidence interval (95%CI) 5.1–6.5) per 1000 patient years; this incidence dropped from 8.1 (95%CI 5.4–11.9) per 1000 patient years in 2002 to 2.6 (95%CI 1.3–5.3) in 2014 ( $p = 0.0059$ ). Among 6953 patients with T2DM 310 developed a DFU, corresponding to an incidence of 11.3 (95%CI 10.1–12.6) per 1000 patient years; this incidence dropped from 17.0 (95%CI 12.2–23.8) per 1000 patient years in 2002 to 8.7 (95%CI 5.3–14.1) per 1000 patient year ( $p = 0.0260$ ) in 2014.

**Conclusion:** The incidence of DFU has decreased substantially in T1DM as well as in T2DM. This change was driven by a decrease in incidence of neuropathic ulcers.

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## 1. Background

Diabetic foot ulcer (DFU) is a serious complication with an increasing burden for health care systems [1]. It has been

estimated that up to 25% of all patients with diabetes develop DFU during their lifetime and foot ulcers precede 80% of all lower leg amputations in diabetic patients [2]. DFU occurs predominantly in patients with peripheral polyneuropathy.

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Healing is slow and more than half are complicated by infection and/or peripheral vascular disease (PAD) [3]. This results in poor outcome including failure to heal, recurrent ulceration, amputation and increased mortality [4,5]. Moreover, DFU is associated with decreased health-related quality of life, not only for the patients [6–9], but also for the caregivers [10].

Previous studies from high income countries have shown large variations of DFU incidence and prevalence due to the inclusion of mixed populations of patients with type 1 diabetes (T1DM) and type 2 diabetes (T2DM) as well as patients with previous foot ulcerations. For example in a population at high risk of DFU a prevalence of 25.3% has been reported [11]. Another study reported a prevalence of 1.6% for an in-hospital population and 0.03% in the community [12]. The incidence rates of DFU from the few studies conducted in high – and middle income countries range from 2.1%/year to 5.8%/year; all of these performed before 2000 [13–17].

The standard of treatment has changed substantially since 2000, especially for patients with T2DM. Intensive antihypertensive and statin treatment are now standard; this was not the case previously. Moreover, glycemic control has generally improved in both types of diabetes. How this has affected the incidence of DFU is unknown. The purpose of the present study is to report time trends in incidence of DFU according to etiology over the 14-year period 2001–2014.

## 2. Methods

The electronic patient record (EPR) system of a large specialized diabetes hospital in Denmark was consulted to obtain data. The hospital is specialized in diabetes care and serves as an integrated part of the public health care system in the Capital Region of Denmark.

In Denmark the National Board of Health has issued guidelines in relation to treatment of patients with T2DM, and here it is defined that patients with T2DM should be considered complicated if they have at least one of the following characteristics: poor metabolic control, HbA1c > 9% (74 mmol/ml) despite intensive management in 6 months, very variable blood sugar including hypoglycemia, poor blood pressure control, BP > 160/90 despite intensive management in 6 months, presence of severe microalbuminuria or macroalbuminuria, presence of progressive diabetic eye disease including macular edema and/or proliferative retinopathy, presence of advanced neuropathy (<https://www.sst.dk/~media/5C35B9DEA91B4E0A91458076F1994019.ashx>).

Approximately 3500 adult patients with T1DM are followed, corresponding to 35% of all adult patients with T1DM in the Capital Region of Denmark. Patients with T2DM are referred from primary care for optimization of treatment; typically for a period of 6 to 12 months. When treatment goals are reached, and no diabetic complications are present, they are referred back to general practice. Patients needing intensive control and treatment, due to complicated diabetes as described above, are offered life-long follow-up at the clinic. At any time approximately 2000 patients with complicated T2DM are followed in the clinic. Generally, the patients registered in the electronic patient records are representative of Danish patients with T1DM and the 10% most complicated

patients with T2DM [18]. Moreover, the patients followed in the hospital are comparable to patients followed in other Danish hospital diabetes outpatient clinics with regard to distribution of age and duration of diabetes [19].

A multidisciplinary foot clinic has been available in the hospital for about five decades. All followed patients have a foot examination once a year, and in case of risk factors for DFU, or frank DFU, the patients are referred to the foot clinic as well. The treatment in the clinic is standardized according to International Consensus on the Diabetic Foot [20].

### 2.1. Study population

Persons aged 18 or more followed in the clinic at some point as patients with T1DM and T2DM from January 2001 through December 2014 were included. Patients with secondary diabetes and MODY were excluded.

An EPR system has been in use since 2001 and the present study is based on the information entered here each time a patient attended the foot clinic.

For the analyses of incidence, the date of the first DFU after the start of the electronic recording was registered and the etiology of the ulcers determined through biothesiometry and examination of palpable pulses on the feet; if palpable pulsation was lacking, ankle- and toe pressures were measured with strain-gauge technique. Furthermore, the sex and age for each calendar year the patient was followed in the clinic were registered. Also the type of diabetes was registered based on the last registered information. DFUs diagnosed in the two years before the EPR system was taken into use were transferred into the electronic records and was used to identify patients with a prevalent or previous DFU diagnosis.

Patients with diabetes were followed from the start of the EPR system in 2001 or after the day from entry date to the hospital, until the first DFU, death or the last update of the EPR (2014). To characterize the patient population in the present study, the following information was extracted from the first available record for each patient: year of treatment start at the clinic, type of diabetes, sex, age, body-mass index (BMI), smoking, insulin use, history of cardiovascular disease (CVD), hemoglobin A1c (HbA1c), diabetes duration before recording start, renal function (urinary albumin excretion), visual acuity and retinopathy. Since the recorded type of diabetes may change during follow-up, the numbers of patients having each of the diabetes types may be different between the characterization of the patient population and the incidence analyses.

### 2.2. Definitions and classifications

The etiology of a DFU was determined as follows [20]:

- Neuropathic ulcer: foot pulses present and vibration threshold >25 mV.
- Neuro-ischemic ulcer: Toe pressure 40–70 mmHg and or/ankle pressure index <90% but >75 mmHg and vibration threshold >25 mV.
- Ischemic ulcer: Toe pressure <40 mmHg and/or ankle <75 mmHg.

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