The diabetic foot syndrome, diagnosis and consequences
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Chapter 1

Introduction and outline of the thesis
1.1 Introduction

A very disabling long-term complication of diabetes mellitus (DM) is the diabetic foot syndrome. The diabetic foot syndrome can be defined as an array of foot abnormalities, resulting from peripheral neuropathy, macro-angiopathy and other consequences of metabolic disturbances. These different causal factors may be present alone, but mostly 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. A clinical important manifestation of the diabetic foot syndrome is the diabetic foot ulcer, sometimes followed by amputation.

In 2000, worldwide 157 million people are suffering from DM, of which about 20 million in Europe. In 1994 the prevalence of DM in the Netherlands among men and women of 20 years and older was estimated to be 33.4/1000, and 42.5/1000, respectively, leading to 442.300 people with DM. About 50% of these people are undiagnosed. Type 2 DM is most frequent, with a presence of 80-90%, type 1 DM is present in 10-20% of the population. As a sequence of demographic changes of the Dutch society, as there are growth of the population and changes in age and sex distribution, the prevalence of DM will increase with 35-45% during the period 1994-2015. This increase will be even higher due to the development of more adequate case finding/screening techniques and the tendency of increasing incidence rates in certain population subgroups.

An ulcer will affect 15-25% of all individuals with diabetes at least once in their lifetime, with an annual incidence of 2 - 3%. A cross-sectional study in 4 general practitioner practices in the Netherlands showed that the prevalence of an infected foot lesion or ulcer in patients with diabetes was 3%. Another study showed that 5% had an ulcer or had undergone an amputation. Thus, diabetic foot problems are common in our society.

The relative risk of diabetes related lower extremity amputation has been reported to vary between 10 (United Kingdom) and 40 (USA). The incidence of amputation in the Northern part of the Netherlands has been studied by van Houtum et al. and Rommers et al. Van Houtum found an age-adjusted incidence rate of 8/100.000 in the non-diabetic population and 345/100.000 in the diabetic population in the province of Groningen in 1991-1992, with a relative risk for patients with DM of 45. The percentage of amputations due to diabetes was 62%. For the entire Dutch population, the age adjusted incidence in the non-diabetic population was 12/100.000, for the diabetic population 250/100.000, with a relative risk of 20. The percentage of amputations due to diabetes was 47%. Rommers et al. found an incidence...
rate of amputations of 18-20/100,000 in the northern region of the Netherlands. This rate was rather constant from 1982-1994 and showed no sharp decrease in frequency despite new techniques such as used in intervention radiology and in vascular surgery. Unfortunately, the contribution of diabetes is not known in these data.

Apelqvist et al. showed that the recurrence of foot ulcers after 1, 3 and 5 years of observation was 34%, 61% and 70% in diabetic patients with previous foot ulcers, respectively. The long-term survival after amputation was 80%, 59%, and 27% after 1, 3 and 5 years of observation. In patients with primary healed ulcers, without the need of amputation, this was 92%, 73% and 58%, respectively. Once amputated, 30-50% of the patients undergo amputation of the contralateral leg within 3 years.

This leads to a major burden both on the patient and the health care system. The risk of amputation is a life long threat to the diabetic patient, and the costs due to diabetic ulcers and amputation are high. In 1989, 3790 patients were hospitalised due to diabetic foot ulcer in the Netherlands, costs of hospital stay only already were estimated 45 million euro. In 1992, 1810 amputations were performed in diabetic patients, the medical costs were estimated 20 million euro, costs of absenteeism and rehabilitation were not taken into account. Ragnarson-Tennvall and Apelqvist studied the cost-effectiveness of the management of diabetic foot ulcers. Although methodological aspects caused difficulties in comparing results between countries and settings, they state that treatment alternatives in which the limb is saved are more effective according long-term economic and quality of life aspects.

Frequent assessment of risk factors is necessary for early detection of patients at risk, followed by strict diabetes regulation, patient education about foot care and appropriate footwear. These measures can reduce or even prevent amputations for diabetic foot disease. Bakker et al. evaluated the effectiveness of a Dutch diabetic foot clinic. Co-ordinated screening, prevention and multidisciplinary treatment at this specialised clinic resulted in a decrease in number and duration of hospital admissions due to foot ulcers. Furthermore, a reduction was found in amputations of 43%. Edmonds et al. achieved healing in 86% of neuropathic ulcers and 72% of ischaemic ulcers, and a reduction of 50% of amputations, with a specialised foot clinic.

This is also the goal of the St. Vincent declaration 1989: a reduction of 50% of amputation in diabetic patients.

The high number of amputations in patients with DM in the Northern part of the Netherlands, more specific in the province of Groningen, illustrated that
there was an urgent need to evaluate the care for the diabetic foot in that region. In the early nineties, no specific screening and prevention programmes existed, and foot complications were treated by various specialists, without multidisciplinary attunement.

At the University Hospital Groningen, the care for diabetic foot disorders became more organised after starting a study in 1993. In this study, the Departments of Rehabilitation Medicine, Internal Medicine and Endocrinology were collaborating. This resulted in this thesis and in a multidisciplinary approach of the diabetic foot in the University Hospital.

This present study focuses on the extent of the problem of the diabetic foot syndrome, the consequences of the diabetic foot syndrome on quality of life, the development of tests to diagnose diabetic neuropathy, and the relation between neuropathy and angiopathy in diabetes.
1.2 Aims of the study and outline of the thesis

This study was performed at the diabetes outpatient clinic of the Department of Endocrinology of the University Hospital Groningen, and at the Department of Diabetes and Vascular Diseases of the Rehabilitation Centre Beatrixoord, to investigate the following questions:

1 How many patients from the diabetes outpatient clinic of a University Hospital, unknown with diabetic foot complications, are at risk to develop these complications and what is their actual state of prevention?

In chapter 2 the current diabetic foot screening and prevention programme of the diabetes outpatient clinic of the University Hospital Groningen has been evaluated. Therefore, 50 patients with diabetes mellitus, unknown with foot complications, were selected at random to assess a risk-profile and the preventative status. The aim was to get insight in the extent of the local population at risk and to form a basis for further development and organisation of diabetic foot care at our hospital and rehabilitation centre.

2 What is the influence of having a present or former foot ulcer on the quality of life of patients with diabetes mellitus?

In chapter 3 quality of life was measured in a group of diabetic patients with present or former foot ulcers and compared with diabetic patients unknown with foot complications. Quality of life was studied on the domains physical, social and psychological functioning. Special attention was paid to mobility and physical disabilities because of expected limitations on these items.

3 Is it possible to modify the Neuropathy Symptom Score (NSS) and the Neurological Disability Score (NDS) into valid, easily managed, graded and accurate scoring systems for diagnosing distal symmetric polyneuropathy in diabetes mellitus?

Neuropathy, especially distal symmetric polyneuropathy, is a major etiological factor in diabetic foot complications; in 85% of the diabetic patients with ulcers neuropathy is present. Because of the lack of a gold standard to diagnose neuropathy, the San Antonio Consensus Statement of 1988 recommended to perform at least one measurement of 5 different diagnostic categories, including a symptom score and a physical examination.
score. Several scores are used, the Neuropathy Symptom Score (NSS) and the Neurological Disability Score (NDS) are the most accepted scores. Both are scores for neuropathy in general and not specific for distal symmetric polyneuropathy. The aim of this study was to adapt the NSS and NDS into valid, easily managed, graded and accurate scoring systems for diagnosing distal symmetric polyneuropathy. These studies are described in chapter 4, 5 and 6, respectively.

4 Is polyneuropathy present in patients with DM before any sign of micro- or macroangiopathy is detectable? Does sensory polyneuropathy occur prior to motor neuropathy or do they occur simultaneously?

In the pathogenesis of diabetic neuropathy a vascular and a metabolic hypothesis exist. In this study, presence of sensory and motor polyneuropathy was evaluated in diabetic patients without micro- or macroangiopathy. In distal symmetric polyneuropathy, sensory dysfunction seems to run ahead of motor dysfunction, because of compensating mechanisms, such as collateral innervation and muscle fiber hypertrophy. Invasive muscle fiber conduction velocity (I-MFCV) offers sensitive information about muscle fiber volume and conduction velocity, and thus of early denervation. In chapter 7, I-MFCV was used as an indicator for early motor dysfunction in diabetic patients.

5 Do cardiovascular autonomic neuropathy tests reflect diabetic polyneuropathy or diabetic vasculopathy?

The frequently used Ewing Battery is known to have a high predictive value in the development of diabetic foot complications. The San Antonio Consensus Statement recommends cardiovascular autonomic neuropathy (CAN) tests, as one of the five different categories for diagnosing diabetic neuropathy. However, evidence exists that the association with other diagnostic categories for neuropathy is weak, and that CAN is more strongly related to vasculopathy in diabetes mellitus. Recently, new methods have been developed to measure CAN, such as Heart Rate Variability (HRV) and Baroreflex Sensitivity (BRS). In chapter 8 these tests for cardiovascular dysfunction were studied, and compared with conventional tests for distal symmetric polyneuropathy and vascular examination.
1.3 References


5 Volksgezondheid Toekomst Verkenning 1997, De som der delen.


